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READY-TO-USE POTASSIUM PHOSPHATES IN SODIUM CHLORIDE SOLUTIONS

[0001] This application claims priority to our copending US provisional application with the serial number 63/090,518, which was filed 10/12/2020, and which is incorporated by reference herein.

Field of the Invention

[0002] The field of the invention is compositions and methods for potassium phosphates solutions for injection, especially as it relates to such solutions with ultra-low concentrations of aluminum where the solutions are packaged in a ready-to-use container at volumes and concentrations suitable for direct administration to a patient.

Background

[0003] The following description includes information that may be useful in understanding the present invention. It is not an admission that any of the information provided herein is prior art or relevant to the presently claimed invention, or that any publication specifically or implicitly referenced is prior art.

[0004] All publications identified herein are incorporated by reference to the same extent as if each individual publication or patent application were specifically and individually indicated to be incorporated by reference. Where a definition or use of a term in an incorporated reference is inconsistent or contrary to the definition of that term provided herein, the definition of that term provided herein applies and the definition of that term in the reference does not apply.

[0005] Hypophosphatemia is a clinical condition in which serum phosphate concentrations are less than 2.5 mg/dL (0.81 mmol/L). Causes for such condition can include alcohol use disorder, burns, starvation, and diuretic use, and symptoms include muscle weakness, respiratory failure, heart failure, and seizures and coma can occur. In most cases, the treatment for hypophosphatemia is phosphorus replacement therapy with an intravenous (IV) infusion rate of phosphates that must be adjusted to the patient's age and particular need. Phosphorus replacement therapy is generally administered via peripheral venous catheter or central venous catheter and at a rate according to the maximum recommended concentration and infusion rate as is shown in **Table 1** (Maximum Recommended Daily Concentration of Potassium Phosphates Injection By Age and Route of Administration (Peripheral vs. Central)) and **Table 2** (Maximum Recommended

Infusion Rate of Potassium Phosphates Injection For Adults and Pediatric Patients 12 Years of Age and Older), where the term 'Phosphorus' is equivalent with 'Phosphate' (PO_4^{3-} anion).

Table 1

Patient Population	Peripheral Venous Catheter	Central Venous Catheter
Adults and Pediatric Patients (12 Years of Age and Older)	Phosphorus 6.8 mmol/100 mL (Potassium 10 mEq/100 mL)	Phosphorus 18 mmol/100 mL (Potassium 26.4 mEq/100 mL)
Pediatric Patients (Less than 12 Years of Age)	Phosphorus 0.27 mmol/10 mL (Potassium 0.4 mEq/10 mL)	Phosphorus 0.55 mmol/10 mL (Potassium 0.8 mEq/10 mL)

Table 2

Route of Administration	Maximum Infusion Rate
Peripheral Venous Catheter	Phosphorus 6.8 mmol/hour (Potassium 10 mEq/hour)
Central Venous Catheter	Phosphorus 15 mmol/hour (Potassium 22 mEq/hour)

[0006] Currently approved phosphorus replacement products of potassium phosphorus for IV administration may require continuous electrocardiographic (ECG) monitoring as serious cardiac reactions may occur as well as pulmonary embolisms due to pulmonary vascular precipitates. These serious cardiac and pulmonary risk factors render the accuracy of the concentration and infusion rate of the potassium phosphate critical for patient safety. Furthering these risks, the currently approved potassium phosphorus products are supplied and stored as concentrates and will therefore require aseptic compounding for the needed infusion rate, thereby increasing the risk of error and contamination. While care and monitoring may be implemented to avoid miscalculations, contamination, and serious adverse effects, preparing the IV solution by dilution and programming the correct infusion rate for administration often takes time and additional oversight. Furthermore, in most cases separate preparations are required for each of the central venous and peripheral venous administrations.

[0007] In addition, there are also potential risks with respect to chemical stability and aluminum toxicity, especially in patients with renal impairment. As is well known, phosphate solutions may be subject to crystallization and precipitation, which is exacerbated in the presence of oxygen. For that reason, concentrated solutions must be used within several hours as any remaining volume of such solutions after even limited exposure to oxygen is prone to crystallization and precipitation. To reduce the risk of crystallization during storage, deoxygenated preparations can be prepared as is described in CN106265499. However, such formulations were nevertheless concentrates and as such failed to avoid many of the difficulties associated with concentrates. With respect to levels

of aluminum it should be recognized that while most currently used products are below the maximum allowed aluminum level as determined by the Federal Drug Administration (FDA), some of these aluminum concentrations may nevertheless be toxic in impaired patients. Attempts have been made to produce potassium phosphate compositions with decreased concentrations of aluminum as is disclosed, for example, in US10632150. However, the products described in the '150 patent are still concentrates, and problems associated with such forms remain. Moreover, many of the known concentrated compositions include varying amounts of potassium in the form of potassium dihydrogen phosphate and potassium hydrogen phosphate and may not provide a proper ratio of these critical components, nor do these compositions provide a tonicity agent.

[0008] Therefore, there is still a need for potassium phosphates solutions with reduced aluminum content where such solutions are in a ready-to-administer formulation suitable for phosphorus replacement therapy, and where such solutions have sufficient storage stability.

Summary of The Invention

[0009] The inventive subject matter is directed to various compositions and methods of ready-to-use (RTU) potassium phosphates solutions for intravenous administration to patients in need thereof. Advantageously, the solutions presented herein exhibit excellent storage stability over extended periods of time, include a suitable tonicity agent, have a desirable phosphate to potassium ratio, and have an aluminum content that is equal or less than 50 mcg/L. Such solutions will not require any dilution or other manipulation to adjust the solution to a required phosphate and/or potassium concentration and can be administered as a single unit at a rate of administration that will not require specific calculations.

[0010] In one aspect of the inventive subject matter, the inventors contemplate an isotonic sterile ready-to-use (RTU) aqueous potassium phosphates solution that comprises potassium phosphates and sodium chloride, wherein the solution includes 15 mmol/100 ml phosphorus (0.15 mmol/mL) and equal or less than 50 mcg/L aluminum.

[0011] In some embodiments, the potassium phosphates comprise potassium dihydrogen phosphate (KH_2PO_4) and potassium hydrogen phosphate (K_2HPO_4), wherein the potassium dihydrogen phosphate is present in the solution an amount of about 1,120 mg/100 ml (8.2 mmol/100 ml) phosphorus wherein the potassium hydrogen phosphate is present in the solution in

an amount of about 1,180 mg/100 ml (6.8 mmol/100 ml) phosphorus, and/or wherein potassium is present in the solution in an amount of about 22 mEq/100 mL. Preferably, but not necessarily, sodium chloride is present in the solution in an amount of about 900 mg/100 ml, and/or the solution has a pH of between 6.2 and 6.8.

[0012] In further embodiments, the solution may have, after autoclaving and storage of at least 3 months at 25 °C and 40% relative humidity, a liquid particle count of no more than 360 and 30 for particles at 15 and 25 micrometer size, respectively. Moreover, the solution may have, after autoclaving and storage of at least 3 months at 25 °C and 40% relative humidity, a change in phosphorus of no more than 1% absolute, and/or the solution may have, after autoclaving and storage of at least 3 months at 25 °C and 40% relative humidity, a change in potassium of no more than 2% absolute. It is further generally preferred that the solution is packaged in a flexible (*e.g.*, polyolefin) container, typically at a volume of 100 mL, and the flexible polyolefin container may further be contained in a secondary metallized overwrap.

[0013] Therefore, in still further contemplated aspects, the inventors contemplate a sterile ready-to-use (RTU) premixed pharmaceutical product stored in a flexible polymeric container. While not limiting to the inventive subject matter, the pharmaceutical product may include potassium phosphates in an aqueous sodium chloride solution, containing (a) less than 50 mcg/L aluminum, (b) about 15 mmol/100 ml phosphorus, and (c) about 22 mEq/100 mL potassium.

[0014] Most typically, the potassium phosphates comprise potassium dihydrogen phosphate (KH_2PO_4) and potassium hydrogen phosphate (K_2HPO_4), wherein the potassium dihydrogen phosphate is present in the solution an amount of about 1,120 mg/100 ml (8.2 mmol/100 ml) phosphorus, and wherein the potassium hydrogen phosphate is present in the solution in an amount of about 1,180 mg/100 ml (6.8 mmol/100 ml) phosphorus. It is further preferred that sodium chloride is present in the aqueous sodium chloride solution in an amount of about 900 mg/100 ml.

[0015] The premixed pharmaceutical product in the flexible polymeric container preferably has a volume of 100 mL, and it is further preferred that the flexible polymeric container is enclosed in a secondary metallized overwrap. Therefore, in some embodiments, the premixed pharmaceutical product will comprise about 4.65 mg/mL of phosphorus (0.15 mmol/mL), about 8.50 mg/mL of potassium (0.22 mEq/mL), about 3.57 mg/mL of sodium, and about 5.43 mg/mL of chloride.

[0016] In a still further aspect of the inventive subject matter, the inventors also contemplate a method of administering phosphates to a patient in need of phosphorus replacement therapy, and contemplated methods include a step of administering, without prior dilution, an isotonic, sterile, and ready-to-use (RTU) solution comprising potassium phosphates and sodium chloride solution from a flexible container to the patient at a rate of infusion and by a route of administration corresponding to the patient's age and degree of need of phosphorus replacement. Most typically, the solution comprises about 15 mmol/100 ml phosphorus, about 22 mEq/100 mL potassium, and less than 50 mcg/L aluminum. In further contemplated embodiments, the rate of infusion is 6.8 mmol phosphates per hour or 15 mmol phosphates per hour, and/or the route of administration is a central venous catheter. Furthermore, it is contemplated that the solution can be administered after extended storage (*e.g.*, storage for at least 3 months at 25 °C and 40% relative humidity).

[0017] Various objects, features, aspects and advantages of the inventive subject matter will become more apparent from the following detailed description of preferred embodiments, along with the accompanying drawing figures.

Brief Description of The Drawings

[0018] FIG.1 is an exemplary schematic showing a flexible pouch configuration for storage of the solutions presented herein.

[0019] FIG.2 is an exemplary schematic of a double winged stopper for use with a container of FIG.1.

[0020] FIG.3 is an exemplary flow chart for producing an exemplary solution presented herein.

[0021] FIG.4 is an exemplary linearity curve for determination of phosphorus using ion chromatography.

[0022] FIG.5 is an exemplary linearity curve for determination of chloride using ion chromatography.

[0023] FIG.6 is an exemplary linearity curve for determination of potassium using ion chromatography.

[0024] FIG.7 is an exemplary linearity curve for determination of sodium using ion chromatography.

[0025] FIG.8 is an exemplary linearity curve for determination of aluminum using Inductively Coupled Plasma Mass Spectrometry (ICP-MS).

[0026] FIGS.9-17 are tables providing results for stability conditions for exemplary phosphorus solution as presented herein in various container materials.

Detailed Description

[0027] The inventors have now discovered that potassium phosphates solutions can be prepared that are storage stable, sterile, and ready-to-use (RTU), and as such avoid all of the drawbacks of heretofore known concentrated potassium phosphates solutions that required prior manipulation and had no significant shelf life. Moreover, the potassium phosphates solutions presented herein also exhibit a desirably low aluminum concentration and provide phosphates and potassium at ratios that are suitable for facile administration. Still further, the solutions according to the inventive subject matter are preservative free and have osmolality and pH suitable for direct administration.

[0028] For example, 100 mL of the RTU solution may be packaged into a flexible polymeric container to thereby provide in a sodium chloride solution about 15 mmol total phosphates and about 22 mEq potassium for injection, wherein the RTU solution has equal or less than 50 micrograms/liter (mcg/L or $\mu\text{g/L}$) aluminum. It should be appreciated that such RTU solution allows for simple and direct administration to a patient without the need for further dilution or other manipulation, and that such solution can be infused via a pump at a single infusion rate to thereby deliver appropriate quantities of phosphates and potassium. Moreover, and as described in more detail below, the solutions as presented herein also exhibit excellent storage stability (*i.e.*, will not be subject to crystallization and precipitation and remain free of microbial growth). Having the specified quantities of phosphates and potassium will advantageously enable administration to an adult or pediatric patient via peripheral venous administration or central venous administration.

[0029] Therefore, especially preferred premixed pharmaceutical products that provide a desirable phosphates to potassium ratio will be prepared such that the solution will contain in water 11.2

mg/mL KH_2PO_4 and 11.8 mg/mL K_2HPO_4 for a total 0.15 mmol/mL of phosphates, and 9 mg/mL sodium chloride. Notably, such solutions will not only result in a pH suitable for injection (*i.e.*, pH between 6.0 and 7.0), but also result in a ratio of potassium to phosphorus and overall quantities of potassium and phosphorus desirable or necessary for direct injection.

[0030] In this context it is noted that the term “ready-to-use” or “RTU” when used in conjunction with the solutions presented herein refers to a solution that can be directly administered to a patient without prior need for dilution or other adjustment such as addition of saline or other tonicity agent). Viewed from a different perspective, a “ready-to-use” or “RTU” solution can be delivered from a storage container via peripheral or central catheter to a patient without additional manipulation of the solution in the storage container. Therefore, the terms “ready-to-use” and “RTU” are interchangeably used with the term “ready-to-administer”. Moreover, the term “phosphorus” is used interchangeably with the term “phosphate” or “phosphates” and refers to the PO_4^{3-} anion, regardless of its protonation state and/or presence of counterion(s). Thus, the term phosphorus can refer to K_2HPO_4 , KH_2PO_4 , HPO_4^{2-} , H_2PO_4^- , and/or PO_4^{3-} . Still further, the term “aluminum” as used herein refers to both aluminum ions (*e.g.*, Al^{3+}) as well as metallic aluminum. Likewise, the terms “sodium” and “potassium” as used herein refer to the cationic forms of sodium (Na^+) and potassium (K^+).

[0031] In addition to the contemplated RTU potassium phosphates in sodium chloride solution being more efficient, effective, and safe (*e.g.*, less risk of contamination) to prepare and administer, the potassium phosphates in sodium chloride solution also has preferably less than 50 mcg/L aluminum. However, contemplated solutions are also suitable that have less than 100 mcg/L, less than 90 mcg/L, less than 80 mcg/L, less than 70 mcg/L, less than 60 mcg/L, or less than 55 mcg/L aluminum. More preferably, the potassium phosphates in sodium chloride solution has an aluminum content of no more than 50 mcg/L, not more than 49 mcg/L, not more than 48 mcg/L, not more than 47 mcg/L, not more than 46 mcg/L, 45 mcg/L, 44 mcg/L, 43 mcg/L, 42 mcg/L, 41 mcg/L, 40 mcg/L, 39 mcg/L, 38 mcg/L, 37 mcg/L, 36 mcg/L, 35 mcg/L, 34 mcg/L, 33 mcg/L, 32 mcg/L, 31 mcg/L, 30 mcg/L, 29 mcg/L, 28 mcg/L, 27 mcg/L, 26 mcg/L, 25 mcg/L, 24 mcg/L, 23 mcg/L, 22 mcg/L, 21 mcg/L, or 20 mcg/L, and even less (8 mcg/L). Therefore, and most typically, the contemplated potassium phosphates in sodium chloride solution has equal or less than 50 mcg/L, or equal or less than 40 mcg/L, or equal or less than 50 mcg/L aluminum.

[0032] Therefore, in exemplary embodiments, the RTU potassium phosphates in sodium chloride solution includes potassium dihydrogen phosphate (KH_2PO_4) and potassium hydrogen phosphate (K_2HPO_4). Typically, the potassium dihydrogen phosphate is at an amount of about 1120 mg/100 ml (8.2 mmol/100 ml of phosphorus) and the potassium hydrogen phosphate is at an amount of about 1180mg/100 ml (6.8 mmol/100 ml of phosphorus). Additionally, the sterile RTU aqueous potassium phosphates in sodium chloride solution includes the sodium chloride at an amount of about 900 mg/100 ml.

[0033] Moreover, it is pointed out that contemplated methods of making aqueous potassium phosphates in sodium chloride solutions for phosphorus replacement therapy include adding potassium hydrogen phosphate, potassium dihydrogen phosphate, and sodium chloride to water, wherein each of these components does not contain more than 5 part per million (ppm) or more than 4 ppm, or more than 3 ppm, or more than 2 part per million (ppm, approximately 0.7 mmol/100 ml), or more than 1 ppm aluminum. Accordingly, and in contrast to the currently available products, aluminum content is reduced from the starting materials, thereby avoiding any further compounding of aluminum levels and decreasing the levels of total aluminum in the solutions presented herein.

[0034] In still further contemplated aspects, it is preferred that the solutions presented herein are stored in an autoclavable flexible container that is most typically fabricated from a polymeric material. Notably, and as shown in more detail below, the inventors also discovered that type of polymeric material may have an impact on chemical and storage stability. For example, some polymeric materials were prone to produce higher quantities of crystallized material and/or precipitates (*e.g.*, at an average particle size of about 10 micron or 25 micron), whereas certain other materials were unexpectedly prone to water loss due to water vapor permeability, particularly at extended periods of storage (*e.g.*, one to several months). Therefore, the inventors also used secondary overwraps that contained the primary packaging materials to help maintain predetermined concentration of all solutes. Among other materials, particularly preferred overwrap materials comprised polymeric composite films with at least one metal (*e.g.*, aluminum) layer.

[0035] With respect to suitable polymeric autoclavable containers, various materials are deemed suitable for use herein, and especially preferred polymeric materials include polysulfone,

polycarbonate, polypropylene, polyethylene (LDPE or HDPE), ethylene/propylene copolymers, polyolefins, acrylic-imide copolymers, polyester (*e.g.*, PET, PEN and the like), Teflon, Nylon, acetal (Delrin), polymethylpentene, PVDC, ethylvinylacetate, polyvinyl chloride, and polyolefins. Notably, polyolefin containers remained transparent and dimensionally stable, even after autoclaving and were as such preferred. As will be readily appreciated, the polymeric containers can be prepared in numerous form factors, however, flexible bags are especially preferred. Likewise, the volume of the polymeric container may change considerably. However, it is typically preferred that the container has a volume that accommodates the volume of solution required for a single and complete administration of the solutions presented herein. Therefore, a particularly preferred internal volume of the container is 100 mL. Moreover, it should be appreciated that the polymeric container will have a single or a double port that is typically sealed with a stopper as is well known in the art. **FIG.1** depicts an exemplary flexible container with 100 mL internal volume, and **FIG.2** depicts an exemplary double winged stopper that can be used with the container of FIG.1.

[0036] Most typically, the potassium phosphates in sodium chloride solution in the flexible container will be sterilized in the container by steam sterilization (*e.g.*, autoclaving, 121 °C for about 15 minutes), preferably without altering the thermal properties of the film layers, ports, and closure system as well as maintaining the integrity of the flexible container. In more typical embodiments, the premixed or ready-to-use stable pharmaceutical, formulation of potassium phosphates in sodium chloride at 15 mmol/100 ml of Phosphorus is packaged in a non-PVC plastic container with ports and container closure systems, which is terminally sterilized at a temperature of at least about 110°C to 130°C via autoclaving with a dwelling time ranging from 7 to 30 minutes.

[0037] Within these embodiments, it is preferred that the autoclaving temperature ranges from 110 to 130 °C. The autoclaving temperature can be at a minimum temperature of 111 °C, 112 °C, 113 °C, 114 °C, 115 °C, 116 °C, 117 °C, 118 °C, 119 °C, 120 °C, or 121 °C, and the maximum temperature can be 130 °C, 129 °C, 128 °C, 127 °C, 126 °C, 125 °C, 124 °C, 123 °C, 122 °C, 121 °C, or 120 °C, inclusive of all ranges and sub-ranges embraced therein. Therefore, typical ranges for the autoclaving temperature may include from 111 to 131°C, or from 117 to 125°C. Within these embodiments, it is preferred that the autoclaving time range from 7 to 60 minutes. The autoclaving time can be at a minimum of 7 minutes, 9 minutes, 11 minutes, 13 minutes or 15

minutes and the maximum autoclaving time can be 60 minutes, 45 minutes 30 minutes, 28 minutes, 26 minutes, 25 minutes, 24 minutes, 22 minutes, or 20 minutes, inclusive of all ranges and sub-ranges embraced therein. Exemplary ranges for the autoclaving time include from 7 to 60 minutes, or from 8 to 45 minutes, or from 9 to 30 minutes, or from 10 to 25 minutes, or from 15 to 20 minutes.

[0038] FIG.3 depicts an exemplary process of making a RTU phosphates solution that includes the steps of adding potassium hydrogen phosphate to water at a concentration of 1180 mg/100 ml with stirring, wherein the potassium hydrogen phosphate contains no more than 2 ppm aluminum, adding potassium dihydrogen phosphate to the water at a concentration of 1120 mg/100 ml with stirring, wherein the potassium dihydrogen phosphate contains no more than 2 ppm aluminum, and adding sodium chloride to the water at a concentration of 900 mg/100 ml with stirring, wherein the sodium chloride contains no more than 0.2 ppm aluminum, thereby forming the aqueous potassium phosphates in sodium chloride solution.

[0039] In additional or alternative embodiments, the method of making the aqueous potassium phosphates in sodium chloride solution includes filter sterilizing a fixed volume of the aqueous potassium phosphates in sodium chloride solution into a flexible container. Typically, a fixed volume of the solution is 100 ml provided to a sterile flexible container (*e.g.*, an IV bag). With the fixed volume of the solution dispensed in the flexible container, the flexible container may be terminally sterilized. Preferably, the terminal sterilization is autoclaving to sterility. For storage and/or transport of the terminally sterilized flexible container of RTU aqueous potassium phosphates in sodium chloride solution, the flexible container may be placed inside an aluminum pouch for protective storage and transport.

[0040] In contrast to current practice where remaining concentrated phosphates solutions after withdrawal must be discarded after 24-48 hours (due to crystallization and/or precipitation issues), the inventors unexpectedly discovered that the RTU solutions could remain chemically stable and did not undergo microbial spoilage where RTU solutions were packaged and autoclaved in the package. Most typically, stability and/or concentration of the cations and anions was further promoted where the autoclaved container was packaged into a secondary container (typically containing a metal foil such as aluminum) and/or where the space between the containers was

flushed with nitrogen or other inert gas to remove oxygen before sealing the secondary (overwrap) container. The inventors also observed that the type of polymer had at least some influence on storage stability and dimensional stability under autoclaving conditions.

[0041] Based on stability studies performed by the inventors, contemplated solutions can be stored for extended periods such as at least 1 week, at least 2 weeks, at least 3 weeks, at least 1 month, at least 2 months, at least 3 months, at least 6 months, at least 1 year, and even longer without significant changes in the product composition. Such storage can be performed under refrigerated conditions (*e.g.*, 2-8 °C), at ambient conditions (*e.g.*, 25 °C, 40% relative humidity), at warm conditions (*e.g.*, 30 °C, 65% relative humidity), and even at accelerated storage conditions (*e.g.*, 40 °C, 15% relative humidity).

[0042] For example, the inventors observed that the solutions may have, after autoclaving and storage of at least 3 months at 25 °C and 40% relative humidity, a liquid particle count of no more than 400, or no more than 360, or no more than 330, or no more than 300, or no more than 170, or no more than 150, or no more than 120, or no more than 100 for particles at 25 micrometer size and no more than 30, or no more than 25, or no more than 20, or no more than 17, or no more than 14, or no more than 10 for particles at 15 micrometer size. Alternatively, or additionally, the solutions may have, after autoclaving and storage of at least 3 months at 25 °C and 40% relative humidity, a change in phosphorus and/or potassium content of no more than +/- 3% (absolute), or no more than +/- 2.5% (absolute), or no more than +/- 2.0% (absolute), or no more than +/- 1.5% (absolute), or no more than +/- 1.0% (absolute), or no more than +/- 0.8% (absolute), or no more than +/- 0.6% (absolute), relative to initial conditions. Likewise, the solutions may have, after autoclaving and storage of at least 3 months at 25 °C and 40% relative humidity, a change in sodium and/or chloride of no more than +/- 2.5% (absolute), or no more than +/- 2.0% (absolute), or no more than +/- 1.5% (absolute), or no more than +/- 1.0% (absolute), or no more than +/- 0.8% (absolute), or no more than +/- 0.6% (absolute), or no more than +/- 0.4% (absolute), relative to initial conditions.

[0043] Notably, the inventive RTU aqueous potassium phosphates in sodium chloride solution may be efficiently administered to a patient in need of phosphorus replacement therapy. Advantageously, the method includes easily administering the sterile ready-to-use (RTU)

potassium phosphates in sodium chloride solution from the flexible container to the patient at a rate of infusion and by a route of administration corresponding to the patient's age and degree of need of phosphorus replacement. As the flexible container comprises a fixed volume (*e.g.*, 100 ml) of the sterile RTU potassium phosphates in sodium chloride solution includes 15 mmol/100 ml Phosphorus, administration to adult or pediatric patients by peripheral venous catheter or central venous catheter may be readily accomplished based on programming the infusion rate accordingly.

[0044] In preferred embodiments, the rate of infusion of the sterile RTU potassium phosphates in sodium chloride solution into the patient is selected from 6.8 mmol/hour or 15 mmol/hour. In typical embodiments, the sterile RTU potassium phosphates in sodium chloride solution is administered to an adult or pediatric patient 12 years of age and older by peripheral venous catheter at 6.8 mmol/hour. In more preferred embodiments, the concentration of phosphates administered by peripheral venous catheter is not more than 6.8 mmol/100 ml in adult patients or pediatric patient 12 years of age and older and not more than 2.7 mmol/100 ml in pediatric patients less than 12 years of age.

[0045] In other typical embodiments, the sterile RTU potassium phosphates in sodium chloride solution is administered to an adult or pediatric patient 12 years of age and older by central venous catheter at 15 mmol/hour. In more preferred embodiments, the concentration of phosphates administered by central venous catheter is not more than 18 mmol/100 ml in adult patients or pediatric patient 12 years of age and older and not more than 5.5 mmol/100 ml in pediatric patients less than 12 years of age.

Examples

[0046] Formulation of ingredients for potassium phosphates in sodium chloride injection 15 mmol/100 ml solution. As set forth in **Tables 3-4** below, exemplary amounts of potassium phosphate monobasic (potassium dihydrogen phosphate, KH_2PO_4), potassium phosphate dibasic (potassium hydrogen phosphate, K_2HPO_4) are the active pharmaceutical ingredients (API), thereby serving an active function. For a 15 mmol/100 ml concentration of phosphorus, 11.2 mg/mL KH_2PO_4 and 11.8 mg/mL K_2HPO_4 are added to water with mixing as disclosed herein. The deionized water is to volume (*quantum satis* (Q.S.)), which for the ready-to-use (RTU) formulation

disclosed herein, is fixed at 100 ml. Sodium chloride (NaCl) is an admixture carrier and tonicity agent having a IIG limit of 0.9% weight/volume (w/v). Accordingly, for a 100 ml solution, 900 mg of NaCl is added.

[0047] Table 5 provides specifications for Monobasic Potassium Phosphate, **Table 6** provides specifications for Dibasic Potassium Phosphate, **Table 7** provides specifications for Sodium Chloride, and **Table 8** provides specifications for Potassium Phosphates in Sodium Chloride Injection, RTU.

[0048] Table 3. Formulation of potassium phosphates in sodium chloride injection solution (15 mmol/100 ml of Phosphorus and 22 mEq/100 mL of Potassium)

Table 3

Active and Excipient Details	IIG Limit (mg/mL)	Function	Formulation
Potassium Phosphate monobasic	Not Applicable	Active	11.2 mg
Potassium Phosphate dibasic	Not Applicable	Active	11.8 mg
Sodium Chloride	0.9%w/v	Admixture carrier	9 mg
Water for Injection / Deionized Water	Q.S. to mL	Vehicle	100 mL

[0049] Table 4. Batch formulation of potassium phosphates injection solution (15 mmol/100 ml of Phosphorus and 22 mEq/100 mL of Potassium) in 1 liter (1000 ml).

