

Provisional Application for Patent Cover Sheet

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c)

Inventor(s)

Inventor 1

[Remove](#)

Given Name	Middle Name	Family Name	City	State	Country i
Brijeshkumar	B.	Pandya	Sacramento	CA	US

Inventor 2

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Given Name	Middle Name	Family Name	City	State	Country i
Govind	R.	Jagadale	Sacramento	CA	US

Inventor 3

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Given Name	Middle Name	Family Name	City	State	Country i
Dasaradhi		Lakkaraju	Sacramento	CA	US

Inventor 4

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Given Name	Middle Name	Family Name	City	State	Country i
Bala	Tripura Sundari	Chodavarapu	Davis	CA	US

Inventor 5

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Given Name	Middle Name	Family Name	City	State	Country i
Anand		Shukla	Denver	CO	US

Inventor 6

[Remove](#)

Given Name	Middle Name	Family Name	City	State	Country i
Jwalant		Shukla	Sacramento	CA	US

All Inventors Must Be Listed – Additional Inventor Information blocks may be generated within this form by selecting the **Add** button.[Add](#)

Title of Invention	READY-TO-USE POTASSIUM PHOSPHATES IN SODIUM CHLORIDE SOLUTIONS
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Attorney Docket Number (if applicable)	104078.0005PRO
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Correspondence Address

Doc Code: **TR.PROV**

Document Description: Provisional Cover Sheet (SB16)

PTO/SB/16 (02-18)

Approved for use through 11/30/2020. OMB 0851-0032

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Direct all correspondence to (select one):

☒ The address corresponding to Customer Number

☐ Firm or Individual Name

Customer Number

149344

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

Yes, the invention was made by an agency of the United States Government. The U.S. Government agency name is:

Yes, the invention was under a contract with an agency of the United States Government. The name of the U.S. Government agency and Government contract number are:

Entity Status**Applicant asserts small entity status under 37 CFR 1.27 or applicant certifies micro entity status under 37 CFR 1.29**

- ☒ Applicant asserts small entity status under 37 CFR 1.27
- ☐ Applicant certifies micro entity status under 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
- ☐ No

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 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.

Signature

Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/Nicole Ballew Chang/		Date (YYYY-MM-DD)	2020-10-12
First Name	Nicole	Last Name	Ballew Chang	Registration Number (If appropriate)
				61611

This collection of information is required by 37 CFR 1.51. 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 8 hours 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. **This form can only be used when in conjunction with EFS-Web. If this form is mailed to the USPTO, it may cause delays in handling the provisional application.**

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.

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	104078.0005PRO
		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.)
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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		104078.0005PRO	
		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	104078.0005PRO
		Application Number	
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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	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	104078.0005PRO	Small Entity Status Claimed	☒
Application Type	Provisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	12	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	104078.0005PRO
		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		Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
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	104078.0005PRO
		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	104078.0005PRO
		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	104078.0005PRO
		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		
Address 2	Suite 100		
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.

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	104078.0005PRO
		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. ☐				
Prefix	Given Name	Middle Name	Family Name	Suffix
Mailing Address Information For Assignee including Non-Applicant Assignee:				
Address 1				
Address 2				
City		State/Province		
Country		Postal Code		
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:[Remove](#)

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	/Nicole Ballew Chang/		Date (YYYY-MM-DD)	2020-10-12
First Name	Nicole	Last Name	Ballew Chang	Registration Number
				61611
Additional Signature may be generated within this form by selecting the Add button. Add				

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	104078.0005PRO
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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

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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).
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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.
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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 100 mcg/L aluminum.

CLAIMS

What is claimed is:

1. A sterile ready-to-use (RTU) aqueous potassium phosphates in sodium chloride solution comprising potassium phosphates and sodium chloride, wherein the solution comprises 15 mmol/100 ml phosphorus (0.15 mmol/mL) and less than 100 mcg/L aluminum.
2. The solution of claim 1, wherein the sterile RTU aqueous potassium phosphates in sodium chloride solution is packaged in a flexible container.
3. The solution of claim 1 or claim 2, wherein the potassium phosphates comprise potassium dihydrogen phosphate and potassium hydrogen phosphate.
4. The solution of claim 3, wherein the potassium dihydrogen phosphate is at an amount of about 1120 mg/100 ml or 8.2 mmol/100 ml phosphorus and the potassium hydrogen phosphate is at an amount of about 1180 mg/100 ml or 6.8 mmol/100 ml phosphorus.
5. The solution of any preceding claim, wherein the sodium chloride is at an amount of about 900 mg/100 ml.
6. The solution of any preceding claim, wherein the RTU potassium phosphates in sodium chloride solution has undergone sterilization selected from terminal sterilization or filter sterilization.
7. The solution of any preceding claim, wherein the sterile RTU aqueous potassium phosphates in sodium chloride solution is packaged in a flexible container at a fixed volume.
8. The solution of claim 7, wherein the fixed volume is 100 ml.
9. The solution of claim 7 or claim 8, wherein the flexible container is stored in an aluminum pouch.