Table 4

Formulation for Bulk solution of Potassium Phosphates in Sodium Chloride Injection, RTU		
Active and Excipient Details	Formulation	
	Batch Size : 1000 mL	
	Composition per mL	Batch Qty. per 1000 mL
Potassium Phosphate monobasic	11.2 mg	11.2 g or 11200 mg
Potassium Phosphate dibasic	11.8 mg	11.8 g or 11800 mg
Sodium Chloride	9 mg	9 g or 9000 mg
Water for Injection/Deionized Water	1 mL	1000 mL

Table 5. Specification of Monobasic Potassium Phosphate API*Table 5*

Sr. No.	Test	Specification	Reference
1.	Description	Colorless crystals or white, granular or crystalline powder	USP
2.	Solubility	Freely soluble in water; practically insoluble in alcohol	USP
3.	Identification tests		
3.1.	Potassium	Meet the requirement	USP<191>
3.2.	Phosphate	Meet the requirement	USP <191>
4.	LOD@105°C	Not more than 1.0%	USP monograph
5.	Assay	Not less than 98.0% and Not more than 100.5% on the dried basis	USP monograph
6.	Insoluble substances	Not more than 0.2% (NMT 20 mg)	USP monograph
7.	Impurities		
7.1.	Arsenic	Not more than 3 ppm (NMT 3 µg/g)	USP <211>, Method I
7.2.	Lead	Not more than 5 ppm (NMT 5 µg/g)	USP <251>
7.3.	Limit of Fluoride	Not more than 0.001% (NMT 10 µg/g)	USP monograph
8.	Aluminum content	Not more than 2 ppm	In-House
9.	Bacterial Endotoxin	Not more than 0.1 EU/mg of Monobasic Potassium phosphate	USP <85>
10.	Microbial Enumeration Tests		
	Total Aerobic Microbial Count (TAMC)	Not more than 1000 cfu/g	USP <61> & <1111>
	Total Combined Yeasts and Molds Count (TYMC)	Not more than 100 cfu/g	
11.	Total Coliforms	Negative	USP <62> & <1111>
12.	Residual Solvents	Meets the requirement	USP

[0050] Table 6. Specification of Dibasic Potassium Phosphate API*Table 6*

Sr. No.	Test	Specification	Reference
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1.	Description	Colorless or white, somewhat hygroscopic, granular powder.	USP
2.	Solubility	Freely soluble in water; very slightly soluble in alcohol.	USP
3.	Identification tests		
3.1.	Potassium	Meet the requirement	USP<191>
3.2.	Phosphate	Meet the requirement	USP <191>
4.	LOD@105°C	1.0% of its weight.	USP <731>
5.	pH (5%)	8.5 - 9.6	USP <791>
6.	Assay	Not less than 98.0% and Not more than 100.5% on the dried basis	USP monograph
7.	Impurities		
7.1.	Insoluble substances	The weight of the residue is Not more than 20 mg (Not more than 0.2 %).	USP monograph
7.2.	Carbonate	NMT a few bubbles are evolved.	USP monograph
7.3.	Chloride and Sulfate, Chloride	Shows no more chloride than corresponds to 0.40 mL of 0.020 N hydrochloric acid (Not more than 0.03%)	USP <221>
7.4.	Chloride and Sulfate, Sulfate	Shows no more sulfate than corresponds to 0.20 mL of 0.020 N sulfuric acid (Not more than 0.1%)	USP <221>
7.5.	Arsenic	Not more than 3 ppm (3 µg/g)	USP <211>, Method I
7.6.	Iron	Any red color produced within 1 h is not darker than that of a control prepared from 1 mL of Standard Iron Solution: Not more than 30 ppm (0.003%)	USP <241>
7.7.	Sodium	A solution (1 in 10) tested on a platinum wire imparts no pronounced yellow color to a nonluminous flame.	USP monograph
7.8.	Limit of Fluoride	Not more than 0.001% (10 µg/g)	USP monograph
7.9.	Limit of Monobasic/Tribasic salt	A blue color is produced, which is changed to yellow (with a greenish tinge) by the addition of NMT 0.4 mL of 1 N hydrochloric acid.	USP monograph
8.	Aluminum content	Not more than 2 ppm	In-House

9.	Bacterial Endotoxin	Not more than 0.1 EU/mg of Dibasic Potassium phosphate	USP <85>
10.	Microbial Enumeration Tests		
	Total Aerobic Microbial Count (TAMC)	Not more than 1000 cfu/g	USP <61> & <1111>
	Total Combined Yeasts and Molds Count (TYMC)	Not more than 100 cfu/g	
11.	Total Coliforms	Negative	USP <62> & <1111>
12.	Residual Solvents	Meets the requirement	USP

[0051] Table 7. Specification of Sodium Chloride

Table 7

Sr. No.	Test	Specification	Reference
1.	Description	Colorless, cubic crystals or white crystalline powder. Has a saline taste	USP
2.	Solubility	Freely soluble in water; soluble in glycerin; slightly soluble in alcohol	USP
3.	Identification tests		
3.1.	Sodium	Meet the requirement	USP<191>
3.2.	Chloride	Meet the requirement	USP <191>
4.	LOD@105°C	0.5%of its weight.	USP <731>
5.	Assay	Not less than 99.0% and Not more than 100.5% on the dried basis	USP monograph
6.	Appearance of Solution	Meet the requirement	USP monograph
7.	Acidity or Alkalinity	Meet the requirement	USP monograph
8.	Impurities		
8.1.	Aluminum (Al)	Not more than 0.2 ppm	USP monograph
8.2.	Arsenic	Not more than 1 ppm	USP <211>, Method 1
8.3.	Barium	Should be complies	USP monograph
8.4.	Ferrocyanide	Should be complies	USP monograph
8.5.	Iodide	Should be complies	USP monograph
8.6.	Iron	Not more than 2 ppm	USP monograph
8.7.	Bromides	Not more than 100 ppm	USP monograph
8.8.	Phosphates	Not more than 25 ppm	USP monograph
8.9.	Potassium	Not more than 500 ppm	USP monograph
8.10.	Magnesium and Alkaline Earth Metals (as Ca)	Not more than 100 ppm	USP monograph
8.11.	Nitrite (Absorbance Value)	Not more than 0.01%	USP monograph
8.12.	Sulfate	Not more than 200 ppm	USP monograph
9.	Sterility	Meets the requirement	USP<71>

10.	Bacterial Endotoxin	Not more than 0.1 EU/mg of Dibasic Potassium phosphate	USP <85>
11.	Residual Solvents	Meets the requirement	USP

[0052] Table 8. Specification of Potassium Phosphates in Sodium Chloride Injection, RTU

Table 8

Sr. No.	Test	Release Specification	Shelf Life Specification	Reference
1.	Description	clear colorless solution, free from visible particles	clear colorless solution, free from visible particles	In-House
2.	Identification tests			
7.1	Potassium	Meet the requirement	Not Applicable	USP<191>
7.2	Phosphate	Meet the requirement	Not Applicable	USP <191>
7.3	Sodium	Meet the requirement	Not Applicable	USP<191>
7.4	Chloride	Meet the requirement	Not Applicable	USP <191>
3.	pH	Between 6.0 and 7.0	Between 6.0 and 7.0	In-House
4.	Osmolality	550-700 mOsmol/kg	550-700 mOsmol/kg	USP <785>
5.	Aluminum content	Not more than 50 µg/L	Not more than 50 µg/L	In-house
6.	Particulate matter			
3.1	A) Visible particles			USP<790>
	Visual inspection	Should be free of visible particles	Should be free of visible particles	
3.2	B) Sub-visible Particles (By Light Obscuration method)			USP<788>, Method-I;B
	10 µm size particles	Not more than 6000 particles per container	Not more than 6000 particles per container	
	25 µm size particles	Not more than 600 particles per container	Not more than 600 particles per container	
7.	Container content for Injections	Not less than 100.0 mL	Not less than 100.0 mL	USP<697>

8.	Assay of Potassium (Label Claim: Each 100 mL bag contains 8.50 mg/mL of Potassium)	Not less than 95.0% and Not more than 105.0%	Not less than 90.0% and Not more than 110.0%	In-house
9.	Assay of Phosphorus (Label Claim: Each 100 mL bag contains 4.65 mg/mL of Phosphorus)	Not less than 95.0% and Not more than 105.0%	Not less than 90.0% and Not more than 110.0%	In-house
10.	Assay of Sodium (Label Claim: Each 100 mL bag contains 3.57 mg/mL of Sodium)	Not less than 95.0% and Not more than 105.0%	Not less than 90.0% and Not more than 110.0%	In-house
11.	Assay of Chloride (Label Claim: Each 100 mL bag contains 5.43 mg/mL of Chloride)	Not less than 95.0% and Not more than 105.0%	Not less than 90.0% and Not more than 110.0%	In-house
12.	Sterility	Meets the requirement	Meets the requirement	USP<71>
13.	Bacterial endotoxins	Not more than 1.10 USP EU/mg	Not more than 1.10 USP EU/mg	USP<85>
14.	Residual Solvents	Meets the requirement	Not Applicable	USP <467> (Option 1)
15.	Container Closure integrity test	Meets the requirement	Meets the requirement	USP <1207.2>

[0053] Ion Chromatography Methods:

[0054] Assay of Anions (Phosphorus and Chloride) and Cations (Potassium and Sodium) By Ion Chromatography: All the solution preparations (Mobile Phase, Standard, Sample) should be prepared in plastic ware (Volumetric flask, beakers, pipette tips, eluent bottles, etc.).

[0055] Preparation of Mobile Phases:

[0056] Mobile Phase for Anions (9 mM Na₂CO₃): Take 18.0 mL of Dionex Sodium Carbonate concentrate (0.5M) and dilute to 1000 mL with IC grade water (18.2 MΩ.cm, 0.22 μm filtered), mixed well and degas it for 10 minutes. Purge the solution with helium at 8-10 psi for 10 minutes. After purging blanket/pressurize the container with helium at 8-10 psi for 10 minutes.

[0057] Mobile Phase for Cations (20 mM Methanesulfonic Acid (MSA)): Take 50.0 mL of Dionex CS12A Eluent concentrate (0.4M Methanesulfonic Acid) and dilute to 1000 mL with IC grade water (18.2 MΩ.cm, 0.22 μm filtered), mixed well and degas it for 10 minutes.

[0058] Diluent: Use IC grade water (18.2 MΩ.cm, 0.22 µm filtered) as Diluent.

[0059] IC Conditions: The liquid chromatography equipped with conductivity detector, an injector and a data processor.

[0060] Chromatographic Conditions for Anions are shown in **Table 9**.

Table 9

Parameters	Conditions
Guard Column	Dionex IonPac RFIC AG9-HC (2 x 50 mm)
Column	Dionex IonPac RFIC AS9-HC (2 x 250 mm)
Flow rate	0.4 mL/min.
Detector	Suppressed conductivity
Injection volume	50 µL
Run time	15 Minutes
Cell Temperature	30°C
Sample Cooler Temp.	25°C
Suppressor	AERS 500e 2 mm (constant voltage & recycle mode) (18 mA)

[0061] Chromatographic Conditions for Anions are shown in **Table 10**.

Table 10

Parameters	Conditions
Guard Column	Dionex IonPac RFIC CG12A (4 x 50 mm)
Column	Dionex IonPac RFIC CS12A (4 x 250 mm)
Flow rate	0.7 mL/min.
Detector	Suppressed conductivity
Injection volume	50 µL
Run time	15 Minutes
Cell Temperature	30°C
Sample Cooler Temp.	25°C
Suppressor	CDRS 600 4 mm (constant voltage & recycle mode) (41 mA)

[0062] Preparation of Analytical Solutions:

[0063] Preparation of Standard Solution-1 Set-1 (For Anions): Transfer 0.465 mL of Phosphate Phosphorus Standard Solution for IC and 0.543 mL of Chloride Standard Solution for IC into 25 mL of plastic volumetric flask made up to the mark with diluent, mixed well. Further diluted 5.0 mL above solution into 25 mL of plastic volumetric flask made up to the mark with diluent, mixed well. (This solution contains 3.720 µg/mL of Phosphorus and 4.344 µg/mL of Chloride).

[0064] Preparation of Standard Solution-1 Set-2 (For Anions): Transfer 0.465 mL of Phosphate Phosphorus Standard Solution for IC and 0.543 mL of Chloride Standard Solution for IC into 25

mL of plastic volumetric flask made up to the mark with diluent, mixed well. Further diluted 5.0 mL above solution into 25 mL of plastic volumetric flask made up to the mark with diluent, mixed well. (This solution contains 3.720 µg/mL of Phosphorus and 4.344 µg/mL of Chloride).

[0065] Preparation of Standard solution-2 Set-1 (For Cations): Transfer 0.850 mL of Potassium Standard Solution for IC and 0.357 mL of Sodium Standard Solution for IC into 25 mL of plastic volumetric flask made up to the mark with diluent, mixed well. Further diluted 5.0 mL above solution into 25 mL of plastic volumetric flask made up to the mark with diluent, mixed well. (This solution contains 6.800 µg/mL of Potassium and 2.856 µg/mL of Sodium).

[0066] Preparation of Standard solution-2 Set-2 (For Cations): Transfer 0.850 mL of Potassium Standard Solution for IC and 0.357 mL of Sodium Standard Solution for IC into 25 mL of plastic volumetric flask made up to the mark with diluent, mixed well. Further diluted 5.0 mL above solution into 25 mL of plastic volumetric flask made up to the mark with diluent, mixed well. (This solution contains 6.800 µg/mL of Potassium and 2.856 µg/mL of Sodium).

[0067] Preparation of Sample Solution: Transfer 1.0 mL of Finished Product into 100 mL of plastic volumetric flask made up to the mark with diluent, mixed well. Further diluted 4.0 mL above solution into 50 mL of plastic volumetric flask made up to the mark with diluent, mixed well. (This solution contains 3.720 µg/mL of Phosphorus, 4.344 µg/mL of Chloride, 6.800 µg/mL of Potassium and 2.856 µg/mL of Sodium).

[0068] Injection Sequence for Anions is shown in **Table 11**:

Table 11

Sr. No.	Solution Name	Number of Injection
1.	Column Condition	3
2.	Diluent	1
3.	Standard Solution-1 Set-1 (For Anions)	6
4.	Standard Solution-1 Set-2 (For Anions)	2
5.	Diluent	1
6.	Sample Solution-1 to 6	2
7.	Diluent	1
8.	Bracketing Standard Solution-1 Set-1 (For Anions)	1 (Inject after 6 Test Samples)

[0069] Injection Sequence for Anions is shown in **Table 12**:

Table 12

Sr. No.	Solution Name	Number of Injection
---------	---------------	---------------------

1.	Column Condition	3
2.	Diluent	1
3.	Standard Solution-2 Set-1 (For Cations)	6
4.	Standard Solution-2 Set-2 (For Cations)	2
5.	Diluent	1
6.	Sample Solution-1 to 6	2
7.	Diluent	1
8.	Bracketing Standard Solution-2 Set-1 (For Cations)	1 (Inject after 6 Test Samples)

[0070] System Suitability Requirements are shown in **Table 13**:

Parameter	Phosphorus Peak	Chloride Peak	Potassium Peak	Sodium Peak
% Correlation between Standard Solution Set-1 and Set-2	No Less Than 98.0 and No More Than 102.0			
%RSD of Standard	No More Than 2.0			
USP tailing of standard	No More Than 2.0			
USP plate count of standard	No More Than 2000			
Overall %RSD of Standard	No More Than 2.0			

[0071] Calculate the % correlation in standard solution and report the value. If any peak response identified in Diluent at principal peaks then mean the peak response of each individual principal peak from all the diluent injected in sequence and subtract that individual peak response from Standard and Sample respectively.

[0072] % Correlation between Standard Solution Set-1 and Set-2 is calculated as

$$\frac{R_{std\ 2}}{R_{std\ 1}} \times \frac{V_{std\ 1}}{V_{std\ 2}} \times 100$$

[0073] Where Rstd 1 is Average Peak area of each individual peak in Standard Solution Set-1, Rstd 2 is Average Peak area of each individual peak in Standard Solution Set-2, Vstd 1 is Dilution of Standard Solution Set-1, and Vstd 2 is Dilution of Standard Solution Set-2.

[0074] Calculations

[0075] Calculate the Assay in test solution and report the value. Note: If any peak response identified in Diluent at principal peaks then mean the peak response of each individual principal

peak from all the diluent injected in sequence and subtract that individual peak response from Standard and Sample respectively.

[0076] % Assay is calculated as follows:

$$\frac{R_u}{R_s} \times \frac{V_s}{25} \times \frac{5.0}{25} \times \frac{100}{V_t} \times \frac{50}{4.0} \times \frac{P}{L.C.}$$

[0077] Where R_u is Average Peak area of each individual peak in Sample Solution, R_s is Average Peak area of each individual peak in Standard Solution Set-1, V_s is Volume of each Anion Standards (Phosphorus and Chloride) and Cation Standards (Potassium and Sodium) (in mL), V_t is Volume of Sample Solution (in mL), P is Potency of each individual Standard, and L.C. is Label Claim of each Anions and Cations as follows: Phosphorus (Anion)- 4.65 mg/mL, Chloride (Anion)- 5.43 mg/mL, Potassium (Cation)- 8.50 mg/mL, and Sodium (Cation)- 3.57 mg/mL.

[0078] Validation for Ion Chromatography:

[0079] The Ion Chromatographic process was then tested and validated, and exemplary results are shown in FIGS.4-7 depicting excellent linearity in the relevant range for the various ions. More specifically, **FIG.4** depicts the linearity curve for phosphorus, **FIG.5** depicts the linearity curve for chloride, **FIG.6** depicts the linearity curve for potassium, and **FIG.7** depicts the linearity curve for sodium, and **Table 13** provides exemplary results from these linearity curves.

Table 13

Name	Anions		Cations	
	Phosphorus	Chloride	Potassium	Sodium
Correlation coefficient	0.9998	0.9996	1.0000	1.0000
R ² Value	0.9995	0.9992	1.0000	1.0000
Slope of regression line	0.8266	0.9917	0.5345	0.8214
Y intercept	-0.2310	-0.4332	-0.0084	0.0031

[0080] Tables 14-17 provide further data for the accuracies for phosphorus (**Table 14**), chloride (**Table 15**), potassium (**Table 16**), and sodium (**Table 17**).

Table 14

Sr No.	Sample name	Amount added	Amount recovered	% Recovery
1	Accuracy Level-50% Set-1	2.3483	2.3752	101.1
2	Accuracy Level-50% Set-2	2.3489	2.3674	100.8
3	Accuracy Level-50% Set-3	2.3513	2.3592	100.3
Mean				100.7
STD Dev				0.4
% RSD				0.4
1	Accuracy Level-100% Set-1	4.6924	4.6986	100.1
2	Accuracy Level-100% Set-2	4.6967	4.7287	100.7
3	Accuracy Level-100% Set-3	4.6987	4.7609	101.3
Mean				100.7
STD Dev				0.6
% RSD				0.6
1	Accuracy Level-150% Set-1	7.0437	7.0506	100.1
2	Accuracy Level-150% Set-2	7.0428	7.0125	99.6
3	Accuracy Level-150% Set-3	7.0436	7.0702	100.4
Mean				100.0
STD Dev				0.4
% RSD				0.4

Table 15

Sr No.	Sample name	Amount added	Amount recovered	% Recovery
1	Accuracy Level-50% Set-1	2.7056	2.7676	102.3
2	Accuracy Level-50% Set-2	2.7079	2.7514	101.6
3	Accuracy Level-50% Set-3	2.7050	2.7540	101.8
Mean				102.0
STD Dev				0.5
% RSD				0.5
1	Accuracy Level-100% Set-1	5.4170	5.5163	101.8
2	Accuracy Level-100% Set-2	5.4148	5.5327	102.2
3	Accuracy Level-100% Set-3	5.4067	5.5532	102.7
Mean				102.0
STD Dev				0.3
% RSD				0.3
1	Accuracy Level-150% Set-1	8.1173	8.2750	101.9
2	Accuracy Level-150% Set-2	8.1221	8.2221	101.2
3	Accuracy Level-150% Set-3	8.1206	8.2802	102.0
Mean				101.7
STD Dev				0.4
% RSD				0.4

Table 16

Sr No.	Sample name	Amount added	Amount recovered	% Recovery
1	Accuracy Level-50% Set-1	4.2860	4.2825	99.9
2	Accuracy Level-50% Set-2	4.2890	4.2816	99.8
3	Accuracy Level-50% Set-3	4.2875	4.2808	99.8
Mean				99.8
STD Dev				0.1
% RSD				0.1
1	Accuracy Level-100% Set-1	8.5660	8.5052	99.3
2	Accuracy Level-100% Set-2	8.5716	8.5544	99.8
3	Accuracy Level-100% Set-3	8.5774	8.6057	100.3
Mean				99.8
STD Dev				0.5
% RSD				0.5
1	Accuracy Level-150% Set-1	12.8574	12.8679	100.1
2	Accuracy Level-150% Set-2	12.8568	12.7590	99.2
3	Accuracy Level-150% Set-3	12.8577	12.8449	99.9
Mean				99.7
STD Dev				0.5
% RSD				0.5

Table 17

Sr No.	Sample name	Amount added	Amount recovered	% Recovery
1	Accuracy Level-50% Set-1	1.7779	1.7785	100.0
2	Accuracy Level-50% Set-2	1.7795	1.7730	99.6
3	Accuracy Level-50% Set-3	1.7776	1.7744	99.8
Mean				99.8
STD Dev				0.3
% RSD				0.3
1	Accuracy Level-100% Set-1	3.5597	3.5414	99.5
2	Accuracy Level-100% Set-2	3.5583	3.5502	99.8
3	Accuracy Level-100% Set-3	3.5530	3.5647	100.3
Mean				99.7
STD Dev				0.2
% RSD				0.2
1	Accuracy Level-150% Set-1	5.3342	5.3404	100.1
2	Accuracy Level-150% Set-2	5.3374	5.3049	99.4
3	Accuracy Level-150% Set-3	5.3364	5.3340	100.0
Mean				99.8
STD Dev				0.4
% RSD				0.4

[0081] Table 18 depicts exemplary results for cation and anion recovery.

Table 18

Ions	Recovery Levels	Mean % Recovery	% RSD
Phosphorus	50% Level	100.7	0.4
	100% Level	100.7	0.6
	150% Level	100.0	0.4
Chloride	50% Level	102.0	0.5
	100% Level	102.0	0.3
	150% Level	101.7	0.4
Potassium	50% Level	99.8	0.1
	100% Level	99.8	0.5
	150% Level	99.7	0.5
Sodium	50% Level	99.8	0.3
	100% Level	99.7	0.2
	150% Level	99.8	0.4

[0082] In conclusion, it should therefore be appreciated that the above test method established that the method is specific, linear, accurate, precise, robust and stable. Based on solution stability data (data not shown), it was concluded that standard solution are stable up to 168 Hrs at room temperature, that sample solutions are stable up to 168 Hrs at room temperature, and that mobile phases were stable up to 72 Hrs at room temperature under continuous chromatographic conditions.

[0083] Aluminum Detection

[0084] In a similar manner, the inventors set further out to detect and quantify aluminum levels in the solutions presented herein, and **FIG.8** depicts an exemplary linearity curve for aluminum in

the potassium phosphates solutions presented herein. **Table 19** provides exemplary results for Accuracy & Method Precision at 100% Spiked Level by Inductively Coupled Plasma Mass Spectrometry (ICP-MS).

Table 19

Accuracy & Method Precision @ 100% Spiked Level					
Sets/Levels	% Recovery	Average % Recovery	AVG.	SD	% RSD
LOQ_25%_Set-1	113.84	113.92	105.75	9.8281	9.3
	113.99				
LOQ_25%_Set-2	109.62	110.06			
	110.50				
LOQ_25%_Set-3	93.04	93.26			
	93.48				
50%_Set-1	104.27	103.36	104.44	3.5114	3.4
	102.45				
50%_Set-2	101.87	101.25			
	100.63				
50%_Set-3	108.41	108.70			
	108.99				
100%_Set-1	99.52	99.77	99.76	4.5208	4.5
	100.02				
100%_Set-2	99.66	100.01			
	100.35				
100%_Set-3	95.48	96.02			
	96.57				
100%_Set-4	99.33	100.35			
	101.37				
100%_Set-5	107.55	107.97			
	108.39				
100%_Set-6	93.73	94.42			
	95.12				
200%_Set-1	99.74	99.67	97.29	2.9961	3.1
	99.59				
200%_Set-2	99.59	98.53			
	97.47				
200%_Set-3	94.70	93.68			
	92.65				
400%_Set-1	96.32	96.07	95.77	0.3961	0.4
	95.82				
400%_Set-2	95.55	95.38			

	95.21			
400%_Set-3	96.08	95.87		
	95.65			

[0085] Stability Studies

[0086] For the stability studies, the inventors investigated stability of a phosphorus solution containing saline that was prepared according to FIG.3 from water and potassium dihydrogen phosphate (KH_2PO_4), potassium hydrogen phosphate (K_2HPO_4), and sodium chloride (NaCl), wherein the potassium dihydrogen phosphate was present in the solution an amount of about 1,120 mg/100 ml (8.2 mmol/100 ml), wherein the potassium hydrogen phosphate was present in the solution in an amount of about 1,180 mg/100 ml (6.8 mmol/100 ml), and wherein the sodium chloride was present in the solution in an amount of about 900 mg/100 ml. Thus, the solution contained 15 mmol/100 ml phosphorus (0.15 mmol/mL), 22 mEq/100 mL potassium, and had an aluminum content of about 30 mcg/L. **Table 20** provides an overview of the packaging materials used and filling/autoclaving conditions employed.

Table 20

Potassium Phosphates in Sodium Chloride Injection (15 mmol/100 mL of Phosphorus and 22 mEq/100 mL of Potassium) Secondary packaging for all samples was an aluminum pouch (PET/ALU/PET/PP) and bag fill volume was 100 mL							
Bag Source	Bag Film Material	Bag Material	Bag Injection Port	Bag Injection Port material	Bag Tube Material	Batch No. (Stability Batches and Results)	Sterilization Method
TechnoFlex	PP Film/Layflat Inerta 103 (0.20-NCT)	PP	1	Twist off Port 823-PP INERTA016	PP-4618 Ø 6.15 x 8.2 Tube-NCT	NPO2052 (6 Months)	Terminal Sterilization (121°C for 15 Minutes)
						NPO2092 (6 Months)	Terminal Sterilization (121°C for 15 Minutes)

						NPO21001 (6 Months)	Aseptic Filling, Terminal Sterilization (121°C for 15 Minutes), Terminal Sterilization (115°C for 20 Minutes)
TechnoFlex	PP Film/Layflat Inerta 103 (0.20-NCT)	PP	2	Twist off Port 823- PP INERTA016 and Injection Port	PP-4618 Ø 6.15 x 8.2 Tube-NCT	NPO2052 (6 Months), NPO2092 (6 Months)	Terminal Sterilization (121°C for 15 Minutes)
TechnoFlex	PVC/Layflat MediPack- 3222 (0.32- NCT)	PVC	2	Twist off 450 Welded PVC 3222 and Injection Port	PVC-3227 Ø 6.15 x 8.2 Tube- NCT	NPO2052 (6 Months)	Terminal Sterilization (121°C for 15 Minutes)
Grifols	Not Available	PP	1	PP Plug for Twist off	Not Available	NPO2052 (6 Months), NPO2092 (6 Months)	Terminal Sterilization (121°C for 15 Minutes)
Bausch	APP 114S 200µm Film 160mm Width	PP	2	PP Plug for Twist off and Injection Port	APP 107 Tubing Ø 8.2 x 6.2	NPO2052 (6 Months)	Terminal Sterilization (121°C for 15 Minutes)
HaemoPharm	NEXCEL M312A Film (Sealed Air) 135 x 0.40	Polyolefins	1	PP Plug for Twist off in Melitek	Raumedic Tube Ø 6.2 x 8.3	NPO21001 (6 Months)	Aseptic Filling, Terminal Sterilization (121°C for 15 Minutes), Terminal Sterilization (115°C for 20 Minutes)
						B#192073_11 (6 Months)	Terminal Sterilization (121°C for 15 Minutes)
HaemoPharm	NEXCEL M312 Film (Sealed Air) 135 x 0.40	Polyolefins	1	PP Plug for Twist off in Melitek	Raumedic Tube Ø 6.2 x 8.3	NPO21006 (6 Months)	Aseptic Filling, Terminal Sterilization (121°C for 15 Minutes)

						NPO21007 (6 Months)	Aseptic Filling, Terminal Sterilization (121°C for 15 Minutes)
						NPO21008 (6 Months)	Terminal Sterilization (121°C for 15 Minutes)
Infomed Fluids	APP 114S Film (Polycine) 135 x 0.20	Polyolefins	1	1963/SM - winged spike port	APP 107 Tubing Ø 6.8 x 8.8 Roll	NPO21001 (6 Months)	Aseptic Filling, Terminal Sterilization (121°C for 15 Minutes), Terminal Sterilization (115°C for 20 Minutes)
						NPO21007 (6 Months)	Aseptic Filling, Terminal Sterilization (121°C for 15 Minutes)
						NPO21008 (6 Months)	Terminal Sterilization (121°C for 15 Minutes)
						NPO21012 (up to 3 Months)	Terminal Sterilization (121°C for 15 Minutes)
						Engineering Batch Lot#21070832 (Initial)	Aseptic Filling, Terminal Sterilization (121°C for 15 Minutes)
Infomed Fluids	NEXCEL M312 Film (Sealed Air) 135 x 0.20	Polyolefins	1	1963/SM - winged spike port	COEX TUBE PP/EVA Ø 6.8 x 8.8 Roll	NPO21012 (up to 3 Months)	Terminal Sterilization (121°C for 15 Minutes)
						Engineering Batch Lot#21070832 (Initial)	Aseptic Filling, Terminal Sterilization (121°C for 15 Minutes)

[0087] Stability was determined for all samples over various time periods and temperatures as is indicated in the respective “Stability Batches and Results”, with detailed results shown in FIGS. 9-17. More specifically, **FIG.9** depicts stability conditions and results for Stability Batch NPO2052, **FIG.10** depicts stability conditions and results for Stability Batch NPO2092, **FIG.11**

depicts stability conditions and results for Stability Batch NPO21001, **FIG.12** depicts stability conditions and results for Stability Batch B#192073_11, **FIG.13** depicts stability conditions and results for Stability Batch NPO21006, **FIG.14** depicts stability conditions and results for Stability Batch NPO21007, **FIG.15** depicts stability conditions and results for Stability Batch NPO21008, **FIG.16** depicts stability conditions and results for Stability Batch NPO21012, and **FIG.17** depicts stability conditions and results for Stability Batch Engineering Batch Lot#21070832. All formulations listed in FIGS.9-17 had an aluminum content of less than 50 mcg/L, with most formulations having an aluminum concentration of between about 7-27 mcg/L.

[0088] As can be readily seen from the results, the materials of the primary container did exert some influence on storage stability as evidenced by the liquid particle count (LPC) for particle size measurements at 10 and 25 micron. In addition, as can also be seen with certain materials, the presence of an overwrap substantially reduce loss of water via vapor phase as evidenced by the cation and anion concentrations.

[0089] In some embodiments, the numbers expressing quantities of ingredients, properties such as concentration, reaction conditions, and so forth, used to describe and claim certain embodiments of the invention are to be understood as being modified in some instances by the term “about.” Accordingly, in some embodiments, the numerical parameters set forth in the written description and attached claims are approximations that can vary depending upon the desired properties sought to be obtained by a particular embodiment. The recitation of ranges of values herein is merely intended to serve as a shorthand method of referring individually to each separate value falling within the range. Unless otherwise indicated herein, each individual value is incorporated into the specification as if it were individually recited herein.

[0090] As used herein, the term “administering” a pharmaceutical composition or drug refers to both direct and indirect administration of the pharmaceutical composition or drug, wherein direct administration of the pharmaceutical composition or drug is typically performed by a health care professional (*e.g.*, physician, nurse, etc.), and wherein indirect administration includes a step of providing or making available the pharmaceutical composition or drug to the health care professional for direct administration (*e.g.*, via injection, infusion, oral delivery, topical delivery, etc.). It should further be noted that the terms “prognosing” or “predicting” a condition, a

susceptibility for development of a disease, or a response to an intended treatment is meant to cover the act of predicting or the prediction (but not treatment or diagnosis of) the condition, susceptibility and/or response, including the rate of progression, improvement, and/or duration of the condition in a subject.

[0091] All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g. “such as”) provided with respect to certain embodiments herein is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention otherwise claimed. No language in the specification should be construed as indicating any non-claimed element essential to the practice of the invention.

[0092] As used in the description herein and throughout the claims that follow, the meaning of “a,” “an,” and “the” includes plural reference unless the context clearly dictates otherwise. Also, as used in the description herein, the meaning of “in” includes “in” and “on” unless the context clearly dictates otherwise. As also used herein, and unless the context dictates otherwise, the term “coupled to” is intended to include both direct coupling (in which two elements that are coupled to each other contact each other) and indirect coupling (in which at least one additional element is located between the two elements). Therefore, the terms “coupled to” and “coupled with” are used synonymously.

[0093] It should be apparent to those skilled in the art that many more modifications besides those already described are possible without departing from the inventive concepts herein. The inventive subject matter, therefore, is not to be restricted except in the scope of the appended claims. Moreover, in interpreting both the specification and the claims, all terms should be interpreted in the broadest possible manner consistent with the context. In particular, the terms “comprises” and “comprising” should be interpreted as referring to elements, components, or steps in a non-exclusive manner, indicating that the referenced elements, components, or steps may be present, or utilized, or combined with other elements, components, or steps that are not expressly referenced. Where the specification claims refers to at least one of something selected from the group consisting of A, B, C and N, the text should be interpreted as requiring only one element from the group, not A plus N, or B plus N, etc.

CLAIMS

What is claimed is:

1. An isotonic sterile ready-to-use (RTU) aqueous potassium phosphates solution, comprising potassium phosphates and sodium chloride, wherein the solution comprises 15 mmol/100 ml phosphorus (0.15 mmol/mL) and equal or less than 50 mcg/L aluminum.
2. The solution of claim 1, wherein the potassium phosphates comprise potassium dihydrogen phosphate (KH_2PO_4) and potassium hydrogen phosphate (K_2HPO_4), wherein the potassium dihydrogen phosphate is present in the solution an amount of about 1,120 mg/100 ml or 8.2 mmol/100 ml of Phosphorus and wherein the potassium hydrogen phosphate is present in the solution in an amount of about 1,180 mg/100 ml or 6.8 mmol/100 ml of Phosphorus.
3. The solution of claim 1, wherein the potassium is present in the solution in an amount of about 22 mEq/100 mL.
4. The solution of claim 1, wherein the sodium chloride is present in the solution in an amount of about 900 mg/100 ml.
5. The solution of claim 1, wherein the solution has a pH of between 6.2 and 6.8.
6. The solution of claim 1, wherein the solution has, after autoclaving and storage of at least 3 months at 25 °C and 40% relative humidity, a liquid particle count of no more than 360 and 30 for particles at 15 and 25 micrometer size, respectively.
7. The solution of claim 1, wherein the solution has, after autoclaving and storage of at least 3 months at 25 °C and 40% relative humidity, a change in phosphorus of no more than 1% absolute.
8. The solution of claim 1, wherein the solution has, after autoclaving and storage of at least 3 months at 25 °C and 40% relative humidity, a change in potassium of no more than 2% absolute.
9. The solution of claim 1, wherein the solution is packaged in a flexible polyolefin container, optionally at a volume of 100 mL.

10. The solution of claim 1, wherein the flexible polyolefin container is further contained in a secondary metallized overwrap.
11. A sterile ready-to-use (RTU) premixed pharmaceutical product stored in a flexible polymeric container, wherein the pharmaceutical product comprises a potassium phosphates in an aqueous sodium chloride solution containing (a) less than 50 mcg/L aluminum, (b) about 15 mmol/100 ml phosphorus, and (c) about 22 mEq/100 mL potassium.
12. The pharmaceutical product of claim 11, wherein the potassium phosphates comprise potassium dihydrogen phosphate (KH_2PO_4) and potassium hydrogen phosphate (K_2HPO_4), wherein the potassium dihydrogen phosphate is present in the solution an amount of about 1,120 mg/100 ml or 8.2 mmol/100 ml of Phosphorus, and wherein the potassium hydrogen phosphate is present in the solution in an amount of about 1,180 mg/100 ml or 6.8 mmol/100 ml of Phosphorus.
13. The pharmaceutical product of claim 12, wherein the sodium chloride is present in the aqueous sodium chloride solution in an amount of about 900 mg/100 ml.
14. The pharmaceutical product of claim 11, wherein the premixed pharmaceutical product in the flexible polymeric container has a volume of 100 mL.
15. The pharmaceutical product of claim 11, wherein the flexible polymeric container is enclosed in a secondary metallized overwrap.
16. The pharmaceutical product of claim 11, wherein the premixed pharmaceutical product comprises about 4.65 mg/mL of phosphorus (0.15 mmol/mL), about 8.50 mg/mL of potassium (0.22 mEq/mL), about 3.57 mg/mL of sodium, and about 5.43 mg/mL of chloride.
17. A method of administering phosphates to a patient in need of phosphorus replacement therapy, comprising:
 - administering, without prior dilution, an isotonic, sterile, and ready-to-use (RTU) solution comprising potassium phosphates and sodium chloride solution from a flexible container to the patient at a rate of infusion and by a route of administration corresponding to the patient's age and degree of need of phosphorus replacement;

wherein the solution comprises about 15 mmol/100 ml phosphorus, about 22 mEq/100 mL potassium, and less than 50 mcg/L aluminum.

18. The method of claim 17, wherein the rate of infusion is 6.8 mmol phosphates per hour or 15 mmol phosphates per hour.
19. The method of claim 17, wherein the route of administration is a central venous catheter.
20. The method of claim 17, wherein the solution is administered after storage of at least 3 months at 25 °C and 40% relative humidity.

ABSTRACT

A ready-to-use (RTU) potassium phosphates in sodium chloride solution for phosphorus replacement therapy includes potassium phosphate and sodium chloride at a fixed volume with 15 mmol/100 mL phosphorus and 22 mEq/100 mL potassium and less than 50 mcg/L aluminum.

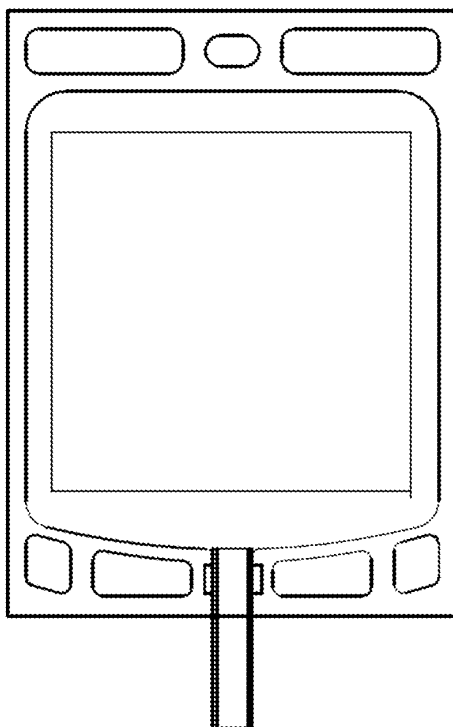


FIG. 1

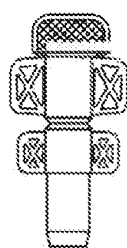


FIG. 2



FIG.3

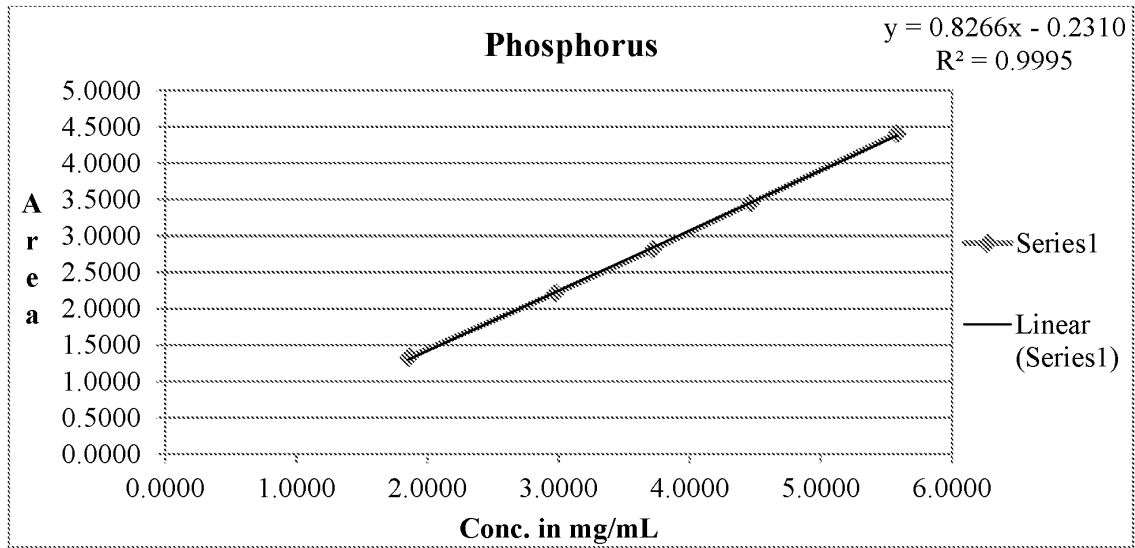


FIG.4

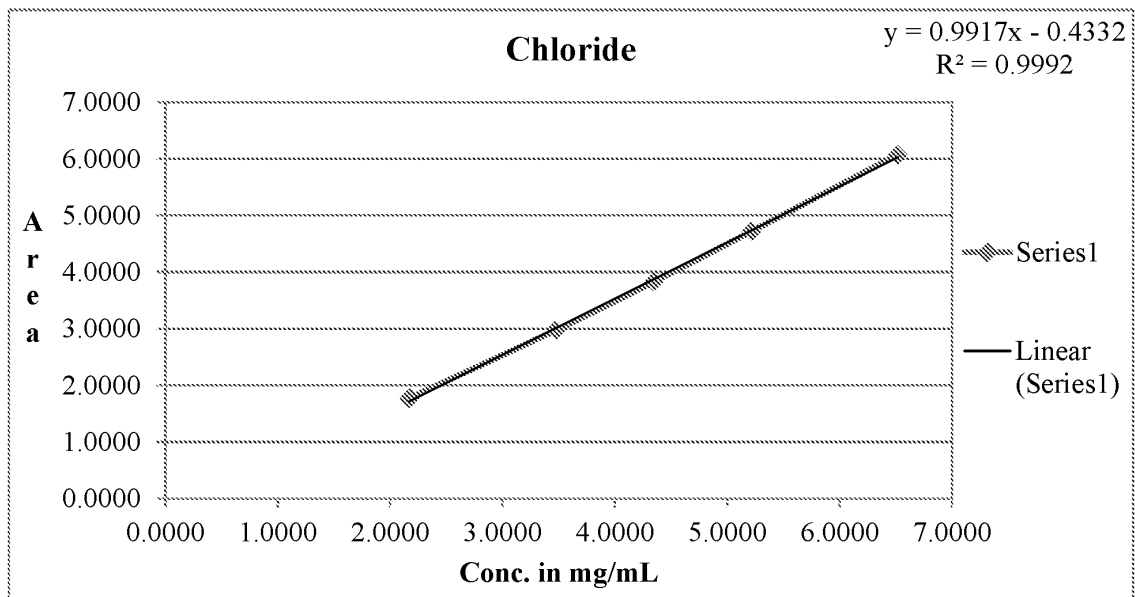


FIG.5

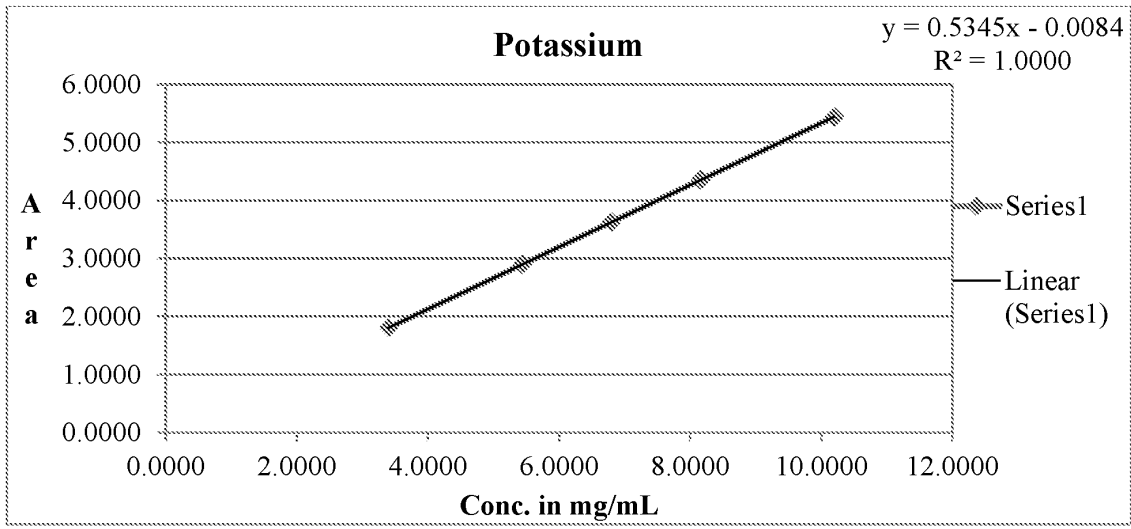


FIG.6

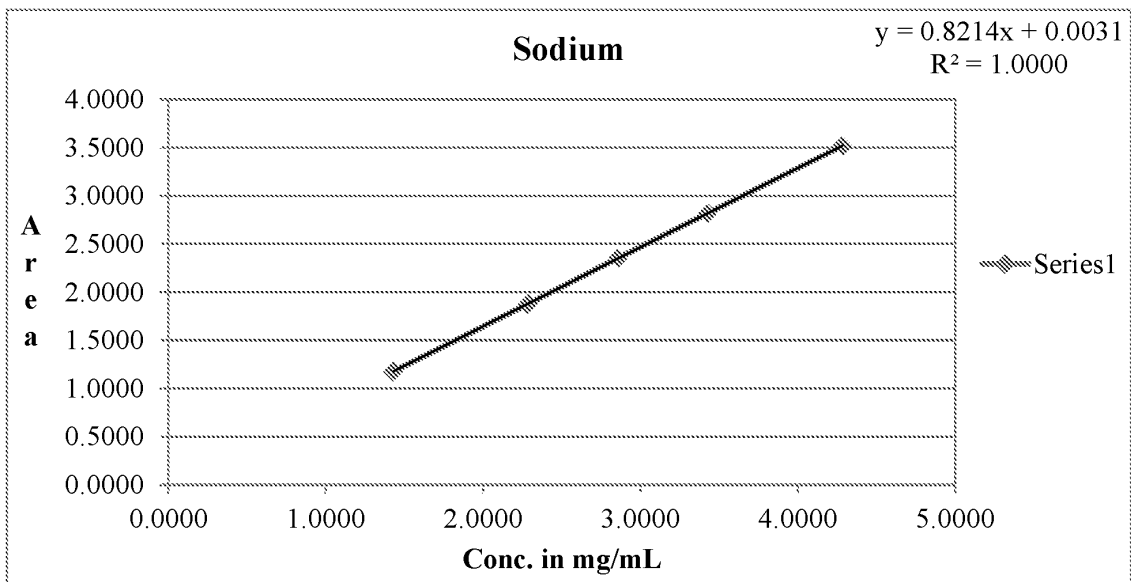


FIG.7

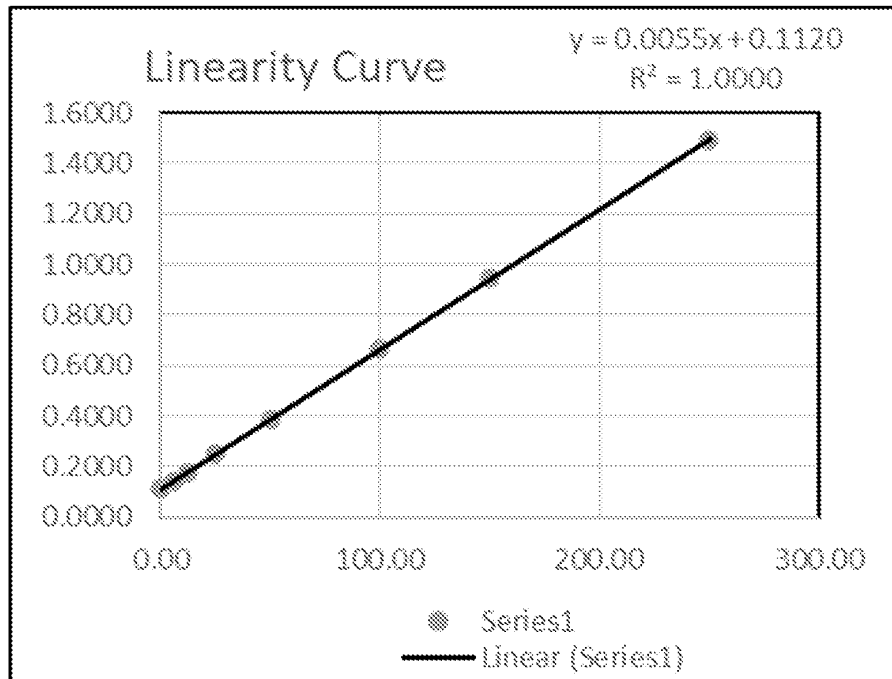


FIG.8

B. No.#NPO2052											
Autoclave @ 121°C for 15 Minutes											
TechnoFlex 1T PP Bag + Al Pouch											
Test	Condition										
	Bulk Solution	Initial	3M 25/40	3M 30/65	3M 40/15	6M 25/40	6M 30/65	6M 40/15			
Description*	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
pH of Solution	6.543	6.551	6.61	6.56	6.62	6.56	6.57				
Osmolality (mOsm/kg)	576	569	565	606	592	588	595				
LPC	18µm	553	113	427	80	233	187				
	25µm	13	7	13	13	7	0				
Assay of Anions	% Phosphorus	101.0	98.0	99.1	94.4	101.6	99.5				
	% Chloride	102.0	101.8	96.7	101.2	102.3	99.1				
Assay of Cations	% Potassium	102.2	102.0	98.6	98.3	101.7	98.6				
	% Sodium	99.8	99.7	99.1	100.5	101.6	98.5				
TechnoFlex 1T PP Bag (Without Al Pouches)											
Test	Condition										
	Bulk Solution	Initial	3M 25/40	3M 30/65	3M 40/15	6M 25/40	6M 30/65	6M 40/15			
Description*	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
pH of Solution	6.543	6.551	6.58	6.58	6.57	6.56	6.54				
Osmolality (mOsm/kg)	576	569	571	608	622	578	560				
LPC	18µm	553	227	440	940	140	407				
	25µm	13	20	7	20	0	27				
Assay of Anions	% Phosphorus	101.0	99.3	100.5	101.0	101.7	101.4				
	% Chloride	102.0	101.8	98.4	99.0	99.8	100.4				
Assay of Cations	% Potassium	102.2	100.5	99.6	100.3	99.9	99.8				
	% Sodium	99.8	99.7	100.9	98.5	99.7	99.7				
CCS- A Clear colorless solution, free from visible foreign particles											

FIG.9

Autoclave @ 121°C for 15 Minutes										
Grifols IT PP Bag + Al Pouch										
Test		Condition								
		Bulk Solution	Initial	3M 25/40	3M 30/65	3M 40/15	6M 25/40	6M 30/65	6M 40/15	
Assay of Anions	% Phosphorus	101.0	100.9	98.8	98.8	95.0	100.3	100.0	100.3	
	% Chloride	102.0	101.9	98.4	97.7	94.6	99.3	99.0	98.6	
Assay of Cations	% Potassium	102.2	101.8	99.9	98.1	96.0	99.7	98.7	98.6	
	% Sodium	99.8	99.4	100.9	96.9	94.6	99.2	98.6	98.2	
Grifols IT PP Bag (Without Al Pouches)										
Test		Condition								
		Bulk Solution	Initial	3M 25/40	3M 30/65	3M 40/15	6M 25/40	6M 30/65	6M 40/15	
Description*	pH of Solution	CCS	6.548	6.62	6.56	6.58	6.59	6.56	6.56	
	Osmolality (mOsm/kg)	576	579	574	604	626	581	591	628	
LPC	10µm	227	187	107	60	587	193	173	107	
	25µm	20	0	7	0	27	7	33	33	
Assay of Anions	% Phosphorus	101.0	100.9	99.5	100.8	102.0	102.8	102.1	111.8	
	% Chloride	102.0	101.9	99.2	99.0	100.5	100.6	101.0	109.7	
Assay of Cations	% Potassium	102.2	101.8	101.2	99.7	102.9	100.4	100.7	109.6	
	% Sodium	99.8	99.4	101.8	98.7	101.3	99.8	100.4	109.3	
* CCS- A Clear colorless solution, free from visible foreign particles										

FIG.9 cont'd

Autoclave @ 121°C for 15 Minutes												
TechnoFlex 2T PP Bag + Al Pouch												
Test	Bulk Solution	Initial	Condition								6M 30/65	6M 40/15
			3M 25/40	3M 30/65	3M 40/15	6M 25/40	6M 30/65	6M 40/15	6M 25/40	6M 30/65		
Description*	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
pH of Solution	6.543	6.549	6.61	6.63	6.58	6.54	6.57	6.58	6.54	6.57	6.57	6.58
Osmolality (mOsm/kg)	576	570	568	601	569	577	577	569	577	577	577	572
LPC	10µm	227	360	893	183	520	180	183	520	180	180	100
	25µm	20	30	33	20	47	27	20	47	27	27	13
Assay of Anions	% Phosphorus	101.0	98.5	98.4	97.9	100.3	98.7	97.9	100.3	98.7	98.7	100.5
Assay of Cations	% Chloride	102.0	97.7	97.5	96.2	99.4	97.7	96.2	99.4	97.7	97.7	98.6
	% Potassium	102.2	99.7	97.7	98.3	99.5	97.4	98.3	99.5	97.4	97.4	98.9
	% Sodium	99.8	100.2	96.7	96.6	99.0	97.3	96.6	99.0	97.3	97.3	98.6
TechnoFlex 2T PP Bag (Without Al Pouches)												
Test	Bulk Solution	Initial	Condition								6M 30/65	6M 40/15
			3M 25/40	3M 30/65	3M 40/15	6M 25/40	6M 30/65	6M 40/15	6M 25/40	6M 30/65		
Description*	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
pH of Solution	6.543	6.549	6.63	6.58	6.6	6.57	6.57	6.6	6.57	6.57	6.57	6.56
Osmolality (mOsm/kg)	576	570	573	604	620	584	585	620	584	585	585	615
LPC	10µm	227	133	353	1867	167	240	1867	167	240	240	460
	25µm	20	7	7	20	0	7	20	0	7	7	13
Assay of Anions	% Phosphorus	101.0	98.8	100.1	103.0	109.2	102.5	103.0	109.2	102.5	102.5	109.5
Assay of Cations	% Chloride	102.0	98.2	99.2	102.1	112.4	101.0	102.1	112.4	101.0	101.0	107.4
	% Potassium	102.2	100.6	99.4	104.1	100.4	100.7	104.1	100.4	100.7	100.7	107.3
	% Sodium	99.8	101.1	96.5	102.3	100.0	100.5	102.3	100.0	100.5	100.5	107.0
* CCS- A Clear colorless solution, free from visible foreign particles												

FIG.9 cont'd

Autoclave @ 121°C for 15 Minutes												
Bausch 2T PP Bag + Al Pouch												
Test		Condition										
		Bulk Solution	Initial	3M 25/40	3M 30/65	3M 40/15	6M 25/40	6M 30/65	6M 40/15	6M 25/40	6M 30/65	6M 40/15
Description *	pH of Solution	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
		6.543	6.553	6.63	6.62	6.59	6.53	6.58	6.58	6.53	6.58	6.58
Osmolality (mOsm/kg)	LPC	576	572	567	599	591	582	580	581	582	580	581
		227	153	127	427	240	153	240	333	153	240	333
Assay of Anions	% Phosphorus	20	13	13	20	0	7	7	7	7	7	7
		101.0	101.6	98.0	98.9	96.8	101.2	100.0	100.8	101.2	100.0	100.8
Assay of Cations	% Chloride	102.0	102.6	97.7	102.6	95.9	99.3	98.8	99.2	99.3	98.8	99.2
		102.2	102.4	99.6	98.8	103.2	99.7	98.7	99.3	99.7	98.7	99.3
Assay of Cations	% Sodium	99.8	100.2	100.3	102.0	96.3	99.0	98.5	99.0	99.0	98.5	99.0
Bausch 2T PP Bag (Without Al Pouches)												
Test		Condition										
		Bulk Solution	Initial	3M 25/40	3M 30/65	3M 40/15	6M 25/40	6M 30/65	6M 40/15	6M 25/40	6M 30/65	6M 40/15
Description *	pH of Solution	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
		6.543	6.553	6.62	6.56	6.62	6.59	6.56	6.56	6.59	6.56	6.56
Osmolality (mOsm/kg)	LPC	576	572	571	610	625	578	593	618	578	593	618
		227	153	193	93	40	127	247	240	127	247	240
Assay of Anions	% Phosphorus	20	13	0	0	0	0	0	20	0	0	20
		101.0	101.6	96.8	99.5	102.1	104.2	102.3	109.7	104.2	102.3	109.7
Assay of Cations	% Chloride	102.0	102.6	96.2	98.8	100.8	104.1	100.6	108.0	104.1	100.6	108.0
		102.2	102.4	98.6	98.7	103.1	100.7	100.0	107.7	100.7	100.0	107.7
Assay of Cations	% Sodium	99.8	100.2	99.1	98.1	102.1	100.5	99.9	107.2	100.5	99.9	107.2
* CCS- A Clear colorless solution, free from visible foreign particles												

FIG.9 cont'd

Autoclave @ 121°C for 15 Minutes											
TechnoFlex 2T PVC Bag + Al Pouch											
Test	Description*	Condition									
		Bulk Solution	Initial	3M 25/40	3M 30/65	3M 40/15	6M 25/40	6M 30/65	6M 40/15		
pH of Solution	Description*	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
		6.543	6.550	6.61	6.57	6.57	6.57	6.57	6.57	6.57	6.56
Osmolality (mOsm/kg)	Description*	576	573	573	606	606	584	589	581	581	581
		227	153	267	600	360	313	193	87	87	87
LPC	Description*	20	13	13	33	7	0	7	7	7	7
		% Phosphorus	101.0	99.4	99.7	100.5	102.6	101.3	102.9	102.9	102.9
Assay of Anions	Description*	% Chloride	102.0	98.8	98.8	99.4	101.1	100.5	101.2	101.2	101.2
		% Potassium	102.2	102.3	100.7	99.1	101.6	102.1	99.7	101.3	101.3
Assay of Cations	Description*	% Sodium	99.8	100.1	101.3	98.2	100.7	99.6	100.9	100.9	100.9
TechnoFlex 2T PVC Bag (Without Al Pouches)											
Test	Description*	Condition									
		Bulk Solution	Initial	3M 25/40	3M 30/65	3M 40/15	6M 25/40	6M 30/65	6M 40/15		
pH of Solution	Description*	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
		6.543	6.550	6.61	6.6	6.6	6.55	6.55	6.45	6.45	6.45
Osmolality (mOsm/kg)	Description*	576	573	607	657	846	636	649	1092	1092	1092
		227	153	320	253	147	933	260	161	161	161
LPC	Description*	20	13	20	13	27	7	13	7	7	7
		% Phosphorus	101.0	104.7	110.4	142.7	123.2	113.7	224.2	224.2	224.2
Assay of Anions	Description*	% Chloride	102.0	104.4	109.8	141.5	116.1	112.3	222.7	222.7	222.7
		% Potassium	102.2	107.1	110.1	145.5	112.7	111.9	218.7	218.7	218.7
Assay of Cations	Description*	% Sodium	99.8	107.6	109.4	142.4	112.3	111.7	217.7	217.7	217.7

CCS - A Clear colorless solution, free from visible foreign particles

* CCS - A Clear colorless solution, free from visible foreign particles

FIG.9 cont'd

B. No.#NPO2092												
Autoclave @ 121°C for 15 Minutes												
TechaoFlex IT PP Bag + Al Pouch												
Test		Condition										
		Bulk Solution	Initial	IM 2-8	IM 25/40	IM 30/65	IM 40/15	6M 2-8	6M 25/40	6M 30/65	6M 40/15	
Description*	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
	pH of Solution	6.61	6.53	6.59	6.1	6.62	6.56	6.67	6.66	6.67	6.69	6.69
Osmolality (mOsm/kg)	574	569	577	580	577	581	573	575	578	578	575	575
	10µm	273	240	213	160	500	307	487	433	327	347	347
LPC	25µm	27	7	7	0	20	20	20	53	7	13	13
	% Phosphorus	100.8	100.8	98.9	97.7	98.3	98.1	99.3	99.9	101.2	101.4	101.4
Assay of Anions	% Chloride	99.0	105.4	96.1	94.6	96.1	95.0	100.7	101.5	101.8	100.7	100.7
	% Potassium	101.1	99.4	98.8	97.4	98.7	98.0	101.1	100.6	101.5	101.7	101.7
Assay of Cations	% Sodium	101.5	95.1	98.3	96.5	98.7	97.5	100.3	99.8	102.2	100.8	100.8
	* CCS- A Clear colorless solution, free from visible foreign particles											
Autoclave @ 121°C for 15 Minutes												
Grifols IT PP Bag + Al Pouch												
Test		Condition										
		Bulk Solution	Initial	IM 2-8	IM 25/40	IM 30/65	IM 40/15	6M 2-8	6M 25/40	6M 30/65	6M 40/15	
Description*	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
	pH of Solution	6.61	6.55	6.58	6.57	6.59	6.60	6.69	6.69	6.67	6.70	6.70
Osmolality (mOsm/kg)	574	572	579	575	578	581	572	573	571	573	573	573
	10µm	273	153	387	1573	527	333	273	287	473	180	180
LPC	25µm	27	7	20	73	53	33	33	27	67	27	27
	% Phosphorus	100.8	101.5	97.3	98.3	98.9	97.5	100.7	100.9	100.3	101.2	101.2
Assay of Anions	% Chloride	99.0	106.4	94.2	94.1	95.5	94.6	101.1	103.3	103.2	102.1	102.1
	% Potassium	101.1	100.2	97.1	98.5	98.7	97.7	100.6	100.7	100.5	100.7	100.7
Assay of Cations	% Sodium	101.5	98.9	96.8	98.0	98.2	97.4	99.9	99.9	99.7	99.9	99.9
	* CCS- A Clear colorless solution, free from visible foreign particles											

FIG.10

E No. #NPO21001															
Aspic Filling															
Infused (Polyline APP148) 1T PP Bag - Al Pouch															
Condition															
Test	Bulk Solution	Bulb IM 2-8	Bulb IM 40/15	Bulb IM 2-8	Bulb IM 40/15	Initial	IM 25/40	IM 40/15	IM 2-8	IM 25/40	IM 40/15	IM 2-8	IM 25/40	IM 40/15	IM 40/15
Description*	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
pH of Solution	6.58					6.60	6.52	6.52	6.57	6.58	6.58	6.68	6.66	6.67	6.68
Ornolide (mOm/kg)	580					570	570	568	569	565	571	587	570	572	569
LPC	Not Applicable					1260.00	92	547	87	127	27	919	3707	1447	27
						0	7	17	0	7	0	0	33	7	0
Assay of Anions	97.3	101.4	103.2	101.5	113.9	58.6	100.2	96.9	106.9	102.4	101.3	102.0	102.7	102.7	102.8
% Chloride	96.5	99.4	101.7	100.2	113.6	97.7	98.1	98.1	103.1	105.0	102.7	100.7	101.3	101.6	101.5
Assay of Cations	102.1	100.9	103.5	99.1	112.0	101.2	100.3	100.0	101.2	102.8	100.9	100.0	100.5	100.5	101.2
% Sodium	101.1	101.2	103.0	98.8	111.8	101.1	100.6	102.4	101.4	102.6	101.0	99.1	98.4	98.5	100.3
* CCS: A Clear colorless solution, free from visible foreign particles															
Aspic Filling															
BaesofPharm (31312A) 1T PP Bag - Al Pouch															
Condition															
Test	Bulk Solution	Bulb IM 2-8	Bulb IM 40/15	Bulb IM 2-8	Bulb IM 40/15	Initial	IM 25/40	IM 40/15	IM 2-8	IM 25/40	IM 40/15	IM 2-8	IM 25/40	IM 40/15	IM 40/15
Description*	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
pH of Solution	6.58					6.59	6.62	6.61	6.57	6.57	6.53	6.69	6.65	6.65	6.7
Ornolide (mOm/kg)	580					572	570	562	572	577	576	588	567	577	597
LPC	Not Applicable					726	100	127	1147	847	1140	820	840	2880	72
						0	13	13	113	47	93	13	49	30	7
Assay of Anions	97.3	101.4	103.2	101.5	113.9	97.9	100.9	101.5	101.8	102.0	102.3	102.7	103.0	102.7	103.1
% Chloride	96.5	99.4	101.7	100.2	113.6	97.1	98.7	99.4	103.4	103.1	103.9	101.4	101.8	101.3	101.9
Assay of Cations	102.1	100.9	103.5	99.1	112.0	102.6	100.8	101.0	103.3	101.8	101.2	100.6	100.8	100.4	101.1
% Sodium	101.1	101.2	103.0	98.8	111.8	101.5	101.1	102.0	101.6	101.9	101.3	99.7	99.8	99.4	100.6
* CCS: A Clear colorless solution, free from visible foreign particles															

FIG.11

Aspiric Filling													
Technofas IT PP Bag + Al Pouch													
Test	Condition												
	Bulk Solution	Bulk IM 2.8	Bulk IM 40/15	Bulk IM 2.8	Bulk IM 40/15	Initial	IM 25/40	IM 40/15	IM 2.8	IM 25/40	IM 40/15	IM 2.8	IM 25/40
Description*	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
pH of Solution	6.53					6.6	6.53	6.53	6.50	6.6	6.6	6.56	6.6
Ononidite (mOnon/kg)	580					581	568	560	571	571	570	573	569
LPC	Not Applicable					487	27	93	123	463	327	873	337
Assay of Anions						0	7	13	7	49	7	13	20
Assay of Cations						98.0	100.2	99.6	100.3	102.5	100.9	103.3	102.7
						97.3	99.3	98.3	100.4	104.0	101.9	102.2	101.4
						102.1	103.5	102.6	102.9	101.5	99.6	101.2	101.0
						101.1	103.6	101.3	95.7	96.7	95.3	100.1	99.7
* CCS: A Clear colorless solution, free from visible foreign particles													
Autoclave @ 121°C for 15 Minutes (Autoclave Pressure: Max 3.18 bar, Min 3.00 bar)													
Inflamed (PolylineAPPI145) IT PP Bag + Al Pouch													
Test	Condition												
	Bulk Solution	Bulk IM 2.8	Bulk IM 40/15	Bulk IM 2.8	Bulk IM 40/15	Initial	IM 25/40	IM 40/15	IM 2.8	IM 25/40	IM 40/15	IM 2.8	IM 25/40
Description*	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
pH of Solution	6.52					6.52	6.53	6.55	6.38	6.59	6.38	6.67	6.63
Ononidite (mOnon/kg)	580					589	581	584	590	569	571	574	570
LPC	Not Applicable					747	230	67	33	267	173	253	107
Assay of Anions						13	6	0	0	47	13	19	39
Assay of Cations						103.0	100.2	96.1	100.9	103.6	101.1	102.6	102.0
						107.2	98.1	97.2	102.3	103.1	102.3	101.4	102.0
						113.1	106.3	99.7	109.0	96.8	102.5	100.6	101.3
						111.8	101.0	102.3	106.7	100.2	102.4	100.1	100.2
* CCS: A Clear colorless solution, free from visible foreign particles													

FIG.11 cont'd

Amneal @ 22°C for 15 Minutes (Autoclave Pressure: Max-3.18 bar, Min-3.00 bar)														
Hemopharm (M312A) 11 PP Bag - Al Pouch														
Condition														
Test	Bulk Solution	Bulk IM 2-8	Bulk IM 4015	Bulk IM 2-8	Bulk IM 4015	Initial	IM 25-40	IM 4015	IM 2-8	IM 25-40	IM 4015	IM 2-8	IM 25-40	IM 4015
Description*	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
pH of Solution	6.53					6.53	6.50	6.50	6.50	6.50	6.53	6.7	6.61	6.68
Osmolality (mOsm/kg)	530					565	583	582	577	574	575	576	572	568
LPC	Not Applicable					987	206	113	1007	2440	727	487	2033	160
Assay of Anions	% Phosphorus	97.3	101.4	103.2	101.5	115.9	99.6	99.8	101.8	102.0	101.8	102.7	103.8	103.2
	% Chloride	95.5	99.4	101.7	100.2	115.0	97.2	97.5	103.6	103.4	103.3	102.0	103.1	102.7
Assay of Cations	% Potassium	102.1	100.9	103.5	99.1	112.0	96.8	106.2	101.3	101.0	99.9	101.0	101.9	100.1
	% Sodium	101.1	101.2	103.9	98.8	111.8	100.3	100.8	102.1	101.5	100.3	100.7	101.3	100.8
* CCS: A Clear colorless solution, free from visible foreign particles														
Tachaflex 11 PP Bag - Al Pouch														
Autoclave @ 22°C for 4 Minutes (Autoclave Pressure: Max-3.19 bar, Min-2.98 bar)														
Condition														
Test	Bulk Solution	Bulk IM 2-8	Bulk IM 4015	Bulk IM 2-8	Bulk IM 4015	Initial	IM 25-40	IM 4015	IM 2-8	IM 25-40	IM 4015	IM 2-8	IM 25-40	IM 4015
Description*	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
pH of Solution	6.53					6.50	6.55	6.50	6.50	6.6	6.6	6.64	6.66	6.64
Osmolality (mOsm/kg)	530					567	581	585	569	568	567	575	570	570
LPC	Not Applicable					340	40	60	400	300	287	93	173	207
Assay of Anions	% Phosphorus	97.3	101.4	103.2	101.5	115.9	99.5	99.2	101.2	101.6	102.3	102.5	103.0	102.8
	% Chloride	96.5	99.4	101.7	100.2	115.0	97.6	97.6	103.7	103.6	102.6	101.8	102.2	101.7
Assay of Cations	% Potassium	102.1	100.9	103.5	99.1	112.0	100.4	100.4	101.1	101.2	100.9	100.7	101.1	101.0
	% Sodium	101.1	101.2	103.9	98.8	111.8	100.9	101.1	95.7	96.7	95.5	100.2	100.6	100.5
* CCS: A Clear colorless solution, free from visible foreign particles														

FIG.11 cont'd

Anode @ 115°C for 20 Minutes (Anode Pressure: Max-2.61 bar, Min-2.45 bar)														
Infused (Polyimide/PP146) IT PP Bag - Al Pouch														
Test		Condition												
		Bulk Solution	Bulk IM 2-8	Bulk IM 4015	Bulk 6M 2-8	Bulk 6M 4015	Initial	IM 25/40	IM 4015	IM 2-8	IM 25/40	IM 4015	6M 2-8	6M 25/40
Description*	CCS													
	6.58													
pH of Solution		5.58												
Osmolality (mOsm/kg)		289												
LPC		Not Applicable												
Assay of Anions		97.3	101.4	103.2	101.3	113.9	98.4	101.9	101.6	100.5	101.1	101.1	102.1	102.5
Assay of Cations		102.1	102.9	103.5	99.1	112.6	102.9	99.6	100.0	101.1	101.1	101.6	100.2	100.5
Assay of Sodium		101.1	101.2	103.9	93.8	111.8	101.8	100.3	100.6	100.3	100.4	101.2	100.1	100.9
* CCS: A Clear colorless solution, free from visible foreign particles														
Anode @ 115°C for 20 Minutes (Anode Pressure: Max-2.61 bar, Min-2.45 bar)														
Infused (Polyimide/PP146) IT PP Bag - Al Pouch														
Test		Condition												
		Bulk Solution	Bulk IM 2-8	Bulk IM 4015	Bulk 6M 2-8	Bulk 6M 4015	Initial	IM 25/40	IM 4015	IM 2-8	IM 25/40	IM 4015	6M 2-8	6M 25/40
Description*	CCS													
	6.58													
pH of Solution		5.58												
Osmolality (mOsm/kg)		289												
LPC		Not Applicable												
Assay of Anions		97.3	101.4	103.2	101.5	113.9	98.3	101.8	100.9	101.1	101.6	101.6	102.9	102.9
Assay of Cations		102.1	102.9	103.5	99.1	112.6	102.3	99.5	100.3	100.6	101.2	100.9	100.6	100.0
Assay of Sodium		101.1	101.2	103.9	93.8	111.8	101.2	100.1	100.6	100.0	100.6	100.5	99.5	98.5
* CCS: A Clear colorless solution, free from visible foreign particles														

FIG.11 cont'd

Autoclave @ 118°C for 20 Minutes (Autoclave Pressure: Max 2.61 bar, Min 2.45 bar) Technoflex IT PP Bag + Al Pouch													
Test	Condition												
	Bulk Solution	Bulk 1M 2-8	Bulk 1M 4015	Bulk 6M 2-8	Bulk 6M 4015	Initial	1M 15-40	1M 4015	3M 2-8	3M 25-40	3M 4015	6M 2-8	6M 15-40
Description ^a	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
pH of Solution	6.33	Not Applicable											
Osmolality (mOsm/kg)	560												
LPC	Not Applicable												
Assay of Anions	% Phosphate 97.3	101.4	105.2	101.5	115.9	98.0	101.8	101.3	103.3	102.4	101.5	103.0	102.8
	% Chloride 94.5	99.4	101.7	100.2	115.0	97.3	99.5	99.1	104.0	102.6	102.9	101.1	100.3
Assay of Cations	% Potassium 102.1	100.9	103.5	99.1	112.0	102.9	100.2	106.0	102.2	100.2	100.3	99.9	99.6
	% Sodium 101.1	101.2	102.9	98.8	111.8	102.0	101.8	100.8	97.3	95.0	96.4	98.6	98.3
^a CCS - A Clear colorless solution, free from visible foreign particles													

FIG.11 cont'd

B. No.192073_11													
Autoclave @ 121°C for 15 Minutes (Autoclave Pressure: Max.3.19 bar , Min.2.99 bar)													
HaemoPharm (M312A) II PP Bag + Al Pouch													
Test		Initial	1M 2.8	1M 25:40	1M 40:15	3M 2.8	3M 25:40	3M 30:65	3M 40:15	6M 2.8	6M 25:40	6M 30:65	6M 40:15
Description *		CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
pH of Solution		6.56	6.61	6.60	6.58	6.66	6.65	6.66	6.67	6.59	6.58	6.58	6.58
Osmolality (mOsm/kg)		569	579	581	589	576	580	578	577	579	577	573	571
LPC	10µm	433	980	553	220	240	187	107	207	337	173	300	80
	25µm	13	47	20	7	13	0	13	13	7	20	7	0
Assay of Anions	% Phosphorus	100.9	98.7	98.8	99.4	102.5	104.9	104.7	103.4	98.6	100.2	99.0	99.6
	% Chloride	100.0	97.3	97.8	98.5	101.8	104.1	104.0	102.9	99.3	100.8	99.5	100.2
Assay of Cations	% Potassium	101.8	102.7	103.4	103.8	100.0	101.8	101.7	100.7	101.6	100.0	99.2	99.8
	% Sodium	100.7	101.9	102.3	103.0	99.0	101.0	102.8	99.9	100.3	100.8	98.0	98.6
* CCS- A Clear colorless solution, free from visible foreign particles													

FIG.12

B. No.2NPO21096														
Aseptic Filling														
Haemofarm (M312) IT PP Bag + Al Pouch														
Test		Condition												
		Bulk Solution	Initial	IM 2-8	IM 25-40	IM 40/15	3M 2-8	3M 25-40	3M 30/65	3M 40/15	6M 2-8	6M 25-40	6M 30/65	6M 40/15
Description*	pH of Solution	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	
		6.60	6.52	6.68	6.68	6.56	6.56	6.56	6.56	6.56	6.59	6.58	6.6	6.6
Osmolality (mOsm/kg)	Not Applicable	561	577	578	347	253	87	574	576	578	574	300	579	580
		267	253	87	127	140	140	200	160	260				
LPC	25µm	47	13	13	7	13	20	6	7	13	27			
		102.9	103.6	103.3	103.4	100.5	102.3	102.2	103.7	103.8	103.0			
Assay of Anions	% Chloride	100.0	101.1	102.9	101.0	104.1	104.2	101.3	103.1	102.8	103.5	102.7	102.3	
		101.1	102.2	102.8	104.3	101.5	101.6	99.3	101.1	100.0	100.4	100.5	101.5	
Assay of Cations	% Sodium	101.6	102.5	101.6	101.8	102.0	99.6	101.4	99.5	100.0	100.2	100.4		
		* CCS: A Clear colorless solution, free from visible foreign particles.												
Autoclave @ 121°C for 15 Minutes (Autoclave Pressure: Max.3.24 bar . Min.2.98 bar)														
Haemofarm (M312) IT PP Bag + Al Pouch														
Test		Condition												
		Bulk Solution	Initial	IM 2-8	IM 25-40	IM 40/15	3M 2-8	3M 25-40	3M 30/65	3M 40/15	6M 2-8	6M 25-40	6M 30/65	6M 40/15
Description*	pH of Solution	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	
		6.60	6.52	6.67	6.67	6.56	6.54	6.55	6.55	6.55	6.58	6.6	6.59	6.61
Osmolality (mOsm/kg)	Not Applicable	563	577	575	663	447	554	577	573	583	572	580	574	574
		307	363	447	80	133	80	307	1040	300	127			
LPC	25µm	13	0	20	20	0	0	27	0	13	20	7	13	
		101.7	100.8	102.1	102.6	102.5	104.2	102.4	103.9	102.3	103.7			
Assay of Anions	% Chloride	100.0	101.1	103.3	102.7	103.4	103.2	105.0	102.2	103.8	102.3	103.5		
		101.1	101.8	101.4	103.0	101.0	101.0	102.3	99.4	100.8	101.7	100.5		
Assay of Cations	% Sodium	101.6	102.3	100.8	101.4	101.1	102.5	98.7	100.0	99.7	100.0	99.7	99.9	
		* CCS: A Clear colorless solution, free from visible foreign particles.												

FIG.13

B. No.#NFO21007														
Aseptic Filling														
HaemoPharm (M112) IT PP Bag - Al Pouch														
Test		Condition												
Description*	Bulk Solution	Initial	3M 2-8											6M 4015
			CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	
pH of Solution	6.58	6.65	6.56	6.57	6.56	6.48	6.48	6.48	6.49	6.49	6.49	6.49	6.49	6.6
Osmolality (mOsm/kg)	Not Applicable	575	573	574	575	540	540	575	578	577	565	567	569	569
LPC	10µm	246	933.33	606.67	2346.67	473	1530	187	187	167	113	833	433	107
	25µm	7	6.57	0	46.67	13	13	33	33	29	13	47	33	7
Assay of Anions	% Phosphorus	101.9	102.2	104.6	103.1	98.9	98.2	99.3	99.3	99.6	102.8	102.0	102.4	101.9
Assay of Cations	% Chloride	101.5	101.8	101.6	103.2	100.0	99.2	100.7	100.7	100.2	101.1	102.2	102.6	102.1
	% Potassium	99.4	99.7	101.0	102.6	101.6	102.2	100.2	100.2	99.6	100.9	101.0	101.4	101.0
	% Sodium	98.8	100.5	102.4	101.7	99.5	97.0	98.1	98.1	97.6	100.6	101.3	101.9	101.6
* CCS- A Clear colorless solution, free from visible foreign particles														
Infused (Polyon APP148) IT PP Bag + Al Pouch														
Test		Condition												
Description*	Bulk Solution	Initial	3M 2-8											6M 4015
			CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	
pH of Solution	6.58	6.67	6.57	6.58	6.58	6.49	6.49	6.49	6.5	6.5	6.58	6.58	6.58	6.58
Osmolality (mOsm/kg)	Not Applicable	573	573	571	575	575	580	582	574	580	577	579	578	578
LPC	10µm	193	2063.33	9433.33	340	233	313	80	293	73	207	173	173	1767
	25µm	0	306	133.33	11.33	26	26	7	40	7	7	27	47	47
Assay of Anions	% Phosphorus	102.5	103.4	106.3	102.0	99.1	97.4	98.2	98.2	98.3	103.2	103.5	103.5	103.4
Assay of Cations	% Chloride	101.5	103.8	106.4	102.1	100.3	98.7	99.6	99.7	99.7	103.5	103.7	103.8	103.3
	% Potassium	99.4	100.1	99.7	100.9	100.4	99.1	100.7	99.7	99.7	101.9	101.8	101.5	101.6
	% Sodium	98.8	102.5	98.3	100.8	97.2	95.9	97.7	98.2	98.2	102.5	102.5	102.3	102.1
* CCS- A Clear colorless solution, free from visible foreign particles														

FIG.14

Autoclave @ 121°C for 15 Minutes (Autoclave Pressure: Max-3.16 bar , Min-2.97 bar)														
Haemopharm (M112) IT PP Bag - Al Pouch														
Test		Condition												
		Bulk Solution	Initial	IM 2-8	IM 25-40	IM 40-15	IM 1-8	IM 25-40	IM 30-65	IM 40-15	IM 2-8	IM 25-40	IM 30-65	IM 40-15
Description*		CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
pH of Solution		0.38	0.63	6.37	6.56	6.57	6.49	6.49	6.49	6.49	6.59	6.59	6.59	6.59
Osmolality (mOsm/kg)		Not Applicable	577	581	572	574	576	575	580	578	569	568	570	566
LPC	10um		473	333.33	2893.33	646.97	147	147	253	100	73	260	413	60
	25um		20	40	30	46.67	18	7	27	7	27	20	40	7
Assay of Anions	% Phosphorus		192.1	103.9	103.7	104.0	102.1	98.9	98.7	100.9	102.3	103.0	103.2	102.1
	% Chloride		102.0	105.4	103.9	104.9	103.5	106.4	99.7	101.6	102.5	103.4	103.4	102.2
Assay of Cations	% Potassium		99.6	103.1	102.1	103.0	102.6	99.9	99.9	101.8	100.8	101.0	101.2	100.9
	% Sodium		98.2	101.1	102.2	102.6	101.1	97.6	97.3	98.5	101.1	101.5	101.7	101.5
* CCS- A Clear colorless solution, free from visible foreign particles														
Autoclave @ 121°C for 15 Minutes (Autoclave Pressure: Max-3.20 bar , Min-2.97 bar)														
Infomed (Polydin APP148) IT PP Bag - Al Pouch														
Test		Condition												
		Bulk Solution	Initial	IM 2-8	IM 25-40	IM 40-15	IM 1-8	IM 25-40	IM 30-65	IM 40-15	IM 2-8	IM 25-40	IM 30-65	IM 40-15
Description*		CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
pH of Solution		0.38	0.65	6.37	6.57	6.57	6.5	6.49	6.5	6.49	6.58	6.58	6.58	6.58
Osmolality (mOsm/kg)		Not Applicable	573	569	569	569	575	572	572	576	576	579	573	571
LPC	10um		120	393.33	853.33	3166.67	173	127	563	107	107	120	147	367
	25um		7	30	13.33	91.33	13	7	27	7	13	0	13	20
Assay of Anions	% Phosphorus		191.6	105.1	104.4	104.3	98.7	98.5	98.4	98.8	102.8	102.8	103.1	102.8
	% Chloride		101.6	105.1	106.7	105.2	99.7	99.6	99.5	99.9	104.0	103.0	103.3	103.0
Assay of Cations	% Potassium		99.6	101.4	104.1	103.2	99.7	103.3	99.2	99.7	102.1	101.3	101.4	101.1
	% Sodium		98.0	103.1	103.1	103.4	96.1	103.8	96.2	96.1	102.2	101.6	101.8	101.4
* CCS- A Clear colorless solution, free from visible foreign particles														

FIG.14 cont'd

B. No.2NPO21068																	
Autoclave @ 121°C for 15 Minutes (Autoclave Pressure: Max-3.15 bar , Min-2.95 bar)																	
HaemaPharm (M312) IT PP Bag + Al Pouch																	
Test		Condition															
Description*	Bulk Solution	Initial	IM 2-8	IM 25/40	IM 40/15	IM 2-8	IM 25/40	IM 30/65	IM 40/15	IM 2-8	IM 25/40	IM 30/65	IM 40/15	IM 2-8	IM 25/40	IM 30/65	IM 40/15
	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
pH of Solution	6.57	6.68	6.58	6.59	6.58	6.58	6.58	6.56	6.57	6.61	6.61	6.56	6.57	6.61	6.61	6.62	6.61
	Not Applicable	574	576	575	574	562	747	267	273	349	349	578	574	578	576	575	578
Osmolality (mOsm/kg)	240	866.67	166.67	273.33	273.33	747	267	273	400	349	349	578	574	578	576	575	578
	7	20	6.67	20	20	67	20	13	20	13	13	0	0	0	0	0	0
LPC	25µm																
Assay of Anions	% Phosphorus	101.8	102.1	102.3	102.5	102.0	102.6	102.6	103.3	101.6	102.3	102.2	103.3	101.6	102.3	102.2	102.8
	% Chloride	101.3	102.2	102.2	101.6	102.6	101.3	100.9	101.3	102.1	102.6	102.2	101.3	102.1	102.6	102.2	102.9
Assay of Cations	% Potassium	100.5	99.9	100.2	99.5	100.4	101.8	101.6	102.1	100.8	101.2	103.0	101.2	100.8	101.2	103.0	101.6
	% Sodium	99.8	98.4	98.0	98.0	98.8	98.7	98.8	99.1	101.1	101.4	101.4	101.4	101.1	101.4	101.4	101.7
* CCS- A Clear colorless solution, free from visible foreign particles																	
Autoclave @ 121°C for 15 Minutes (Autoclave Pressure: Max-3.20 bar , Min-3.00 bar)																	
Infomed (Polyim APP114S) IT PP Bag + Al Pouch																	
Test		Condition															
Description*	Bulk Solution	Initial	IM 2-8	IM 25/40	IM 40/15	IM 2-8	IM 25/40	IM 30/65	IM 40/15	IM 2-8	IM 25/40	IM 30/65	IM 40/15	IM 2-8	IM 25/40	IM 30/65	IM 40/15
	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS
pH of Solution	6.57	6.68	6.58	6.59	6.59	6.58	6.58	6.58	6.59	6.62	6.62	6.58	6.59	6.62	6.62	6.61	6.61
	Not Applicable	573	572	572	576	571	575	574	574	577	572	574	574	577	572	575	573
Osmolality (mOsm/kg)	327	360	920	1226.67	1226.67	340	440	213	107	149	313	167	180	149	313	167	180
	7	13.33	60	33.33	33.33	0	0	0	7	33	20	0	0	33	20	0	27
LPC	25µm																
Assay of Anions	% Phosphorus	101.0	105.0	103.2	103.2	102.0	101.0	100.2	100.8	102.4	103.2	103.3	103.3	102.4	103.2	103.3	102.8
	% Chloride	101.4	105.2	102.7	102.5	101.5	99.3	98.8	99.1	102.7	103.1	102.9	103.1	102.7	103.1	102.9	103.0
Assay of Cations	% Potassium	100.5	99.3	100.6	100.3	101.3	99.6	98.9	99.2	101.3	101.8	102.4	101.5	101.3	101.8	102.4	101.5
	% Sodium	98.7	96.4	97.2	98.4	96.7	96.2	96.4	96.2	101.3	101.6	102.2	101.5	101.3	101.6	102.2	101.5
* CCS- A Clear colorless solution, free from visible foreign particles																	

FIG.15

B. No.#NPO21012													
Autoclave @ 121°C for 15 Minutes (Autoclave Pressure: Max-3.24 bar , Min-2.99 bar)													
Infomed (Nexcel M312) IT PP Bag + Al Pouch													
Test	Condition												
	Bulk Solution	Initial	IM 2-8	IM 25/40	IM 40/15	3M 2-8	3M 25/40	3M 30/65	3M 40/15				
Description*	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS				
pH of Solution	6.53	6.54	6.56	6.62	6.61	6.59	6.56	6.55	6.57				
Osmolality (mOsm/kg)	573	574	570	565	569	569	572	572	568				
LPC	10µm	67	320	726	380	520	227	1125	187				
	25µm	0	20	166.67	53.33	33.33	0	33	7				
Assay of Anions	% Phosphorus	101.7	101.6	98.5	98.1	98.9	101.1	100.9	100.0	100.6			
	% Chloride	99.7	99.4	99.2	98.7	99.5	98.9	98.2	98.8	98.5			
Assay of Cations	% Potassium	101.7	101.5	99.2	98.9	99.8	100.1	100.3	99.9	99.6			
	% Sodium	99.3	99.2	98.8	97.3	98.2	98.8	99.1	98.9	98.4			
* CCS- A Clear colorless solution, free from visible foreign particles													
Autoclave @ 121°C for 15 Minutes (Autoclave Pressure: Max-3.24 bar , Min-2.99 bar)													
Infomed (Polychie APP114S) IT PP Bag + Al Pouch													
Test	Condition												
	Bulk Solution	Initial	IM 2-8	IM 25/40	IM 40/15	3M 2-8	3M 25/40	3M 30/65	3M 40/15				
Description*	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS	CCS				
pH of Solution	6.53	6.54	6.55	6.54	6.54	6.57	6.56	6.56	6.58				
Osmolality (mOsm/kg)	573	575	570	570	570	568	570	566	570				
LPC	10µm	67	1526.67	2053.33	1193.33	993	287	647	153				
	25µm	0	0	6.67	13.33	13	27	13	0				
Assay of Anions	% Phosphorus	101.7	101.2	98.8	98.0	100.6	99.8	100.7	100.5				
	% Chloride	99.7	99.2	99.9	98.4	99.8	98.6	98.6	98.4				
Assay of Cations	% Potassium	101.7	101.2	99.9	98.6	100.9	99.5	99.9	99.6				
	% Sodium	99.3	98.9	98.3	97.1	99.9	98.4	98.5	98.4				
* CCS- A Clear colorless solution, free from visible foreign particles													

FIG.16

Engineering Batch_Lot#21070832 (Finished Product)					
Autoclave @ 121°C for 15 Minutes					
Infomed (Nexcel M312) 1T PP Bag + Al Pouch					
Test		Condition			
		Bulk Solution			Initial
		Sampling Time: 5 Minutes	Sampling Time: 10 Minutes	Sampling Time: 15 Minutes	
Description*		CCS	CCS	CCS	CCS
pH of Solution		6.64	6.63	6.64	6.61
Osmolality (mOsm/kg)		559	556	555	566
LPC	10µm	1006.67	466.67	300	60
	25µm	66.67	40	13.33	0
Assay of Anions	% Phosphorus	98.7	98.2	97.8	98.6
	% Chloride	98.9	98.7	98.0	98.9
Assay of Cations	% Potassium	99	98.7	97.8	99.0
	% Sodium	97.3	96.7	95.9	97.3
* CCS- A Clear colorless solution, free from visible foreign particles					
Autoclave @ 121°C for 15 Minutes					
Infomed (Polycine APP114S) 1T PP Bag + Al Pouch					
Test		Condition			
		Bulk Solution			Initial
		Sampling Time: 5 Minutes	Sampling Time: 10 Minutes	Sampling Time: 15 Minutes	
Description*		CCS	CCS	CCS	CCS
pH of Solution		6.64	6.63	6.64	6.61
Osmolality (mOsm/kg)		559	556	555	564
LPC	10µm	1006.67	466.67	300	260
	25µm	66.67	40	13.33	46.67
Assay of Anions	% Phosphorus	98.7	98.2	97.8	98.8
	% Chloride	98.9	98.7	98.0	98.9
Assay of Cations	% Potassium	99	98.7	97.8	99.5
	% Sodium	97.3	96.7	95.9	97.5
* CCS- A Clear colorless solution, free from visible foreign particles					

FIG.17

Aseptic Filling					
Infomed (Nexcel M312) IT PP Bag + Al Pouch					
Test		Condition			
		Bulk Solution			Sampling: Beginning
		Sampling Time: 5 Minutes	Sampling Time: 10 Minutes	Sampling Time: 15 Minutes	
Description*		CCS	CCS	CCS	CCS
pH of Solution		6.64	6.63	6.64	6.61
Osmolality (mOsm/kg)		559	556	555	562
LPC	10µm	1006.67	466.67	300	66.67
	25µm	66.67	40	13.33	0
Assay of Anions	% Phosphorus	98.7	98.2	97.8	99.7
	% Chloride	98.9	98.7	98.0	99.9
Assay of Cations	% Potassium	99	98.7	97.8	99.5
	% Sodium	97.3	96.7	95.9	97.8
* CCS- A Clear colorless solution, free from visible foreign particles					
Aseptic Filling					
Infomed (Polycine APP114S) IT PP Bag + Al Pouch					
Test		Condition			
		Bulk Solution			Sampling: Beginning
		Sampling Time: 5 Minutes	Sampling Time: 10 Minutes	Sampling Time: 15 Minutes	
Description*		CCS	CCS	CCS	CCS
pH of Solution		6.64	6.63	6.64	6.61
Osmolality (mOsm/kg)		559	556	555	560
LPC	10µm	1006.67	466.67	300	453.33
	25µm	66.67	40	13.33	33.33
Assay of Anions	% Phosphorus	98.7	98.2	97.8	98.3
	% Chloride	98.9	98.7	98.0	98.4
Assay of Cations	% Potassium	99	98.7	97.8	98.3
	% Sodium	97.3	96.7	95.9	96.3
* CCS- A Clear colorless solution, free from visible foreign particles					

FIG.17 cont'd

Engineering Batch_Lot#21070832 (Placebo)					
Autoclave @ 121°C for 15 Minutes					
Infomed (Nexcel M312) IT PP Bag + Al Pouch					
Test		Condition			Initial
		Bulk Solution			
		Sampling Time: 5 Minutes	Sampling Time: 10 Minutes	Sampling Time: 15 Minutes	
Description*		NA			CCS
pH of Solution					6.28
Osmolality (mOsm/kg)					289
LPC	10µm				813.33
	25µm				13.33
Assay of Anions	% Phosphorus				NA
	% Chloride				100.0
Assay of Cations	% Potassium				NA
	% Sodium	99.1			
* CCS- A Clear colorless solution, free from visible foreign particles					
Autoclave @ 121°C for 15 Minutes					
Infomed (Polycine APP114S) IT PP Bag + Al Pouch					
Test		Condition			Initial
		Bulk Solution			
		Sampling Time: 5 Minutes	Sampling Time: 10 Minutes	Sampling Time: 15 Minutes	
Description*		NA			CCS
pH of Solution					6.3
Osmolality (mOsm/kg)					287
LPC	10µm				806.67
	25µm				6.67
Assay of Anions	% Phosphorus				NA
	% Chloride				100.9
Assay of Cations	% Potassium				NA
	% Sodium	99.4			
* CCS- A Clear colorless solution, free from visible foreign particles					

FIG.17 cont'd

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	104078.0005US
		Application Number	
Title of Invention	Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor	1				Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Brijeshkumar	B.	Pandya		
Residence Information (Select One) • US Residency Non US Residency Active US Military Service					
City	Sacramento	State/Province	CA	Country of Residence	US
Mailing Address of Inventor:					
Address 1		3050 Fite Circle			
Address 2		Suite 100			
City	Sacramento	State/Province	CA		
Postal Code	95827	Country i	US		
Inventor	2				Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Govind	R.	Jagadale		
Residence Information (Select One) • US Residency Non US Residency Active US Military Service					
City	Sacramento	State/Province	CA	Country of Residence	US
Mailing Address of Inventor:					
Address 1		3050 Fite Circle			
Address 2		Suite 100			
City	Sacramento	State/Province	CA		
Postal Code	95827	Country i	US		
Inventor	3				Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Dasaradhi		Lakkaraju		
Residence Information (Select One) • US Residency Non US Residency Active US Military Service					

Application Data Sheet 37 CFR 1.76		Attorney Docket Number		104078.0005US	
		Application Number			
Title of Invention		Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions			

City	Sacramento	State/Province	CA	Country of Residence ⁱ	US
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Mailing Address of Inventor:

Address 1	3050 Fite Circle				
Address 2	Suite 100				
City	Sacramento	State/Province	CA		
Postal Code	95827	Country ⁱ	US		
Inventor	4				Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Bala	Tripura Sundari	Chodavarapu		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Davis	State/Province	CA	Country of Residence ⁱ	US

Mailing Address of Inventor:

Address 1	3050 Fite Circle				
Address 2	Suite 100				
City	Sacramento	State/Province	CA		
Postal Code	95827	Country ⁱ	US		
Inventor	5				Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Anand		Shukla		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Denver	State/Province	CO	Country of Residence ⁱ	US

Mailing Address of Inventor:

Address 1	3050 Fite Circle				
Address 2	Suite 100				
City	Sacramento	State/Province	CA		
Postal Code	95827	Country ⁱ	US		
Inventor	6				Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Jwalant		Shukla		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
City	Sacramento	State/Province	CA	Country of Residence ⁱ	US

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	104078.0005US
		Application Number	
Title of Invention	Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions		

Mailing Address of Inventor:

Address 1	3050 Fite Circle		
Address 2	Suite 100		
City	Sacramento	State/Province	CA
Postal Code	95827	Country	US
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.			

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).			
☐ An Address is being provided for the correspondence information of this application.			
Customer Number	149344		
Email Address	patents@umbergzipser.com	Add Email	Remove Email

Application Information:

Title of the Invention	Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions		
Attorney Docket Number	104078.0005US	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	25	Suggested Figure for Publication (if any)	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐ Request Not to Publish. I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	104078.0005US
		Application Number	
Title of Invention	Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions		

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.			
Please Select One:			
	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)
Customer Number	149344		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Claims benefit of provisional	63090518	2020-10-12
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.			Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)ⁱ the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

			Remove
Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ⁱ (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			Add

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	104078.0005US
		Application Number	
Title of Invention	Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions		

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013. NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	104078.0005US
		Application Number	
Title of Invention	Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions		

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	104078.0005US
		Application Number	
Title of Invention	Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions		

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.			
Applicant	1		Remove
If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.			
		Clear	
☒ Assignee	Legal Representative under 35 U.S.C. 117		Joint Inventor
Person to whom the inventor is obligated to assign.		Person who shows sufficient proprietary interest	
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:			
Name of the Deceased or Legally Incapacitated Inventor:			
If the Applicant is an Organization check here. ☒			
Organization Name	Nivagen Pharmaceuticals, Inc.		
Mailing Address Information For Applicant:			
Address 1	3050 Fite Circle, Suite 100		
Address 2			
City	Sacramento	State/Province	CA
Country	US	Postal Code	95827
Phone Number		Fax Number	
Email Address			
Additional Applicant Data may be generated within this form by selecting the Add button.			Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	104078.0005US
		Application Number	
Title of Invention	Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions		

Assignee	1		
Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.			
			Remove
If the Assignee or Non-Applicant Assignee is an Organization check here. ☒			
Organization Name	Nivagen Pharmaceuticals, Inc.		
Mailing Address Information For Assignee including Non-Applicant Assignee:			
Address 1	3050 Fite Circle, Suite 100		
Address 2			
City	Sacramento	State/Province	CA
Country ⁱ	US	Postal Code	95827
Phone Number		Fax Number	
Email Address			
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.			Add

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). However, if this Application Data Sheet is submitted with the **INITIAL** filing of the application and either box A or B is **not** checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Martin Fessenmaier/		Date (YYYY-MM-DD)	2021-10-12	
First Name	Martin	Last Name	Fessenmaier	Registration Number	46697
Additional Signature may be generated within this form by selecting the Add button.				Add	

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	104078.0005US
		Application Number	
Title of Invention	Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions		

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal				
Application Number:				
Filing Date:				
Title of Invention:		READY-TO-USE POTASSIUM PHOSPHATES IN SODIUM CHLORIDE SOLUTIONS		
First Named Inventor/Applicant Name:		Brijeshkumar B. Pandya		
Filer:		Martin Fessenmaier/Danielle Moroz		
Attorney Docket Number:		104078.0005US		
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	80	80
UTILITY SEARCH FEE	2111	1	350	350
UTILITY EXAMINATION FEE	2311	1	400	400
Pages:				
Claims:				
Miscellaneous-Filing:				
LATE FILING FEE FOR OATH OR DECLARATION	2051	1	80	80
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				910

Electronic Acknowledgement Receipt	
EFS ID:	44005933
Application Number:	17499001
International Application Number:	
Confirmation Number:	1080
Title of Invention:	READY-TO-USE POTASSIUM PHOSPHATES IN SODIUM CHLORIDE SOLUTIONS
First Named Inventor/Applicant Name:	Brijeshkumar B. Pandya
Customer Number:	149344
Filer:	Martin Fessenmaier/Danielle Moroz
Filer Authorized By:	Martin Fessenmaier
Attorney Docket Number:	104078.0005US
Receipt Date:	12-OCT-2021
Filing Date:	
Time Stamp:	13:11:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$910
RAM confirmation Number	E20210BD11572778
Deposit Account	601823
Authorized User	Danielle Moroz
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

37 CFR 1.19 (Document supply fees)					
37 CFR 1.20 (Post Issuance fees)					
37 CFR 1.21 (Miscellaneous fees and charges)					
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		APP-FILED_2021_10_11_APPLN_RE V011.pdf	3792612	yes	61
			c91045e5d2cdb02218c836de301be2e585a6ba7d		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Specification		1	32	
	Claims		33	35	
	Abstract		36	36	
	Drawings-only black and white line drawings		37	61	
Warnings:					
Information:					
2	Application Data Sheet	ADS.pdf	1874377	no	10
			825fa6f13ba55d03248fb990f4677604d596e95d		
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	46390	no	2
			f094ceac9d2609b68f58cd42dd132153135b940c		
Warnings:					
Information:					
Total Files Size (in bytes):			5713379		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

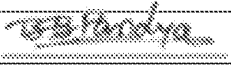
National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions
As the below named inventor, I hereby declare that: This declaration is directed to: ☐ The attached application, or ☒ United States application or PCT international application number <u>17/499,001</u> filed on <u>2021-10-12</u> The above-identified application was made or authorized to be made by me. I believe that I am the original inventor or an original joint inventor of a claimed invention in the application. I hereby acknowledge that any wilful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both. WARNING: Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.	
LEGAL NAME OF INVENTOR	
Inventor: <u>Brijeshkumar B. Pandya</u> Date (Optional): <u>12-Oct-2021</u>	
Signature: <u></u>	
Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.	

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions
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LEGAL NAME OF INVENTOR	
Inventor: <u>Govind R. Jagdale</u> Date (Optional): <u>12-Oct-2021</u>	
Signature: <u></u>	
Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.	

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions
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LEGAL NAME OF INVENTOR	
Inventor: <u>Dasaradhi Lakkaraju</u> Date (Optional): <u>12 Oct 2021</u>	
Signature: <u>L Dasaradhi</u>	
Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.	

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions	
As the below named inventor, I hereby declare that:		
This declaration is directed to: ☐ The attached application, or		
☒ United States application or PCT international application number <u>17/499,001</u>		
filed on <u>2021-10-12</u>		
The above-identified application was made or authorized to be made by me.		
I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.		
I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.		
WARNING:		
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LEGAL NAME OF INVENTOR		
Inventor: <u>Bala Tripura Sundari Chodavarapu</u>		Date (Optional): <u>12-Oct-2021</u>
Signature: <u>Ch. B. T. Sundari</u>		
Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.		

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions
---------------------------	---

As the below named inventor, I hereby declare that:

This declaration
is directed to:☐

The attached application, or

☒United States application or PCT international application number 17/499,001filed on 2021-10-12

The above-identified application was made or authorized to be made by me.

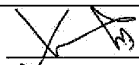
I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

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LEGAL NAME OF INVENTOR

Inventor: Anand ShuklaDate (Optional): 12-OCT-2021Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions
---------------------------	---

As the below named inventor, I hereby declare that:

This declaration
is directed to:☐

The attached application, or

☒United States application or PCT international application number 17/499,001filed on 2021-10-12

The above-identified application was made or authorized to be made by me.

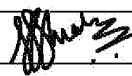
I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

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LEGAL NAME OF INVENTOR

Inventor: Jwalant ShuklaDate (Optional): 12-Oct-2021Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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Electronic Acknowledgement Receipt	
EFS ID:	44024813
Application Number:	17499001
International Application Number:	
Confirmation Number:	1080
Title of Invention:	Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions
First Named Inventor/Applicant Name:	Brijeshkumar B. Pandya
Customer Number:	149344
Filer:	Martin Fessenmaier/Danielle Moroz
Filer Authorized By:	Martin Fessenmaier
Attorney Docket Number:	104078.0005US
Receipt Date:	13-OCT-2021
Filing Date:	
Time Stamp:	19:32:44
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment		no			
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Oath or Declaration filed	Declaration_B_Pandya-Signed.pdf	567851 021095403208b2aaf1133b174ced5e00677fc557	no	1
Warnings:					

Information:					
2	Oath or Declaration filed	Declaration_G_Jagadale-Signed.pdf	445085	no	1
			6cad940d03e51d265a352dad9c9de5f08cfb206d		
Warnings:					
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3	Oath or Declaration filed	Declaration_D_Lakkaraju-Signed.pdf	448842	no	1
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Warnings:					
Information:					
4	Oath or Declaration filed	Declaration_B_Chodavarapu-Signed.pdf	1175044	no	1
			e7a9683fd24a5629203dedf68c50f80cb17f88c0		
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5	Oath or Declaration filed	Declaration_A_Shukla-Signed.pdf	393420	no	1
			b2cd574c982f69951da84acac3db366bd571b421		
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Information:					
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			178e8ea3833b9d4bd57ada37e9fac62847da4b7f		
Warnings:					
Information:					
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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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New International Application Filed with the USPTO as a Receiving Office

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
17/499,001	10/12/2021	1629	910	104078.0005US	20	3

CONFIRMATION NO. 1080

FILING RECEIPT



CC000000129272445

149344
Umberg Zipser LLP
1920 Main Street Suite 750
Irvine, CA 92614

Date Mailed: 10/22/2021

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

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Inventor(s)

Brijeshkumar B. Pandya, Sacramento, CA;
Govind R. Jagadale, Sacramento, CA;
Dasaradhi Lakkaraju, Sacramento, CA;
Bala Tripura Sundari Chodavarapu, Davis, CA;
Anand Shukla, Denver, CO;
Jwalant Shukla, Sacramento, CA;

Applicant(s)

Nivagen Pharmaceuticals, Inc., Sacramento, CA;

Assignment For Published Patent Application

Nivagen Pharmaceuticals, Inc., Sacramento, CA

Power of Attorney: None

Domestic Priority data as claimed by applicant

This appln claims benefit of 63/090,518 10/12/2020

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

page 1 of 4

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 10/21/2021

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/499,001**

Projected Publication Date: 04/14/2022

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions

Preliminary Class

514

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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page 2 of 4

this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 17/499,001			
APPLICATION AS FILED - PART I									
(Column 1)		(Column 2)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY			
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)		
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	80		N/A			
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	350		N/A			
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	400		N/A			
TOTAL CLAIMS (37 CFR 1.16(j))	20	minus 20 = *	x 50 =	0.00	OR				
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3	minus 3 = *	x 240 =	0.00					
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00					
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL		TOTAL			
				830					
APPLICATION AS AMENDED - PART II									
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY	
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)	
	Total (37 CFR 1.16(i))	*	Minus **	x	=		x	=	
	Independent (37 CFR 1.16(h))	*	Minus ***	x	=		x	=	
	Application Size Fee (37 CFR 1.16(s))								
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
				TOTAL ADD'L FEE		TOTAL ADD'L FEE			
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)	
	Total (37 CFR 1.16(i))	*	Minus **	x	=		x	=	
	Independent (37 CFR 1.16(h))	*	Minus ***	x	=		x	=	
	Application Size Fee (37 CFR 1.16(s))								
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
				TOTAL ADD'L FEE		TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.									

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17499001
	Filing Date	2021-10-12
	First Named Inventor	Brijeshkumar B. Pandya
	Art Unit	1629
	Examiner Name	
	Attorney Docket Number	104078.0005US

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear		
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	2	10632150	B1	2020-04-28	Thomas et al.			
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	1	106265499	CN	A	2017-01-04	Wu et al.		×

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17499001
	Filing Date		2021-10-12
	First Named Inventor	Brijeshkumar B. Pandya	
	Art Unit	1629	
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	Attorney Docket Number	104078.0005US	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17499001
	Filing Date		2021-10-12
	First Named Inventor	Brijeshkumar B. Pandya	
	Art Unit	1629	
	Examiner Name		
	Attorney Docket Number	104078.0005US	

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Martin Fessenmaier/	Date (YYYY-MM-DD)	2022-01-12
Name/Print	Martin Fessenmaier	Registration Number	46697

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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Patents

16/389,181



A kind of compound potassium dihydrogen phosphate pharmaceutical composition

Abstract

A kind of pharmaceutical composition, is made up of 217-218g potassium dihydrogen phosphates, 319-320g dipotassium hydrogen phosphates and the water as adjuvant as active component in every 1000ml, it is characterized in that the oxygen content in compositions is at below 2mg/L.

Classifications

A61K33/42 Phosphorus; Compounds thereof

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CN106265499A

China

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Other languages: Chinese

Inventor: 吴晓娟, 吴国杰, 张磊

Worldwide applications

2016

Application CN201610831541.8A **events**

 2016-09-18 *Application filed by 江苏合维药业有限公司*

 2016-09-18 *Priority to CN201610831541.8A*

 2017-01-04 *Publication of CN106265499A*
Info: [Patent citations](#) (3), [Non-patent citations](#) (1), [Cited by](#) (2), [Legal events](#), [Similar documents](#), [Priority and Related Applications](#)
External links: [Espacenet](#), [Global Dossier](#), [Discuss](#)

Claims (6)

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1. a pharmaceutical composition, by as the 217-218g potassium dihydrogen phosphate of active component, 319-320g phosphorus in every 1000ml Acid hydrogen dipotassium and the water as adjuvant form, and it is characterized in that the oxygen content in compositions is at below 2mg/L.
2. a preparation method for the pharmaceutical composition described in claim 1, is characterized in that compositions cumulative volume more than 60% Water put in container, add potassium dihydrogen phosphate, dipotassium hydrogen phosphate the most molten after, be cooled to 5-10 DEG C, then heat to 80-90 DEG C, then it is cooled to room temperature, then weighs in 0.3% medicinal charcoal addition container, stir evenly, decarbonization filtering, mend and add water to full dose, stirring Uniformly, fill after nitrogen it is passed through.
3. the preparation method described in claim 2, filters medicinal liquid through 0.22 μm after it is characterized in that benefit adds water to full dose again Core filters.
4. the preparation method described in claim 2, keeps 15 minutes after it is characterized in that fill under the conditions of 120 ~ 125 DEG C Carry out sterilizing.
5. preparation method as claimed in claim 2, it is characterised in that make the oxygen content in compositions at 2mg/L after being passed through nitrogen Below.
6. the pharmaceutical composition described in a claim 1, it is characterised in that route of administration is to enter internal by injection.

Description

A kind of compound potassium dihydrogen phosphate pharmaceutical composition

Technical field:

The present invention relates to a kind of be made up of potassium dihydrogen phosphate, dipotassium hydrogen phosphate and the water as adjuvant as active component Pharmaceutical composition and preparation method thereof.

Background technology:

The injectable pharmaceutical compositions being made up of potassium dihydrogen phosphate, dipotassium hydrogen phosphate, is mainly used in total parenteral nutrition and treats As the supplement of phosphorus in method, as medium above operation or other wounds need the phosphorus supplement of more than 5 days patients of fasting, as various The multiple chronic disease patients such as operation and wounded patient, cardiovascular and cerebrovascular vessel, hepatopathy, Also can be used for some disease institute to hypophosphatemia.

Kong Xiangwen (disodium hydrogen phosphate and the mensuration respectively of potassium dihydrogen phosphate, Nanjing Medical College in mixed phosphate saline injection 19 88 years the 2nd phases of volume 8 of journal, 173-174 page) report that rod closes phosphate injection and has another name called sodium phosphate injection, it is loaded in "first All hospital preparation compilation" and "preparation handbook" in, its prescription is disodium hydrogen phosphate (being equivalent to anhydrous product 5.75 g) and di(2-ethylhexyl)phosphate Hydrogen potassium (anhydrous product 1.306), adds jetting and makes to 100.0ml This product supplements phosphorus and treatment calcium, potassium, phosphorus generation for intravenous nutrition Thank disorder, the hypercalcemia that Vitamin D excess causes.

The invention of Application No. CN201010208559.5 relates to the production method of a kind of compound potassium dihydrogen phosphate, depends on Secondary including dispensing, decolouring, embedding, sterilizing, leak detection, lamp inspection, scald bottle, lettering and packaging step, described production method also includes After described embedding step, before described packaging step, described injection is carried out heating-cooling at least one times and processes, Described heating-cooling processes and refers to first be warming up to by injection 40 DEG C ~ 100 DEG C, then gives free rain to be cooled to environment temperature Degree. Even if gained injection of the present invention runs into the environment of quenching or there will not be crystallization under low temperature storage environment, it is ensured that The quality of product and serviceability. But this patent only solves dehydrification problem from technique, the most fundamentally solve to ask Topic.

The disclosure of the invention of the Application No. 201210331492.3 Compound Potassium Dihydrogen phosphate drug regimen of a kind of injection Thing, this compound potassium dihydrogen phosphate is made up of potassium dihydrogen phosphate, dipotassium hydrogen phosphate trihydrate, calcium disodium edetate, and every contains There are potassium dihydrogen phosphate 435.4-870.8mg, dipotassium hydrogen phosphate trihydrate 687.7-975.6mg in terms of dipotassium hydrogen phosphate, according to ground Acid calcium sodium 1-2mg, water for injection adds to 2L-4L. Its preparation method is: taking recipe quantity water for injection 70%, temperature is at 70-80 DEG C, add the calcium disodium edetate of recipe quantity, after stirring and dissolving; The potassium dihydrogen phosphate and the dipotassium hydrogen phosphate three that add recipe quantity are hydrated Thing is in terms of dipotassium hydrogen phosphate, and stirring is to dissolving completely; Record original pH, according to original pH, with 4% sodium hydroxide solution and 10% phosphoric acid solution regulation pH value range is at 5.5-6.5; To adding medicinal charcoal, stirring; Sucking filtration, adds water for injection to full dose, Mix homogeneously; Fine straining; Fill; Sterilizing; Lamp inspection; Warehouse-in; Obtain compound potassium dihydrogen phosphate. This Compound Potassium Dihydrogen phosphate medicine group Compound photostability is good, will not produce crystallization, clarity, good stability, and this invention, to improving product yield, reduces cost, Realize industrialization, be preferably applied to clinic, there is more obvious advantage.

The most never find that reducing oxygen content has a certain impact for stability tool.

Summary of the invention:

By long-term test, we have surprisingly found that, by the 217-218g phosphoric acid as active component in every 1000ml The pharmaceutical composition that potassium dihydrogen, 319-320g dipotassium hydrogen phosphate and the water as adjuvant form, when the oxygen content in compositions exists During below 2mg/L, photostability is good, runs into the environment of quenching or there will not be crystallization under low temperature storage environment.

A kind of pharmaceutical composition, by as the 217-218g potassium dihydrogen phosphate of active component, 319-320g in every 1000ml Dipotassium hydrogen phosphate and the water as adjuvant form, and it is characterized in that the oxygen content in compositions is at below 2mg/L.

The preparation method of aforementioned pharmaceutical compositions, is characterized in that the water of compositions cumulative volume more than 60% is put into container in, after addition potassium dihydrogen phosphate, dipotassium hydrogen phosphate are the most molten, it are cooled to 5-10 DEG C, then heat to 80-90 DEG C, be then cooled to room temperature, then weigh in 0.3% medicinal charcoal addition container, stir evenly, decarbonization filtering, mend and add water to full dose, stir, be passed through nitrogen Rear fill.

Above-mentioned preparation method, it is characterized in that adding water to benefit after full dose again by medicinal liquid through 0.22 μ m filter element filtering.

Above-mentioned preparation method, keeps after it is characterized in that fill carrying out sterilizing in 15 minutes under the conditions of 120 ~ 125 DEG C.

Above-mentioned preparation method, it is characterised in that make the oxygen content in compositions at below 2mg/L after being passed through nitrogen.

Above-mentioned pharmaceutical composition, it is characterised in that route of administration is to enter internal by injection.

In the present invention, dipotassium hydrogen phosphate, potassium dihydrogen phosphate can be corresponding hydrates, but corresponding hydrate is all with it in dipotassium hydrogen phosphate, potassium dihydrogen phosphate calculate.

Detailed description of the invention

Embodiment 1

Prescription:

Composition Embodiment 1-1 Embodiment 1-2 Embodiment 1-3 Potassium dihydrogen phosphate (g) 2170 2177 2180 Dipotassium hydrogen phosphate (g) 3190 3195 3200 Water for injection adds to (ml) 10000 10000 10000 Oxygen content (mg/L) 1.53 1.03 1.95

Preparation method:

Putting in container by the water of cumulative volume more than 60%, the addition potassium dihydrogen phosphate of recipe quantity, dipotassium hydrogen phosphate are the most molten After it is cooled to 5-10 DEG C, then heats to 80-90 DEG C, be then cooled to room temperature, then weigh in 0.3% medicinal charcoal addition container, Stir evenly decarbonization filtering, mend and add water to full dose, then by medicinal liquid through 0.22 μ m filter element filtering, stir, be passed through nitrogen and make compositions In oxygen content fill after below the 2mg/L. Keep after fill carrying out sterilizing in 15 minutes under the conditions of 120 ~ 125 DEG C.

Comparative examples 1

Prescription:

Composition Comparative examples 1-1 Comparative examples 1-2 Comparative examples 1-3 Potassium dihydrogen phosphate (g) 2170 2177 2180 Dipotassium hydrogen phosphate (g) 3190 3195 3200 Water for injection adds to (ml) 10000 10000 10000 Oxygen content (mg/L) 3.71 2.19 7.52

Preparation method:

Putting in container by the water of cumulative volume more than 60%, the addition potassium dihydrogen phosphate of recipe quantity, dipotassium hydrogen phosphate are the most molten After it is cooled to 5-10 DEG C, then heats to 80-90 DEG C, be then cooled to room temperature, then weigh in 0.3% medicinal charcoal addition container, Stir evenly decarbonization filtering, mend and add water to full dose, then by medicinal liquid through 0.22 μ m filter element filtering, stir, comparative examples 1-1 and 1-2 is passed through nitrogen, and comparative examples 1-3 is not passed through nitrogen, fill. Keep entering for 15 minutes after fill under the conditions of 120 ~ 125 DEG C Row sterilizing.

Comparative examples 2

Prescription:

Composition Comparative examples 2-1 Comparative examples 2-2 Comparative examples 2-3 Potassium dihydrogen phosphate (g) 2000 2100 2200 Dipotassium hydrogen phosphate (g) 3000 3300 3500 Water for injection adds to (ml) 10000 10000 10000 Oxygen content (mg/L) 1.81 1.23 1.87

Preparation method:

Putting in container by the water of cumulative volume more than 60%, the addition potassium dihydrogen phosphate of recipe quantity, dipotassium hydrogen phosphate are the most molten After then weigh in 0.3% medicinal charcoal addition container, stir evenly, decarbonization filtering, mend and add water to full dose, then medicinal liquid is filtered through 0.22 μ m Core filters, and stir, is passed through nitrogen, fill. Keep after fill carrying out sterilizing in 15 minutes under the conditions of 120 ~ 125 DEG C.

Test example 1 stability contrast experiment

Each 20 batches are prepared respectively according to the method for embodiment 1, comparative examples 1,2, it is divided into 1 group at random by every 10 batches, point Do not carry out high temperature, illumination experiment, visual observations experimental result.

1.1 high temperature experiments:

Being placed 30 days in 60 DEG C of thermostatic drying chambers by sample, observe color sample and transparency, result is as follows.

.2 illumination experiment:

Being placed 30 days in 60 DEG C of thermostatic drying chambers by sample, light irradiates 30d (intensity 3 000lx), observes sample Color and transparency, result is as follows.

Patent Citations (3)

Publication number	Priority date	Publication date	Assignee	Title
WO2016046217A2 *	2008-10-13	2016-04-29	Intas Pharmaceuticals Limited	Fludarabine phosphate composition
CN101926761A *	2010-06-23	2010-12-29	苏州天与医药集团有限公司	Production method of compound potassium dihydrogen phosphate
CN102813875A *	2012-09-07	2012-12-12	天津普康医药科技有限公司	Compound potassium hydrogen phosphate medicine combination for injection
Family To Family Citations				

* Cited by examiner, † Cited by third party

Non-Patent Citations (1)

Title
李威. 等. "《医药学》", 28 February 2014, 医药科学出版社出版 *

* Cited by examiner, † Cited by third party

Cited By (2)

Publication number	Priority date	Publication date	Assignee	Title
CN108619091A *	2018-06-12	2018-10-09	海城正邦医药股份有限公司	A kind of compound potassium dihydrogen phosphate
WO2020081118A1 *	2018-10-19	2020-04-23	Cmp Development Llc	Potassium phosphates composition for injection
Family To Family Citations				

* Cited by examiner, † Cited by third party, ‡ Family to family citation

Similar Documents

Publication	Publication Date	Title
CN102670487A	2012-09-19	Stable S-xidracetam preparation for injection and preparation method of same
TW0475013B	2015-03-11	Process for preparing pharmaceutical formulation in form of antioxidant-free solution for injection containing permethexed or its salt
CN101889668A	2010-11-24	Eternal nutrition emulsion and preparation method thereof
CN1274304C	2006-09-13	Etomidate fatty emulsion injection preparation method
CN1283235C	2006-11-08	Clear and stable propofol composition

8/24/2020

CN106265499A - A kind of compound potassium dihydrogen phosphate pharmaceutical composition - Google Patents

CN102036648B	2012-07-25	Powder injection for treating peptic ulcers and preparation method thereof
CN103483365B	2015-05-20	Zedary oil injection and preparation method thereof
CN101984968A	2011-03-16	Preparation method of pharmaceutical preparation of antitumor agent temozolomide
CN100924181A	2017-07-07	It is mixed with the peripheral vein administrable nutrition infusion of vitamin
EP1029456B1	2005-11-09	Formis for preventing vomiting
CN102429902B	2013-03-20	Pharmaceutical composition of alanyl glutamine and compound amino acid
CN103006751B	2014-12-24	Medium and long chain fat emulsion injection and preparation method thereof
CN104971674A	2015-10-14	Multiple trace element composition and preparation method thereof
CN101991589B	2013-05-15	Glycerol fructose injection and preparation method thereof
EP3254880A2	2017-12-13	Pharmaceutical composition for inhibiting growth of cancer stem cells, containing aldehyde inhibitor and biguanide-based compound
CN101397012A	2009-09-23	Complex vitamin freeze-dried powder injection and preparation method thereof
de Oliveira et al.	2010	Aluminum content in intravenous solutions for administration to neonates: role of product preparation and administration methods
CN104258970A	2015-01-07	Drug composition of oral rehydration salt and preparation method of drug composition
CN104490775A	2015-04-08	Anacetrapib fat emulsion and preparation method thereof
CN102429864B	2013-03-06	Medicinal compound of fat-soluble vitamin injection (II) and water-soluble vitamin for injection and preparation method thereof
WO2017162103A1	2017-09-28	Preparation method for azacitidine injection
CN101455631B	2011-06-15	Meglumine cyclic adenosine injection and preparation technique thereof
CN103349666A	2013-10-16	Pharmaceutical composition injection of compound liposoluble vitamin and preparation method thereof
CN102592294A	2012-07-11	Compound vitamin (3) freeze-dried powder injection for injection and preparation method and analysis method thereof
CN101623254B	2011-02-16	Gastrodin injection and preparation method thereof

Priority And Related Applications

Priority Applications (1)

Application	Priority date	Filing date	Title
CN201610831541.8A	2016-09-18	2016-09-18	A kind of compound potassium dihydrogen phosphate pharmaceutical composition

Applications Claiming Priority (1)

Application	Filing date	Title
CN201610831541.8A	2016-09-18	A kind of compound potassium dihydrogen phosphate pharmaceutical composition

Legal Events

Date	Code	Title	Description
2017-01-04	C06	Publication	
2017-01-04	PB01	Publication	
2017-02-01	C10	Entry into substantive examination	
2017-02-01	SE01	Entry into force of request for substantive examination	
2019-11-22	RJ01	Rejection of invention patent application after publication	
2019-11-22	RJ01	Rejection of invention patent application after publication	Application publication date: 20170104

Concepts

machine-extracted

<https://patents.google.com/patent/CN106265499A/en?q=16%2F369%2c181>

4/6

Download Filter table

Name	Image	Sections	Count	Query match
pharmaceutical compositions		title,claims,abstract,description	12	0.000
potassium		title,description	8	0.000
[O-]P([O-])([O-])=O		title,description	7	0.000
compounds		title,description	6	0.000
Monopotassium phosphate		claims,abstract,description	27	0.000
monopotassium phosphate		claims,abstract,description	21	0.000
Dipotassium phosphate		claims,abstract,description	18	0.000
water		claims,abstract,description	17	0.000
mixtures		claims,abstract,description	13	0.000
oxygen		claims,abstract,description	11	0.000
oxygen		claims,abstract,description	11	0.000
oxygen		claims,abstract,description	11	0.000
adjuvant		claims,abstract,description	5	0.000
adjuvants		claims,abstract,description	5	0.000
monopotassium phosphate		claims,description	20	0.000
preparation methods		claims,description	15	0.000
filtration		claims,description	9	0.000
injection		claims,description	9	0.000
injections		claims,description	9	0.000
nitrogen		claims,description	8	0.000
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charcoal		claims,description	6	0.000
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cumulative		claims,description	5	0.000
decarbonization		claims,description	5	0.000

liquids	claims,description	5	0.000
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stirring	claims,description	4	0.000
hydrogen	claims,description	2	0.000
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hydrogen atoms	claims	1	0.000
X {}			
Show all concepts from the description section			

Electronic Acknowledgement Receipt	
EFS ID:	44728231
Application Number:	17499001
International Application Number:	
Confirmation Number:	1080
Title of Invention:	Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions
First Named Inventor/Applicant Name:	Brijeshkumar B. Pandya
Customer Number:	149344
Filer:	Martin Fessenmaier/Danielle Moroz
Filer Authorized By:	Martin Fessenmaier
Attorney Docket Number:	104078.0005US
Receipt Date:	12-JAN-2022
Filing Date:	12-OCT-2021
Time Stamp:	14:29:21
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment		no			
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	IDS-01.pdf	1053269	no	4
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Warnings:					

Information:					
2	Foreign Reference	CN106265499A_.pdf	1241678	no	6
			2338475dcac917f2465c67346800d8032a198153		
Warnings:					
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Total Files Size (in bytes):			2294947		
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/499,001	10/12/2021	Brijeshkumar B. Pandya	104078.0005US

CONFIRMATION NO. 1080

PUBLICATION NOTICE

149344
Umberg Zipser LLP
1920 Main Street Suite 750
Irvine, CA 92614



Title:Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions

Publication No.US-2022-0110969-A1

Publication Date:04/14/2022

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

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PATENT ASSIGNMENT COVER SHEET

Electronic Version v1.1
 Stylesheet Version v1.2

EPAS ID: PAT7456796

SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	SECURITY INTEREST
CONVEYING PARTY DATA	
Name	Execution Date
NIVAGEN PHARMACEUTICALS, INC.	07/28/2022
RECEIVING PARTY DATA	
Name:	CORBEL CAPITAL PARTNERS SBIC, L.P.
Street Address:	11777 SAN VICENTE BLVD., SUITE 777
City:	LOS ANGELES
State/Country:	CALIFORNIA
Postal Code:	90049
PROPERTY NUMBERS Total: 5	
Property Type	Number
Application Number:	17499001
Application Number:	17466063
Application Number:	17707237
Application Number:	17025881
Application Number:	17871058
CORRESPONDENCE DATA	
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Address Line 2:	660 NEWPORT CENTER DRIVE, SUITE 1600
Address Line 4:	NEWPORT BEACH, CALIFORNIA 92660
ATTORNEY DOCKET NUMBER:	103864-0022
NAME OF SUBMITTER:	ARNOLD V. MINA
SIGNATURE:	/Arnold V. Mina/
DATE SIGNED:	07/28/2022
This document serves as an Oath/Declaration (37 CFR 1.63).	

Total Attachments: 5

source=Corbel.Nivagen- Patent Security Agreement#page1.tif

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PATENT SECURITY AGREEMENT

This PATENT SECURITY AGREEMENT (this “**Patent Security Agreement**”) is made this 28th day of July, 2022, by and among the Grantors listed on the signature pages hereof (collectively, jointly and severally, “**Grantors**” and each individually “**Grantor**”), and CORBEL CAPITAL PARTNERS SBIC, L.P., as administrative agent (“**Agent**”) for the benefit of the Purchasers (as defined below).

W I T N E S S E T H:

WHEREAS, pursuant to that certain Secured Promissory Note and Warrant Purchase Agreement dated as of July 28, 2022 (as amended, restated, supplemented, or otherwise modified from time to time, the “**Note Purchase Agreement**”) by and among Nivagen Pharmaceuticals, Inc., a Delaware corporation (“**Nivagen**”), and one or more additional direct or indirect Subsidiaries of Nivagen hereafter acquired or formed, which become party to the Note Purchase Agreement by executing an Addendum (Nivagen and such other Subsidiaries are sometimes individually referred to herein as an “**Issuer**” and collectively referred to herein as “**Issuers**” or “**Issuer**”), the Purchasers of the Notes named therein (the “**Purchasers**”) and Agent, Agent and the Purchasers agreed to make certain financial accommodations available to Issuers from time to time pursuant to the terms and conditions thereof; and

WHEREAS, Agent and the Purchasers are willing to make the financial accommodations to Issuers as provided for in the Note Purchase Agreement, but only upon the condition, among others, that Grantors shall have executed and delivered to Agent, for the benefit of the Purchasers, that certain Security Agreement, dated as of even date with the Note Purchase Agreement (including all annexes, exhibits or schedules thereto, as from time to time amended, restated, supplemented or otherwise modified, the “**Security Agreement**”); and

WHEREAS, pursuant to the Security Agreement, Grantors are required to execute and deliver to Agent, for the benefit of the Purchasers, this Patent Security Agreement;

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each Grantor hereby agrees as follows:

1. **DEFINED TERMS.** All initially capitalized terms used but not otherwise defined herein have the meanings given to them in the Security Agreement or, if not defined therein, in the Note Purchase Agreement.

2. **GRANT OF SECURITY INTEREST IN PATENT COLLATERAL.** Each Grantor hereby unconditionally grants, assigns, and pledges to Agent, for the benefit of the Purchasers, to secure the Secured Obligations, a continuing security interest (referred to in this Patent Security Agreement as the “**Security Interest**”) in all of such Grantor’s right, title and interest in and to the following, whether now owned or hereafter acquired or arising (collectively, the “**Patent Collateral**”):

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(b) all divisionals, continuations, continuations-in-part, reissues, reexaminations, or extensions of the foregoing; and

(c) all products and proceeds of the foregoing, including any claim by such Grantor against third parties for past, present or future infringement of any Patent or any Patent exclusively licensed under any Intellectual Property License, including the right to receive damages, or right to receive license fees, royalties, and other compensation under any Patent Intellectual Property License.

3. SECURITY FOR SECURED OBLIGATIONS. This Patent Security Agreement and the Security Interest created hereby secures the payment and performance of the Secured Obligations, whether now existing or arising hereafter. Without limiting the generality of the foregoing, this Patent Security Agreement secures the payment of all amounts which constitute part of the Secured Obligations and would be owed by Grantors, or any of them, to Agent, whether or not they are unenforceable or not allowable due to the existence of an Insolvency Proceeding involving any Grantor.

4. SECURITY AGREEMENT. The Security Interest granted pursuant to this Patent Security Agreement is granted in conjunction with the security interests granted to Agent pursuant to the Security Agreement. Each Grantor hereby acknowledges and affirms that the rights and remedies of Agent with respect to the Security Interest in the Patent Collateral made and granted hereby are more fully set forth in the Security Agreement, the terms and provisions of which are incorporated by reference herein as if fully set forth herein. To the extent there is any inconsistency between this Patent Security Agreement and the Security Agreement, the Security Agreement shall control.

5. AUTHORIZATION TO SUPPLEMENT. If any Grantor shall obtain rights to any new patent application or issued patent or become entitled to the benefit of any patent application or patent for any divisional, continuation, continuation-in-part, reissue, or reexamination of any existing patent or patent application, the provisions of this Patent Security Agreement shall automatically apply thereto. Grantors shall give notice in writing to Agent with respect to any such new patent rights in accordance with the terms of the Security Agreement. Without limiting Grantors' obligations under this Section, Grantors hereby authorize Agent unilaterally to modify this Patent Security Agreement by amending Schedule I to include any such new patent rights of each Grantor. Notwithstanding the foregoing, no failure to so modify this Patent Security Agreement or amend Schedule I shall in any way affect, invalidate or detract from Agent's continuing security interest in all Collateral, whether or not listed on Schedule I.

6. COUNTERPARTS. This Patent Security Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, shall be deemed to be an original, and all of which, when taken together, shall constitute but one and the same Patent Security Agreement. Delivery of an executed counterpart of this Patent Security Agreement by telefacsimile or other electronic method of transmission shall be equally as effective as delivery of an original executed counterpart of this Patent Security Agreement. Any party delivering an executed counterpart of this Patent Security Agreement by telefacsimile or other electronic method of transmission also shall deliver an original executed counterpart of this Patent Security Agreement but the failure to deliver an original executed counterpart shall not affect the validity, enforceability, and binding effect of this Patent Security Agreement.

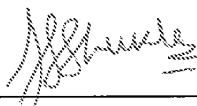
[signature page follows]

Patent Security Agreement

IN WITNESS WHEREOF, the parties hereto have caused this Patent Security Agreement to be executed and delivered as of the day and year first above written.

GRANTOR:

NIVAGEN PHARMACEUTICALS, INC.

By: 
Name: Jay Shukla
Title: President and Chief Executive Officer

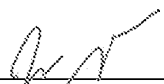
[Signature Page to Patent Security Agreement]

AGENT:

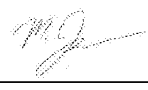
ACCEPTED AND ACKNOWLEDGED BY:

CORBEL CAPITAL PARTNERS SBIC, L.P.

By: Corbel Capital Advisors SBIC, LLC,
its General Partner

By: 
Name: Jeffrey B. Schwartz
Title: Managing Member

By: 
Name: Jeffrey S. Scrota
Title: Managing Member

By: 
Name: Michael H. Jones
Title: Managing Member

[Signature Page to Patent Security Agreement]

SCHEDULE I
to
PATENT SECURITY AGREEMENT

Patents

Title of Invention	Filing/Patent No.	Filing/Issue Date	Owner of Record
Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions	17/499,001	Filed October 12, 2021	Nivagen Pharmaceuticals, Inc.
Pantoprazole Compositions and Methods	17/446,063	Filed August 26, 2021	Nivagen Pharmaceuticals, Inc.
Chlorthalidone Compositions And Methods	17/707,237	Filed May 26, 2021	Nivagen Pharmaceuticals, Inc.
Lyophilized Compositions of Phenobarbital Sodium Salt	17/025,881	Filed September 18, 2020	Nivagen Pharmaceuticals, Inc.
Calcium Gluconate Formulation Without Calcium Saccharate	17/871,058	Filed July 2022	Nivagen Pharmaceuticals, Inc.

Patent Security Agreement



UNITED STATES
PATENT AND TRADEMARK OFFICE

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
17/499,001

RECEIPT DATE / TIME
09/18/2023 09:07:52 PM ET

ATTORNEY DOCKET #
104078.0005US

Title of Invention

Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 1080

FILED BY Danielle Moroz

PATENT CENTER # 62819219

FILING DATE 10/12/2021

CUSTOMER # 149344

FIRST NAMED INVENTOR Brijeshkumar B. Pandya

CORRESPONDENCE ADDRESS -

AUTHORIZED BY Martin Fessenmaier

Documents

TOTAL DOCUMENTS: 3

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
POA_Nivagen Pharmaceuticals Inc-Signed.pdf	2	Power of Attorney	500 KB
Stmt_3-73.pdf	3	Assignee showing of ownership per 37 CFR 3.73	111 KB
Terminal_Disclaimer.pdf	2	Terminal Disclaimer Filed	296 KB

Digest

DOCUMENT

MESSAGE DIGEST(SHA-512)

POA_Nivagen Pharmaceuticals Inc-Signed.pdf	79649D8FBF7782DF54BBA21A824A7B140AF9861E36B61C2877 DCFA262DFECD6EE88A190B7D206B5A3C9470DED009C5DCF 7F1B8301B3004117BF5D18CE0D6B797
Stmt_3-73.pdf	99574A5B594A423CCE2870EF40875C058CD3675252FB08CA07 7EF941199657EC030D44823579ACD1EA0BF25C386E34D0E9B 631697E84DA3C15E23640C1AFD7A5
Terminal_Disclaimer.pdf	BE280EE981053AA421BC11374AC6BA156B5572A216D93BBC8 382993512BA51FB6A3E05539A7B12C32EE702C7758CF615EB9 EA75CBD814EEACFEF4CA9F4564EC8

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

STATEMENT UNDER 37 CFR 3.73(c)Applicant/Patent Owner: Nivagen Pharmaceuticals, Inc.Application No./Patent No.: 17/499,001Filed/Issue Date: 2021-10-12Titled: Ready-To-Use Potassium Phosphates In Sodium Chloride SolutionsNivagen Pharmaceuticals, Inc., a corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☒ The assignee of the entire right, title, and interest.
2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):
- ☐ The extent (by percentage) of its ownership interest is _____. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.
- ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (e.g., bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

- A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 057763, Frame 0066, or for which a copy thereof is attached.

- B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

[Page 1 of 2]

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
 Reel _____, Frame _____, or for which a copy thereof is attached.

4. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
 Reel _____, Frame _____, or for which a copy thereof is attached.

5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
 Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
 Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☒ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Martin Fessenmaier/

September 18, 2023

Signature

Date

Martin Fessenmaier

46697

Printed or Typed Name

Title or Registration Number

[Page 2 of 2]

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:



Practitioners associated with Customer Number:

149344

OR



Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number

Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:



The address associated with Customer Number:

149344

OR



Firm or individual name

Address

City

State

Zip

Country

Telephone

Email

Assignee name and address:
Nivagen Pharmaceuticals, Inc.
3050 Fite Circle, Suite 100
Sacramento, California 95827 United States

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/AIA/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of the practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee.

Signature <i>L.Dasaradhi</i>	Date SEP/05/2023
Name Dr.L.DASARADHI	Telephone 9166348482
Title CSO	

This collection of information is required by 37 CFR 1.31, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public, which is to update (and by the USPTO to process) the file of a patent or reexamination proceeding. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 18 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



ELECTRONIC PAYMENT RECEIPT

APPLICATION #
17/499,001

RECEIPT DATE / TIME
09/18/2023 09:07:52 PM ET

ATTORNEY DOCKET #
104078.0005US

Title of Invention

Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 1080

FILED BY Danielle Moroz

PATENT CENTER # 62819219

AUTHORIZED BY Martin Fessenmaier

CUSTOMER # 149344

FILING DATE 10/12/2021

CORRESPONDENCE ADDRESS -

FIRST NAMED INVENTOR Brijeshkumar B. Pandya

Payment Information

PAYMENT METHOD
CARD / 1034

PAYMENT TRANSACTION ID
E20239HL10266816

PAYMENT AUTHORIZED BY
Danielle Moroz

PRE-AUTHORIZED ACCOUNT
601823

PRE-AUTHORIZED CATEGORY

37 CFR 1.16 (National application filing, search, and examination fees); 37 CFR 1.17 (Patent application and reexamination processing fees); 37 CFR 1.19 (Document supply fees); 37 CFR 1.20 (Post Issuance fees); 37 CFR 1.21 (Miscellaneous fees and charges)

FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
2814	STATUTORY DISCLAIMER, INCLUDING TERMINAL DISCLAIMER	170.00	1	170.00
TOTAL AMOUNT:				\$170.00

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION	Docket Number (Optional) 104078.0005US
In re Application of: Brijeshkumar B. Pandya, et al. Application No.: 17/499,001 Filed: 2021-10-12 For: Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions The applicant, <u>Nivagen Pharmaceuticals, Inc.</u>, owner of <u>100</u> percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number <u>18/460,941</u> filed, <u>2023-09-05</u>, as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns. In making the above disclaimer, the applicant does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that: any such patent granted on the pending reference application expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant. Check either box 1 or 2 below, if appropriate. 1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee. I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both. 2. ☒ The undersigned is an attorney or agent of record. Reg. No. <u>46697</u> <u>/Martin Fessenmaier/</u> Signature <u>2023-09-18</u> Date <u>Martin Fessenmaier</u> Typed or printed name <u>Senior Patent Agent</u> Title <u>(949) 679-0052</u> Telephone Number ☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.	

A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with an information collection subject to the requirements of the Paperwork Reduction Act of 1995, unless the information collection has a currently valid OMB Control Number. The OMB Control Number for this information collection is 0651-0031. Public burden for this form is estimated to average 12 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 or email InformationCollection@uspto.gov. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. If filing this completed form by mail, send to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

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Routine uses of the information in this record may include disclosure to: 1) law enforcement, in the event that the system of records indicates a violation or potential violation of law; 2) a Federal, state, local, or international agency, in response to its request; 3) a contractor of the USPTO having need for the information in order to perform a contract; 4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record; 5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record; 6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations; 7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals; 8) another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)); 9) the Office of Personnel Management (OPM) for personnel research purposes; and 9) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Additional Uses

Additional USPTO uses of the information in this record may include disclosure to: 1) the International Bureau of the World Intellectual Property Organization, if the record is related to an international application filed under the Patent Cooperation Treaty; 2) the public i) after publication of the application pursuant to 35 U.S.C. 122(b), ii) after issuance of a patent pursuant to 35 U.S.C. 151, iii) if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections, or an issued patent, or iv) without publication of the application or patent under the specific circumstances provided for by 37 CFR 1.14(a)(1)(v)-(vii); and/or 3) the National Archives and Records Administration, for inspection of records.

Application Number * 17/499,001 *	Application/Control No. 17/499,001	Applicant(s)/Patent under Reexamination Pandya et al.	
	Examiner AL-AWADI, DANAH J	Art Unit 1615	
Document Code - DISQ		Internal Document - DO NOT MAIL	

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed: <u>18 September 2023</u>	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:
/JEAN PROCTOR/ Technology Center: <u>OPLC</u> Telephone: <u>(571)272-1040</u>



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/499,001	10/12/2021	Brijeshkumar B. Pandya	104078.0005US

149344
Umberg Zipser LLP
1920 Main Street Suite 750
Irvine, CA 92614

CONFIRMATION NO. 1080
POA ACCEPTANCE LETTER



OC000000062162635

Date Mailed: 09/22/2023

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 09/18/2023.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/mbeyene/

<i>Notice of References Cited</i>	Application/Control No. 17/499,001		Applicant(s)/Patent Under Reexamination Pandya et al.	
	Examiner DANAH AL-AWADI		Art Unit 1615	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-11141430-B1	10-2021	Koneru; Phanesh	A61K9/0029	1/1
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

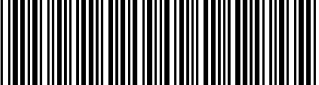
*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

U.S. Patent and Trademark Office
PTO-892 (Rev. 01-2001)

Notice of References Cited

Part of Paper No. 20230923

Issue Classification 	Application/Control No. 17/499,001	Applicant(s)/Patent Under Reexamination Pandya et al.
	Examiner DANAHA AL-AWADI	Art Unit 1615

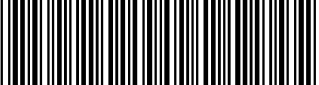
CPC						
Symbol					Type	Version
A61K	/	33	/	42	F	2013-01-01
A61M	/	5	/	168	I	2013-01-01
A61M	/	39	/	0208	I	2013-01-01
A61K	/	9	/	08	I	2013-01-01

CPC Combination Sets							
Symbol				Type	Set	Ranking	Version
	/		/				

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/DANAHA AL-AWADI/ Primary Examiner, Art Unit 1615	23 September 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	none

U.S. Patent and Trademark Office

Part of Paper No.: 20230923

Issue Classification 	Application/Control No. 17/499,001	Applicant(s)/Patent Under Reexamination Pandya et al.
	Examiner DANAH AL-AWADI	Art Unit 1615

INTERNATIONAL CLASSIFICATION			
CLAIMED			
A61K	/	33	/ 42
A61K	/	9	/ 08
A61M	/	39	/ 02
A61M	/	5	/ 168
NON-CLAIMED			
	/		/

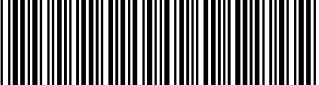
US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				

NONE	Total Claims Allowed:	
(Assistant Examiner)	(Date)	20
/DANAH AL-AWADI/ Primary Examiner, Art Unit 1615	23 September 2023	
(Primary Examiner)	(Date)	
	O.G. Print Claim(s)	O.G. Print Figure
	1	none

U.S. Patent and Trademark Office

Part of Paper No.: 20230923

Issue Classification 	Application/Control No. 17/499,001	Applicant(s)/Patent Under Reexamination Pandya et al.
	Examiner DANAH AL-AWADI	Art Unit 1615

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	10	10	19	19										
2	2	11	11	20	20										
3	3	12	12												
4	4	13	13												
5	5	14	14												
6	6	15	15												
7	7	16	16												
8	8	17	17												
9	9	18	18												

NONE	Total Claims Allowed:	
(Assistant Examiner)	(Date)	20
/DANAH AL-AWADI/ Primary Examiner, Art Unit 1615	23 September 2023	
(Primary Examiner)	(Date)	
		O.G. Print Claim(s)
		1
		O.G. Print Figure
		none

U.S. Patent and Trademark Office

Part of Paper No.: 20230923

<i>Search Notes</i> 	Application/Control No. 17/499,001	Applicant(s)/Patent Under Reexamination Pandya et al.
	Examiner DANAHA AL-AWADI	Art Unit 1615

CPC - Searched*		
Symbol	Date	Examiner
No CPC search performed	09/23/2023	DA

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
	No Classified search performed	09/23/2023	DA

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
Inventor search in PE2E	09/23/2023	DA
PE2E SEARCH and ip.com NPL SEARCH	09/23/2023	DA

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	Interference search performed in PE2E SEARCH	09/23/2023	DA

/DANAHA AL-AWADI/ Primary Examiner, Art Unit 1615	
--	--

Full search history

=> d his full

(FILE 'HOME' ENTERED AT 15:19:31 ON 15 SEP 2023)

D CLUSTER

D SET

FILE 'REGISTRY' ENTERED AT 15:19:57 ON 15 SEP 2023

L1 1 SEA SPE=ON ABB=ON PLU=ON POTASSIUM DIHYDROGEN PHOSPHATE/CN
D RN

L2 72 SEA SPE=ON ABB=ON PLU=ON 7778-77-0/CRN

L3 43 SEA SPE=ON ABB=ON PLU=ON POTASSIUM DIHYDROGEN PHOSPHATE

L4 1 SEA SPE=ON ABB=ON PLU=ON SODIUM CHLORIDE/CN
D RN

L5 640 SEA SPE=ON ABB=ON PLU=ON 7647-14-5/CRN

L6 2244 SEA SPE=ON ABB=ON PLU=ON SODIUM CHLORIDE

L7 0 SEA SPE=ON ABB=ON PLU=ON (L1 OR L2 OR L3) AND (L4 OR L5 OR L6)

FILE 'HCAPLUS' ENTERED AT 15:21:56 ON 15 SEP 2023

E POTASSIUM DIHYDROGEN PHOSPHATE/CT

E POTASSIUM DIHYDROGEN PHOSPHATE+ALL/CT

E MONOPOTASSIUM PHOSPHATE/CT

L8 66684 SEA SPE=ON ABB=ON PLU=ON "MONOPOTASSIUM PHOSPHATE"+NT,PFT,LT
,OLD/CT
E SODIUM CHLORIDE/CT

L9 443978 SEA SPE=ON ABB=ON PLU=ON "SODIUM CHLORIDE"+NT,PFT,LT,OLD/CT
E TONICITY/CT

L10 161 SEA SPE=ON ABB=ON PLU=ON TONICITY+NT,PFT,LT,OLD/CT
E STERILE/CT
E STERILE (MEDICAL)/CT
E STERILE SOLUTIONS/CT
E STERILIZATION AND DISINFECTION/CT

L11 83418 SEA SPE=ON ABB=ON PLU=ON "STERILIZATION AND DISINFECTION"+NT
,PFT,LT,OLD/CT

L12 16636 SEA SPE=ON ABB=ON PLU=ON ((L1 OR L2 OR L3) OR L8 OR KH2PO4
OR MONOPOTASSIUM PHOSPHATE OR POTASSIUM DIHYDROGEN PHOSPHATE)
AND ((L4 OR L5 OR L6) OR L9 OR NACL OR SODIUM CHLORIDE)

L13 357 SEA SPE=ON ABB=ON PLU=ON L12 AND ((L1 OR L2 OR L3) OR L8 OR
KH2PO4 OR MONOPOTASSIUM PHOSPHATE OR POTASSIUM DIHYDROGEN
PHOSPHATE) (L) (PRP/RL) AND ((L4 OR L5 OR L6) OR L9 OR NACL OR
SODIUM CHLORIDE) (L) (PRP/RL)

L14 27 SEA SPE=ON ABB=ON PLU=ON L13 AND (L10 OR ?TONIC? OR
?OSMOT?)

L15 9 SEA SPE=ON ABB=ON PLU=ON L13 AND (L11 OR STERIL? OR SANIT?
OR DISINFECT?)
E READY TO USE SOLUTIONS/CT
E READY TO USE+ALL/CT

L16 16 SEA SPE=ON ABB=ON PLU=ON (L14 OR L15) AND (THU OR DGN OR
DMA OR PAC OR PKT OR ADV)/RL

L17 12 SEA SPE=ON ABB=ON PLU=ON (L14 OR L15 OR L16) AND (.PERCENT.
OR CONC? OR MMOL OR MILLIMOL? OR MOLAR?)

L18 3 SEA SPE=ON ABB=ON PLU=ON L16 AND L17
D AU 1-3
D L15 1-9 AU
D L15 1-9 TI

L19 25 SEA SPE=ON ABB=ON PLU=ON (L16 OR L17 OR L18)
L*** DEL 0 S L19 AND (MG(W)100)
L20 0 SEA SPE=ON ABB=ON PLU=ON L19 AND ("READY TO USE" OR
READY(W) TO(W) USE)
L21 25 SEA SPE=ON ABB=ON PLU=ON (L19 OR L20)
E US 2022-0110969/PN
L22 1 SEA SPE=ON ABB=ON PLU=ON US 2022-0110969/PN
D AU
SEL RN

FILE 'REGISTRY' ENTERED AT 15:35:24 ON 15 SEP 2023

L23 7 SEA SPE=ON ABB=ON PLU=ON (16887-00-6/BI OR 7429-90-5/BI OR
7647-14-5/BI OR 7723-14-0/BI OR 7758-11-4/BI OR 7778-53-2/BI
OR 7778-77-0/BI)
L24 1 SEA SPE=ON ABB=ON PLU=ON L23 AND (L1 OR L2 OR L3)
L25 1 SEA SPE=ON ABB=ON PLU=ON L23 AND (L4 OR L5 OR L6)

FILE 'HCAPLUS' ENTERED AT 15:37:52 ON 15 SEP 2023

L26 13239 SEA SPE=ON ABB=ON PLU=ON L24 AND L25
L27 179 SEA SPE=ON ABB=ON PLU=ON PANDYA, B?/AU
L28 4 SEA SPE=ON ABB=ON PLU=ON JAGADALE, G?/AU
L29 7 SEA SPE=ON ABB=ON PLU=ON LAKKARAJU, D?/AU
L30 7 SEA SPE=ON ABB=ON PLU=ON CHODAVARAPU, B?/AU
L31 4793 SEA SPE=ON ABB=ON PLU=ON SHUKLA, A?/AU
L32 900 SEA SPE=ON ABB=ON PLU=ON SHUKLA, J?/AU
L33 2 SEA SPE=ON ABB=ON PLU=ON L27 AND L28 AND L29 AND L30 AND
L31 AND L32
L34 3 SEA SPE=ON ABB=ON PLU=ON (L27 OR L28 OR L29 OR L30 OR L31
OR L32 OR L33) AND ((L1 OR L2 OR L3) OR L8 OR KH2PO4 OR
MONOPOTASSIUM PHOSPHATE OR POTASSIUM DIHYDROGEN PHOSPHATE) AND
((L4 OR L5 OR L6) OR L9 OR NAACL OR SODIUM CHLORIDE)
L35 0 SEA SPE=ON ABB=ON PLU=ON L34 AND (?TONIC? OR ?OSMOT?)
L36 0 SEA SPE=ON ABB=ON PLU=ON (L33 OR L34) AND (STERIL? OR
SANIT? OR DISINFECT?)
L37 2 SEA SPE=ON ABB=ON PLU=ON (L33 OR L34) AND (.PERCENT. OR
CONC? OR MMOL OR MILLIMOL? OR MOLAR? OR MG(W)100)
L38 3 SEA SPE=ON ABB=ON PLU=ON (L33 OR L34 OR L35 OR L36 OR L37)
AND (THU OR DGN OR DMA OR PAC OR PKT OR ADV OR PRP)/RL
L39 4 SEA SPE=ON ABB=ON PLU=ON (L33 OR L34 OR L35 OR L36 OR L37
OR L38)

FILE 'MEDLINE, BIOSIS, EMBASE, DRUGU' ENTERED AT 15:47:06 ON 15 SEP 2023

L40 0 SEA SPE=ON ABB=ON PLU=ON L33
L41 0 SEA SPE=ON ABB=ON PLU=ON (L27 OR L28 OR L29 OR L30 OR L31
OR L32 OR L33) AND (L1 OR KH2PO4 OR MONOPOTASSIUM PHOSPHATE OR
POTASSIUM DIHYDROGEN PHOSPHATE) AND (L4 OR NAACL OR SODIUM
CHLORIDE)
L42 1 SEA SPE=ON ABB=ON PLU=ON (L27 OR L28 OR L29 OR L30 OR L31
OR L32 OR L33) AND (?TONIC? OR ?OSMOT?) AND (STERIL? OR SANIT?
OR DISINFECT?)
L43 0 SEA SPE=ON ABB=ON PLU=ON (L40 OR L41)

FILE 'WPIX' ENTERED AT 15:49:17 ON 15 SEP 2023

L44 2 SEA SPE=ON ABB=ON PLU=ON L27 AND L28 AND L29 AND L30 AND
L31 AND L32

L45 3 SEA SPE=ON ABB=ON PLU=ON (L27 OR L28 OR L29 OR L30 OR L31
OR L32 OR L33) AND (L1 OR KH2PO4 OR MONOPOTASSIUM PHOSPHATE OR
POTASSIUM DIHYDROGEN PHOSPHATE) AND (L4 OR NACL OR SODIUM
CHLORIDE)

L46 2 SEA SPE=ON ABB=ON PLU=ON (L27 OR L28 OR L29 OR L30 OR L31
OR L32 OR L33) AND (?TONIC? OR ?OSMOT?) AND (STERIL? OR SANIT?
OR DISINFECT?)

L47 2 SEA SPE=ON ABB=ON PLU=ON (L44 OR L45 OR L46) AND (.PERCENT.
OR CONC? OR MMOL OR MILLIMOL? OR ?MOLAR? OR MG(W)100)

L48 5 SEA SPE=ON ABB=ON PLU=ON (L44 OR L45 OR L46 OR L47)

L49 420 SEA SPE=ON ABB=ON PLU=ON (L1 OR KH2PO4 OR MONOPOTASSIUM
PHOSPHATE OR POTASSIUM DIHYDROGEN PHOSPHATE) AND (L4 OR NACL
OR SODIUM CHLORIDE) AND (?TONIC? OR ?OSMOT? OR ISOTONI?)

L50 420 SEA SPE=ON ABB=ON PLU=ON L49 AND (KH2PO4 OR MONOPOTASSIUM
PHOSPHATE OR POTASSIUM DIHYDROGEN PHOSPHATE) (L) (NACL OR
SODIUM CHLORIDE)

L51 390 SEA SPE=ON ABB=ON PLU=ON L49 AND (KH2PO4 OR MONOPOTASSIUM
PHOSPHATE OR POTASSIUM DIHYDROGEN PHOSPHATE) (S) (NACL OR
SODIUM CHLORIDE)

L52 174 SEA SPE=ON ABB=ON PLU=ON (L50 OR L51) AND (?TONIC? OR
?OSMOT? OR ISOTONI?) (L) (STERIL? OR SANIT? OR DISINFECT?)

L53 162 SEA SPE=ON ABB=ON PLU=ON L51 AND L52

L54 83 SEA SPE=ON ABB=ON PLU=ON L53 AND (.PERCENT. OR CONC? OR
MMOL OR MILLIMOL? OR ?MOLAR? OR MG(W)100)

L55 38 SEA SPE=ON ABB=ON PLU=ON L54 AND (THERAP? OR TREAT? OR
ADMINIST?)

L56 2 SEA SPE=ON ABB=ON PLU=ON L55 AND (AL OR ALUMIN?) (S) (FREE OR
ABSEN? OR SCAVENG? OR REMOV? OR CHELAT?)

L57 5 SEA SPE=ON ABB=ON PLU=ON (L55 OR L56) AND (PO4 OR PHOSPHAT?
OR PHOSPHOR?) (S) (DEFICI? OR LOW OR REPLAC?)

L58 7 SEA SPE=ON ABB=ON PLU=ON (L56 OR L57)

L59 174 SEA SPE=ON ABB=ON PLU=ON (L1 OR KH2PO4 OR MONOPOTASSIUM
PHOSPHATE OR POTASSIUM DIHYDROGEN PHOSPHATE) AND (L4 OR NACL
OR SODIUM CHLORIDE) AND (?TONIC? OR ?OSMOT? OR ISOTONI?) (L) (STE
RIL? OR SANIT? OR DISINFECT?)

L60 1 SEA SPE=ON ABB=ON PLU=ON L59 AND (HYPOPHOSPH? OR PHOSPHATEMI
?)

L61 19 SEA SPE=ON ABB=ON PLU=ON (L59 OR L60) AND (PO4 OR PHOSPHAT?
OR PHOSPHOR?) (S) (DEFICI? OR LOW OR REPLAC?)

L62 2 SEA SPE=ON ABB=ON PLU=ON (L59 OR L60 OR L61) AND (AL OR
ALUMIN?) (S) (FREE OR ABSEN? OR SCAVENG? OR REMOV? OR CHELAT?)

L63 13 SEA SPE=ON ABB=ON PLU=ON (L60 OR L61 OR L62) AND (THERAP?
OR TREAT? OR ADMINIST?)

L64 22 SEA SPE=ON ABB=ON PLU=ON (L60 OR L61 OR L62 OR L63)
D STAT QUERY L21
D STAT QUERY L64
D STAT QUERY L58

FILE 'HCAPLUS, WPIX' ENTERED AT 16:03:47 ON 15 SEP 2023

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ANSWERS '1-25' FROM FILE HCAPLUS

ANSWERS '26-47' FROM FILE WPIX
D L65 1-25 IBIB ED ABS HITRN
D L65 26-47 IBIB ED ABS HIT
D STAT QUERY L39
D STAT QUERY L43
D STAT QUERY L48
L66 7 DUP REM L39 L43 L48 (2 DUPLICATES REMOVED)
ANSWERS '1-4' FROM FILE HCAPLUS
ANSWERS '5-7' FROM FILE WPIX
D L66 1-4 IBIB ED ABS HITRN
D L66 5-7 IBIB ED ABS HIT

FILE HOME

FILE REGISTRY

Property values tagged with IC are from the ZIC/VINITI data file provided by InfoChem.

STRUCTURE FILE UPDATES: 14 SEP 2023 HIGHEST RN 2976480-58-5
DICTIONARY FILE UPDATES: 14 SEP 2023 HIGHEST RN 2976480-58-5

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FILE HCAPLUS

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FILE COVERS 1907 - 15 Sep 2023 VOL 184 ISS 2
FILE LAST UPDATED: 14 Sep 2023 (20230914/ED)

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Bibliographic Data

Application No: 17/499,001

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☒ No ☐ Met After Allowance

Verified and Acknowledged: /DANAH AL-AWADI/

Examiner's Signature

Initials

Title: Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
10/12/2021	424	1615	
RULE			

APPLICANTS

Nivagen Pharmaceuticals, Inc., Sacramento, CA, UNITED STATES

INVENTORS

Brijeshkumar B. Pandya, Sacramento, CA, UNITED STATES

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Bala Tripura Sundari Chodavarapu, Davis, CA, UNITED STATES

Anand Shukla, Denver, CO, UNITED STATES

Jwalant Shukla, Sacramento, CA, UNITED STATES

CONTINUING DATA

This application has PRO of 63090518 10/12/2020

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

10/21/2021

** SMALL ENTITY **

STATE OR COUNTRY

UNITED STATES

ADDRESS

FILING FEE RECEIVED

\$910

Main Concept Text

=====

potassium phosphate and phosphorus mmol/mL

Concept Modifiers (5)

=====

5. More Like Text: sodium chloride

4. More Like Text: phosphorous

3. More Like Document: US20220110969 Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions

2. More Like Text: ready to use

1. More Like Text: (mmol/mL)

(No Filters)

=====

Options

=====

De-dup: None

Relevance Cut-off: None

Sort: Relevance

Content: Patents + NPL (192)

=====

US Patents

US Designs

US Applications

EPO Patents

EPO Applications

China Patents

China Applications

Japan Patents

Japan Applications

Korea Patents

Korea Applications

WIPO Applications

Argentina Patents

Argentina Applications

Brazil Patents

Brazil Applications

Canada Patents

Canada Applications
Chile Patents
Chile Applications
Colombia Applications
Costa Rica Applications
Cuba Patents
Cuba Applications
Dominican Republic Applications
Ecuador Patents
Ecuador Applications
El Salvador Applications
Guatemala Applications
Honduras Applications
Mexico Patents
Mexico Applications
Nicaragua Patents
Panama Applications
Peru Applications
Trinidad & Tobago Patents
Uruguay Applications
Austria Patents
Austria Applications
Belarus Patents
Belgium Patents
Belgium Applications
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Bosnia & Herzegovina Applications
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Bulgaria Applications
Croatia Patents
Croatia Applications
Czech Republic Patents
Czech Republic Applications
Czechoslovakia Patents
Czechoslovakia Applications
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Denmark Applications
Estonia Patents
Estonia Applications
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Great Britain Patents
Great Britain Applications
Greece Patents
Greece Applications

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Ireland Applications
Italy Patents
Italy Applications
Latvia Patents
Latvia Applications
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Lithuania Applications
Luxembourg Patents
Luxembourg Applications
Malta Patents
Monaco Patents
Montenegro Patents
Montenegro Applications
Netherlands Patents
Netherlands Applications
Norway Patents
Norway Applications
Poland Patents
Poland Applications
Portugal Patents
Portugal Applications
Republic of Moldova Patents
Republic of Moldova Applications
Romania Patents
Romania Applications
San Marino Patents
San Marino Applications
Serbia Patents
Serbia Applications
Slovakia Patents
Slovakia Applications
Slovenia Patents
Spain Patents
Spain Applications
Sweden Patents
Sweden Applications
Switzerland Patents
Switzerland Applications
Ukraine Patents
Yugoslavia/Serbia and Montenegro Patents
Yugoslavia/Serbia and Montenegro Applications
Armenia Patents
Australia Patents
Australia Applications
Cyprus Patents

Gulf Cooperation Council Patents
Hong Kong Patents
India Patents
India Applications
Indonesia Patents
Indonesia Applications
Israel Patents
Israel Applications
Jordan Patents
Jordan Applications
Kyrgyzstan Patents
Macao Applications
Malaysia Patents
Mongolia Patents
New Zealand Patents
Philippines Patents
Philippines Applications
Saudi Arabia Patents
Saudi Arabia Applications
Singapore Patents
Singapore Applications
Taiwan Patents
Taiwan Applications
Tajikistan Patents
Tajikistan Applications
Thailand Patents
Thailand Applications
Uzbekistan Patents
Vietnam Patents
Algeria Patents
ARIPO Patents
ARIPO Applications
Egypt Patents
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Malawi Patents
Morocco Patents
Morocco Applications
OAPI Patents
South Africa Patents
Tunisia Applications
Zambia Patents
Zimbabwe Patents
EAPO Patents
EAPO Applications
Georgia Patents
Georgia Applications
Kazakhstan Patents
Kazakhstan Applications
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Russia Applications

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OnePetro.org: Conferences at OnePetro.org
Other Literature: IBM Redbooks
Other Literature: PubMed Central
Other Literature: arXiv.org

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1096	0	ready ADJ to ADJ use AND (potassium WITH phosphates)	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/30 01:42 PM
L1097	7019	ready NEAR use AND (potassium WITH phosphates)	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/30 01:43 PM
L1098	468	ready NEAR use AND (potassium WITH phosphates).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/30 01:43 PM
L1099	19	ready NEAR use AND (potassium WITH phosphates).ab.	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/30 01:53 PM
L1100	9	ready NEAR use AND (potassium ADJ phosphates).ab.	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/30 01:54 PM
L1101	0	ready NEAR use AND hypophosphatemia.ab.	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/30 02:03 PM
L1137	54384	phosphorous AND mmol	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 05:07 PM
L1138	8006	phosphorous SAME mmol	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 05:07 PM
L1139	513146	phosphorous SAME mmol sodium ADJ chloride	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 05:07 PM
L1140	4311	phosphorous SAME mmol AND sodium ADJ chloride	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 05:07 PM
L1141	1213	phosphorous SAME mmol AND sodium ADJ chloride AND potassium ADJ phosphate	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 05:08 PM
L1142	323	phosphorous NEAR mmol AND sodium ADJ chloride AND potassium ADJ phosphate	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 05:08 PM
L1143	0	phosphorous NEAR mmol AND sodium ADJ chloride AND potassium ADJ phosphate AND phopshate.ab.	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 05:09 PM
L1144	1	phosphorous NEAR mmol AND sodium ADJ chloride AND potassium ADJ phosphate AND phosphate.ab.	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 05:09 PM
L1246	2	((("NIVAGEN") near3 ("PHARMACEUTICALS ") near3	(USPAT)	OR	ON	ON	2023/09/23 10:28 PM

L1247	43	("INC"))).AS,AANM. (((("PANDYA") near3 ("Brijeshkumar")) OR (("JAGADALE") near3 ("Govind")) OR (("LAKKARAJU") near3 ("Dasaradhi")) OR (("CHODAVARAPU") near3 ("Bala")) OR (("SHUKLA") near3 ("Anand")) OR (("SHUKLA") near3 ("Jwalant"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2023/09/23 10:28 PM
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PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N66	1750	potassium ADJ phosphates AND phosphorus.clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/09/23 10:30 PM
N67	84	potassium ADJ phosphates AND phosphorus.clm. AND (phosphorus SAME (mmol OR molar)).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/09/23 10:31 PM
N68	18	potassium ADJ phosphates AND phosphorus.clm. AND (phosphorus SAME (mmol OR molar)).clm. AND sodium ADJ chloride	(US-PGPUB; USPAT)	OR	ON	ON	2023/09/23 10:32 PM
N69	21	potassium ADJ phosphates AND phosphorus.clm. AND (phosphorus SAME (mmol OR molar OR mole)).clm. AND sodium ADJ chloride	(US-PGPUB; USPAT)	OR	ON	ON	2023/09/23 10:32 PM

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	17499001
	Filing Date	2021-10-12
	First Named Inventor	Brijeshkumar B. Pandya
	Art Unit	1629
	Examiner Name	
	Attorney Docket Number	104078.0005US

U.S.PATENTS							Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	
	1	10342813	B2	2019-07-09	Pizza		
	2	10632150	B1	2020-04-28	Thomas et al.		
	3	11141430	B1	2021-10-12	Koneru et al.		
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	1	20140364503	A1	2014-12-11	Owoo et al.		
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Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²ⁱ	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	106265499	CN	A	2017-01-04	Wu et al.		×

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17499001
	Filing Date		2021-10-12
	First Named Inventor	Brijeshkumar B. Pandya	
	Art Unit	1629	
	Examiner Name		
	Attorney Docket Number	104078.0005US	

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1		
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EXAMINER SIGNATURE			
Examiner Signature	/DANAH AL-AWADI/		Date Considered 09/23/2023
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.			

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		17499001
	Filing Date		2021-10-12
	First Named Inventor	Brijeshkumar B. Pandya	
	Art Unit	1629	
	Examiner Name		
	Attorney Docket Number	104078.0005US	

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Martin Fessenmaier/	Date (YYYY-MM-DD)	2022-01-12
Name/Print	Martin Fessenmaier	Registration Number	46697

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.A/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

149344 7590 09/28/2023
Umberg Zipser LLP
1920 Main Street Suite 750
Irvine, CA 92614

EXAMINER

AL-AWADI, DANAH J

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 09/28/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/499,001	10/12/2021	Brijeshkumar B. Pandya	104078.0005US	1080

TITLE OF INVENTION: Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0.00	\$0.00	\$480	12/28/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

149344 7590 09/28/2023
Umberg Zipser LLP
1920 Main Street Suite 750
Irvine, CA 92614

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/499,001	10/12/2021	Brijeshkumar B. Pandya	104078.0005US	1080

TITLE OF INVENTION: Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0.00	\$0.00	\$480	12/28/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
AL-AWADI, DANAH J	1615	424-601000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required)

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via Patent Center or EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29☐ Applicant asserting small entity status. See 37 CFR 1.27☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/499,001	10/12/2021	Brijeshkumar B. Pandya	104078.0005US	1080
149344	7590	09/28/2023	EXAMINER	
Umberg Zipser LLP 1920 Main Street Suite 750 Irvine, CA 92614			AL-AWADI, DANAH J	
			ART UNIT	PAPER NUMBER
			1615	
DATE MAILED: 09/28/2023				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 17/499,001	Applicant(s) Pandya et al.	
	Examiner DANAH AL-AWADI	Art Unit 1615	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the claims filed 10/12/2021.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 1-20. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
Certified copies:
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)	5. ☒ Examiner's Amendment/Comment
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>1/12/2022</u> .	6. ☒ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.	7. ☐ Other _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.	

/DANAH AL-AWADI/ Primary Examiner, Art Unit 1615	
---	--

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Martin Fessenmaier on 9/18/2023.

1 (currently amended) An isotonic sterile ready-to-use (~~RTU~~) aqueous potassium phosphates solution, comprising potassium phosphates and sodium chloride, wherein the solution comprises 15 mmol/100 ml phosphorus (~~0.15 mmol/mL~~) and equal or less than 50 mcg/L aluminum.

2 (currently amended) The solution of claim 1, wherein the potassium phosphates comprise potassium dihydrogen phosphate (~~KH₂PO₄~~) and potassium hydrogen phosphate (~~K₂HPO₄~~), wherein the potassium dihydrogen phosphate is present in the solution an amount of about 1,120 mg/100 ml or 8.2 mmol/100 ml of Phosphorus and wherein the potassium hydrogen phosphate is present in the solution in an amount of about 1,180 mg/100 ml or 6.8 mmol/100 ml of Phosphorus.

10 (currently amended) The solution of claim ~~4~~9, wherein the flexible polyolefin container is further contained in a secondary metallized overwrap.

11 (currently amended) A sterile ready-to-use (~~RTU~~) premixed pharmaceutical product stored in a flexible polymeric container, wherein the pharmaceutical product comprises a potassium phosphates in an aqueous sodium chloride solution containing (a) less than 50 mcg/L aluminum, (b) about 15 mmol/100 ml phosphorus, and (c) about 22 mEq/100 mL potassium.

12 (currently amended) The pharmaceutical product of claim 11, wherein the potassium phosphates comprise potassium dihydrogen phosphate (~~KH₂PO₄~~) and potassium hydrogen phosphate (~~K₂HPO₄~~), wherein the potassium dihydrogen phosphate is present in the solution an amount of about 1,120 mg/100 ml or 8.2 mmol/100 ml of

Phosphorus, and wherein the potassium hydrogen phosphate is present in the solution in an amount of about 1,180 mg/100 ml or 6.8 mmol/100 ml of Phosphorus.

16 (currently amended) The pharmaceutical product of claim 11, wherein the premixed pharmaceutical product comprises about 4.65 mg/mL of phosphorus (~~0.15 mmol/mL~~), about 8.50 mg/mL of potassium (~~0.22 mEq/mL~~), about 3.57 mg/mL of sodium, and about 5.43 mg/mL of chloride.

17 (currently amended) A method of administering phosphates to a patient in need of phosphorus replacement therapy, comprising: administering, without prior dilution, an isotonic, sterile, and ready-to-use (~~RTU~~) solution comprising potassium phosphates and sodium chloride solution from a flexible container to the patient at a rate of infusion and by a route of administration corresponding to the patient's age and degree of need of phosphorus replacement; wherein the solution comprises about 15 mmol/100 ml phosphorus, about 22 mEq/100 mL potassium, and less than 50 mcg/L aluminum.

EXAMINER'S COMMENT

Claims 1-20 are allowed.

The terminal disclaimer filed on 9/18/2023 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Application No. 18/460941 has been reviewed and is accepted. The terminal disclaimer has been recorded.

REASONS FOR ALLOWANCE

The closest prior art is to Koneru et al. (US Patent 11,141,430) which disclose phosphate compositions with a low aluminum content. The difference being that Koneru et al. disclose total phosphorous concentration which is about 1 mM/mL (see col. 8, lines 57-67). Koneru et al. does not disclose or provide motivation to arrive at 0.15 mM/mL as claimed.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danah Al-awadi whose telephone number is (571) 270-7668. The examiner can normally be reached on 9:00 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Danah Al-Awadi/
Primary Examiner, Art Unit 1615

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

149344 7590 09/28/2023
Umberg Zipser LLP
1920 Main Street Suite 750
Irvine, CA 92614

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

Danielle Moroz	(Typed or printed name)
/Danielle Moroz/	(Signature)
October 9, 2023	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/499,001	10/12/2021	Brijeshkumar B. Pandya	104078.0005US	1080

TITLE OF INVENTION: Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0.00	\$0.00	\$480	12/28/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
AL-AWADI, DANAH J	1615	424-601000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 Umberg Zipser LLP

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

NIVAGEN PHARMACEUTICALS, INC.

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Sacramento, CA

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government4a. Fees submitted: ☒ Issue Fee ☐ Publication Fee (if required)

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☒ Electronic Payment via Patent Center or EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 601823

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29☐ Applicant asserting small entity status. See 37 CFR 1.27☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Martin Fessenmaier/Date October 9, 2023Typed or printed name Martin FessenmaierRegistration No. 46697



UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC PAYMENT RECEIPT

APPLICATION #
17/499,001

RECEIPT DATE / TIME
10/09/2023 02:30:16 PM ET

ATTORNEY DOCKET #
104078.0005US

Title of Invention

Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 1080

FILED BY Danielle Moroz

PATENT CENTER # 62954433

AUTHORIZED BY Martin Fessenmaier

CUSTOMER # 149344

FILING DATE 10/12/2021

CORRESPONDENCE ADDRESS -

FIRST NAMED INVENTOR Brijeshkumar B. Pandya

Payment Information

PAYMENT METHOD
CARD / 1034

PAYMENT TRANSACTION ID
E202309E31459976

PAYMENT AUTHORIZED BY
Danielle Moroz

PRE-AUTHORIZED ACCOUNT
601823

PRE-AUTHORIZED CATEGORY

37 CFR 1.16 (National application filing, search, and examination fees); 37 CFR 1.17 (Patent application and reexamination processing fees); 37 CFR 1.19 (Document supply fees); 37 CFR 1.20 (Post Issuance fees); 37 CFR 1.21 (Miscellaneous fees and charges)

FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
2501	UTILITY ISSUE FEE	480.00	1	480.00
TOTAL AMOUNT:				\$480.00

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement

Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



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PATENT AND TRADEMARK OFFICE

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
17/499,001

RECEIPT DATE / TIME
10/09/2023 02:30:16 PM ET

ATTORNEY DOCKET #
104078.0005US

Title of Invention

Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions

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APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # -

CONFIRMATION # 1080

FILED BY Danielle Moroz

PATENT CENTER # 62954433

FILING DATE 10/12/2021

CUSTOMER # 149344

FIRST NAMED INVENTOR Brijeshkumar B. Pandya

CORRESPONDENCE ADDRESS -

AUTHORIZED BY Martin Fessenmaier

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
Issue_Fee_Payment.pdf	1	Issue Fee Payment (PTO-85B)	166 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
Issue_Fee_Payment.pdf	DA16E216C7DB25AC18284751CB62EA6F0CE6ADCDB55329D9 916B5E9E345EB12CF992EDA1C6F20A4E037C358F47461B6B0 303FAEECE348493FFF9F4770EBB3B3F

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as

described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/499,001	11/14/2023	11813291	104078.0005US	1080
149344	7590	10/25/2023		
Umberg Zipser LLP 1920 Main Street Suite 750 Irvine, CA 92614				

ISSUE NOTIFICATION

The projected patent number and issue date are specified above. The patent will issue electronically. The electronically issued patent is the official patent grant pursuant to 35 U.S.C. § 153. The patent may be accessed on or after the issue date through Patent Center at <https://patentcenter.uspto.gov/>. The patent will be available in both the public and the private sides of Patent Center. Further assistance in electronically accessing the patent, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-888-217-9197.

The USPTO is implementing electronic patent issuance with a transition period, during which period the USPTO will mail a ceremonial paper copy of the electronic patent grant to the correspondence address of record. Additional copies of the patent (i.e., certified and presentation copies) may be ordered for a fee from the USPTO's Certified Copy Center at <https://certifiedcopycenter.uspto.gov/index.html>. The Certified Copy Center may be reached at (800)972-6382.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 290 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Center (<https://patentcenter.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PATENT CENTER site <https://patentcenter.uspto.gov> for additional inventors):

Brijeshkumar B. Pandya, Sacramento, CA;
Govind R. Jagadale, Sacramento, CA;
Dasaradhi Lakkaraju, Sacramento, CA;
Bala Tripura Sundari Chodavarapu, Davis, CA;
Anand Shukla, Denver, CO;

APPLICANT(s) (Please see PATENT CENTER site <https://patentcenter.uspto.gov> for additional applicants):

Nivagen Pharmaceuticals, Inc., Sacramento, CA;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit [SelectUSA.gov](https://selectusa.gov).



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United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/499,001	10/12/2021	Brijeshkumar B. Pandya	104078.0005US	1080
149344	7590	11/14/2023	EXAMINER	
Umberg Zipser LLP			AL-AWADI, DANAH J	
1920 Main Street Suite 750			ART UNIT	PAPER NUMBER
Irvine, CA 92614			1615	
			NOTIFICATION DATE	DELIVERY MODE
			11/14/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

eofficeaction@appcoll.com
patents@umbergzipser.com
rdean@umbergzipser.com



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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.
17/499,001	14-Nov-2023	11813291

Umberg Zipser LLP
1920 Main Street Suite 750
Irvine, CA 92614

EGRANT NOTIFICATION

Your electronic patent grant (eGrant) is now available, which can be accessed via Patent Center at <https://patentcenter.uspto.gov>

The electronic patent grant is the official patent grant under 35 U.S.C. 153. For more information, please visit <https://www.uspto.gov/electronicgrants>

PATENT ASSIGNMENT COVER SHEET

Electronic Version v1.1
 Stylesheet Version v1.2

Assignment ID: PATI224254

SUBMISSION TYPE:	CORRECTIVE ASSIGNMENT	
NATURE OF CONVEYANCE:	Corrective Assignment to correct the patent application no. 17/466,063 as the application number was entered incorrectly due to a typographic error. Such typographic error was made in good faith. The correct patent application number appearing on the recorded document is 17/446,063. previously recorded on Reel 60657 Frame 158. Assignor(s) hereby confirms the Security Interest.	
CONVEYING PARTY DATA		
Name		Execution Date
NIVAGEN PHARMACEUTICALS, INC.		07/28/2022
RECEIVING PARTY DATA		
Company Name:	CORBEL CAPITAL PARTNERS SBIC, L.P.	
Street Address:	11777 San Vicente Blvd., Suite 777	
City:	Los Angeles	
State/Country:	CALIFORNIA	
Postal Code:	90049	
PROPERTY NUMBERS Total: 5		
Property Type	Number	
Application Number:	17499001	
Application Number:	17707237	
Application Number:	17025881	
Application Number:	17871058	
Application Number:	17446063	
CORRESPONDENCE DATA		
Fax Number:	9497254100	
<i>Correspondence will be sent to the e-mail address first; if that is unsuccessful, it will be sent using a fax number, if provided; if that is unsuccessful, it will be sent via US Mail.</i>		
Phone:	9497254043	
Email:	amina@stradlinglaw.com	
Correspondent Name:	Mr. Arnold V Mina	
Address Line 1:	660 Newport Center Drive, Suite 1600	
Address Line 4:	Newport Beach, CALIFORNIA 92660	
ATTORNEY DOCKET NUMBER:	103864-0022	
NAME OF SUBMITTER:	ARNOLD MINA	
SIGNATURE:	ARNOLD MINA	

DATE SIGNED:	05/10/2024
	This document serves as an Oath/Declaration (37 CFR 1.63).
Total Attachments: 7 source=NIVAGEN ASSIGNMENT RECORDATION#page1.tif source=NIVAGEN ASSIGNMENT RECORDATION#page2.tif source=NIVAGEN ASSIGNMENT RECORDATION#page3.tif source=NIVAGEN ASSIGNMENT RECORDATION#page4.tif source=NIVAGEN ASSIGNMENT RECORDATION#page5.tif source=NIVAGEN ASSIGNMENT RECORDATION#page6.tif source=NIVAGEN ASSIGNMENT RECORDATION#page7.tif	

PATENT ASSIGNMENT COVER SHEET

Electronic Version v1.1
 Stylesheet Version v1.2

EPAS ID: PAT7456796

SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	SECURITY INTEREST
CONVEYING PARTY DATA	
Name	Execution Date
NIVAGEN PHARMACEUTICALS, INC.	07/28/2022
RECEIVING PARTY DATA	
Name:	CORBEL CAPITAL PARTNERS SBIC, L.P.
Street Address:	11777 SAN VICENTE BLVD., SUITE 777
City:	LOS ANGELES
State/Country:	CALIFORNIA
Postal Code:	90049
PROPERTY NUMBERS Total: 5	
Property Type	Number
Application Number:	17499001
Application Number:	17466063
Application Number:	17707237
Application Number:	17025881
Application Number:	17871058
CORRESPONDENCE DATA	
Fax Number:	(949)725-4100
<i>Correspondence will be sent to the e-mail address first; if that is unsuccessful, it will be sent using a fax number, if provided; if that is unsuccessful, it will be sent via US Mail.</i>	
Phone:	9497254043
Email:	amina@stradlinglaw.com
Correspondent Name:	ARNOLD V MINA
Address Line 1:	STRADLING YOCCHA CARLSON & RAUTH
Address Line 2:	660 NEWPORT CENTER DRIVE, SUITE 1600
Address Line 4:	NEWPORT BEACH, CALIFORNIA 92660
ATTORNEY DOCKET NUMBER:	103864-0022
NAME OF SUBMITTER:	ARNOLD V. MINA
SIGNATURE:	/Arnold V. Mina/
DATE SIGNED:	07/28/2022
This document serves as an Oath/Declaration (37 CFR 1.63).	

507409868

PATENT
REEL: 060657 FRAME: 0158

Total Attachments: 5

source=Corbel.Nivagen- Patent Security Agreement#page1.tif

source=Corbel.Nivagen- Patent Security Agreement#page2.tif

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source=Corbel.Nivagen- Patent Security Agreement#page4.tif

source=Corbel.Nivagen- Patent Security Agreement#page5.tif

PATENT**REEL: 060657 FRAME: 0159**

PATENT SECURITY AGREEMENT

This PATENT SECURITY AGREEMENT (this “**Patent Security Agreement**”) is made this 28th day of July, 2022, by and among the Grantors listed on the signature pages hereof (collectively, jointly and severally, “**Grantors**” and each individually “**Grantor**”), and CORBEL CAPITAL PARTNERS SBIC, L.P., as administrative agent (“**Agent**”) for the benefit of the Purchasers (as defined below).

W I T N E S S E T H:

WHEREAS, pursuant to that certain Secured Promissory Note and Warrant Purchase Agreement dated as of July 28, 2022 (as amended, restated, supplemented, or otherwise modified from time to time, the “**Note Purchase Agreement**”) by and among Nivagen Pharmaceuticals, Inc., a Delaware corporation (“**Nivagen**”), and one or more additional direct or indirect Subsidiaries of Nivagen hereafter acquired or formed, which become party to the Note Purchase Agreement by executing an Addendum (Nivagen and such other Subsidiaries are sometimes individually referred to herein as an “**Issuer**” and collectively referred to herein as “**Issuers**” or “**Issuer**”), the Purchasers of the Notes named therein (the “**Purchasers**”) and Agent, Agent and the Purchasers agreed to make certain financial accommodations available to Issuers from time to time pursuant to the terms and conditions thereof; and

WHEREAS, Agent and the Purchasers are willing to make the financial accommodations to Issuers as provided for in the Note Purchase Agreement, but only upon the condition, among others, that Grantors shall have executed and delivered to Agent, for the benefit of the Purchasers, that certain Security Agreement, dated as of even date with the Note Purchase Agreement (including all annexes, exhibits or schedules thereto, as from time to time amended, restated, supplemented or otherwise modified, the “**Security Agreement**”); and

WHEREAS, pursuant to the Security Agreement, Grantors are required to execute and deliver to Agent, for the benefit of the Purchasers, this Patent Security Agreement;

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each Grantor hereby agrees as follows:

1. **DEFINED TERMS.** All initially capitalized terms used but not otherwise defined herein have the meanings given to them in the Security Agreement or, if not defined therein, in the Note Purchase Agreement.

2. **GRANT OF SECURITY INTEREST IN PATENT COLLATERAL.** Each Grantor hereby unconditionally grants, assigns, and pledges to Agent, for the benefit of the Purchasers, to secure the Secured Obligations, a continuing security interest (referred to in this Patent Security Agreement as the “**Security Interest**”) in all of such Grantor’s right, title and interest in and to the following, whether now owned or hereafter acquired or arising (collectively, the “**Patent Collateral**”):

(a) all of its Patents and Patent Intellectual Property Licenses to which it is a party including those referred to on Schedule I;

Patent Security Agreement

1

PATENT
REEL: 060657 FRAME: 0160

(b) all divisionals, continuations, continuations-in-part, reissues, reexaminations, or extensions of the foregoing; and

(c) all products and proceeds of the foregoing, including any claim by such Grantor against third parties for past, present or future infringement of any Patent or any Patent exclusively licensed under any Intellectual Property License, including the right to receive damages, or right to receive license fees, royalties, and other compensation under any Patent Intellectual Property License.

3. SECURITY FOR SECURED OBLIGATIONS. This Patent Security Agreement and the Security Interest created hereby secures the payment and performance of the Secured Obligations, whether now existing or arising hereafter. Without limiting the generality of the foregoing, this Patent Security Agreement secures the payment of all amounts which constitute part of the Secured Obligations and would be owed by Grantors, or any of them, to Agent, whether or not they are unenforceable or not allowable due to the existence of an Insolvency Proceeding involving any Grantor.

4. SECURITY AGREEMENT. The Security Interest granted pursuant to this Patent Security Agreement is granted in conjunction with the security interests granted to Agent pursuant to the Security Agreement. Each Grantor hereby acknowledges and affirms that the rights and remedies of Agent with respect to the Security Interest in the Patent Collateral made and granted hereby are more fully set forth in the Security Agreement, the terms and provisions of which are incorporated by reference herein as if fully set forth herein. To the extent there is any inconsistency between this Patent Security Agreement and the Security Agreement, the Security Agreement shall control.

5. AUTHORIZATION TO SUPPLEMENT. If any Grantor shall obtain rights to any new patent application or issued patent or become entitled to the benefit of any patent application or patent for any divisional, continuation, continuation-in-part, reissue, or reexamination of any existing patent or patent application, the provisions of this Patent Security Agreement shall automatically apply thereto. Grantors shall give notice in writing to Agent with respect to any such new patent rights in accordance with the terms of the Security Agreement. Without limiting Grantors' obligations under this Section, Grantors hereby authorize Agent unilaterally to modify this Patent Security Agreement by amending Schedule I to include any such new patent rights of each Grantor. Notwithstanding the foregoing, no failure to so modify this Patent Security Agreement or amend Schedule I shall in any way affect, invalidate or detract from Agent's continuing security interest in all Collateral, whether or not listed on Schedule I.

6. COUNTERPARTS. This Patent Security Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, shall be deemed to be an original, and all of which, when taken together, shall constitute but one and the same Patent Security Agreement. Delivery of an executed counterpart of this Patent Security Agreement by telefacsimile or other electronic method of transmission shall be equally as effective as delivery of an original executed counterpart of this Patent Security Agreement. Any party delivering an executed counterpart of this Patent Security Agreement by telefacsimile or other electronic method of transmission also shall deliver an original executed counterpart of this Patent Security Agreement but the failure to deliver an original executed counterpart shall not affect the validity, enforceability, and binding effect of this Patent Security Agreement.

[signature page follows]

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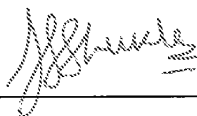
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IN WITNESS WHEREOF, the parties hereto have caused this Patent Security Agreement to be executed and delivered as of the day and year first above written.

GRANTOR:

NIVAGEN PHARMACEUTICALS, INC.

By: 

Name: Jay Shukla

Title: President and Chief Executive Officer

[Signature Page to Patent Security Agreement]

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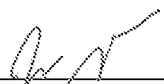
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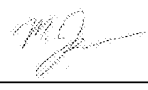
ACCEPTED AND ACKNOWLEDGED BY:

CORBEL CAPITAL PARTNERS SBIC, L.P.

By: Corbel Capital Advisors SBIC, LLC,
its General Partner

By: 
Name: Jeffrey B. Schwartz
Title: Managing Member

By: 
Name: Jeffrey S. Scrota
Title: Managing Member

By: 
Name: Michael H. Jones
Title: Managing Member

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SCHEDULE I
to
PATENT SECURITY AGREEMENT

Patents

Title of Invention	Filing/Patent No.	Filing/Issue Date	Owner of Record
Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions	17/499,001	Filed October 12, 2021	Nivagen Pharmaceuticals, Inc.
Pantoprazole Compositions and Methods	17/446,063	Filed August 26, 2021	Nivagen Pharmaceuticals, Inc.
Chlorthalidone Compositions And Methods	17/707,237	Filed May 26, 2021	Nivagen Pharmaceuticals, Inc.
Lyophilized Compositions of Phenobarbital Sodium Salt	17/025,881	Filed September 18, 2020	Nivagen Pharmaceuticals, Inc.
Calcium Gluconate Formulation Without Calcium Saccharate	17/871,058	Filed July 2022	Nivagen Pharmaceuticals, Inc.

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