10. A ready-to-use (RTU) premixed pharmaceutical product stored in an autoclavable flexible container, wherein the pharmaceutical product comprises a potassium phosphates in sodium chloride solution having less than 100 mcg/L aluminum and comprising 15 mmol/100 ml Phosphorus.

11. The RTU pharmaceutical product of claim 10, wherein the potassium phosphates comprise potassium dihydrogen phosphate and potassium hydrogen phosphate.

12. The RTU pharmaceutical product of claim 11, wherein the potassium dihydrogen phosphate is at an amount of about 1120 mg/100 ml or 8.2 mmol/100 ml of phosphorus and the potassium hydrogen phosphate is at an amount of about 1180 mg/100 ml or 6.8 mmol/100 ml of phosphorus.

13. The RTU pharmaceutical product of any one of claims 10-12, wherein the potassium phosphates in sodium chloride solution comprises sodium chloride at an amount of about 900 mg/100 ml (15 mmol/100 ml).

14. A ready-to-use (RTU) premixed pharmaceutical product stored in an autoclavable flexible container, wherein the pharmaceutical product comprises potassium phosphates in sodium chloride solution having comprising 4.65 mg/mL of Phosphorus (0.15 mmol/mL), 8.50 mg/mL of Potassium (0.22 mEq/mL), 3.57 mg/mL of Sodium and 5.43 mg/mL of Chloride.

15. The RTU pharmaceutical product of any one of claims 10-14, wherein the RTU pharmaceutical product is at a fixed volume of 100 ml in the autoclavable flexible container.

16. The RTU pharmaceutical product of any one of claims 10-15, wherein the autoclavable flexible container is made of a PVC plastic or a non-PVC plastic.

17. The method of making an aqueous potassium phosphates in sodium chloride solution for phosphorous replacement therapy, the method comprising:

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.

18. The method of claim 17, further comprising filter sterilizing a fixed volume of the aqueous potassium phosphates in sodium chloride solution into a flexible container.

19. The method of claim 18, wherein the fixed volume is 100 ml.

20. The method of claim 19, wherein the flexible container comprising the fixed volume of the aqueous phosphates solution in sodium chloride is sterilized by terminal sterilization.

21. The method of claim 20, wherein the terminal sterilization comprises autoclaving the flexible container.

22. The method of claim 20 or claim 21 wherein the flexible container is stored in an aluminum pouch.

23. The method of any one of claims 17-22, wherein the flexible container is made of a flexible plastic polymer.

24. A method of administering phosphates to a patient in need of phosphorous replacement therapy, the method comprising:

administering a sterile ready-to-use (RTU) potassium phosphates in 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 phosphorous replacement,

wherein the sterile ready-to-use (RTU) potassium phosphates in sodium chloride solution comprises 15 mmol/100 ml Phosphorus and less than 100 mcg/L aluminum.

25. The method of claim 24, wherein the rate of infusion is selected from 6.8 mmol/hour or 15 mmol/hour.

26. The method of claim 24 or 25, wherein the potassium phosphates comprise potassium dihydrogen phosphate and potassium hydrogen phosphate.

27. The method of claim 26, wherein the potassium dihydrogen phosphate is at an amount of about 1120 mg/100 ml or 8.2 mmol/100 ml of phosphorus and the potassium hydrogen phosphate is at an amount of about 1180 mg/100 ml or 6.8 mmol/100 ml phosphorus.

28. The method of any of claims 24-27, wherein the potassium phosphates in sodium chloride solution comprises sodium chloride at an amount of about 900 mg/100 ml.

29. The method of any of claims 24-28, wherein the sterile RTU potassium phosphates in sodium chloride solution is administered to an adult or pediatric patient by peripheral venous catheter at 6.8 mmol/hour.

30. The method of claim 29, wherein the maximum daily 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.

31. The method of any of claims 24-28, wherein 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.

32. The method of claim 31, wherein the maximum daily 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 12 years of age and older.

READY-TO-USE POTASSIUM PHOSPHATES IN SODIUM CHLORIDE SOLUTIONS

Field of the Invention

[0001] The field of the invention is a potassium phosphates injection having decreased amounts of aluminum packaged at fixed volume and concentration in a ready-to-use container for effective administration to a patient.

Background

[0002] 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.

[0003] 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.

[0004] Hypophosphatemia is a clinical condition in which serum phosphate concentrations are less than 2.5 mg/dL (0.81 mmol/L). Causes include alcohol use disorder, burns, starvation, and diuretic use. Symptoms include muscle weakness, respiratory failure, heart failure, and seizures and coma can occur. The predominant treatment for hypophosphatemia is phosphorus replacement therapy with an intravenous (IV) infusion rate of phosphates corresponding to the patient's age and need. Phosphorus replacement therapy may be administered by a peripheral venous catheter or a central venous catheter according to the maximum recommended concentration and infusion rate. (Figs. 1A-1B)

[0005] 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 require aseptic compounding for the needed infusion rate thereby increasing the risk of error and contamination.

[0006] 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 takes time and additional oversight. Furthermore, separate preparations are required for each of the central venous and peripheral venous administrations.

[0007] Additional risks of the approved potassium phosphorus products also include aluminum toxicity especially in patients with renal impairment. While the levels of aluminum in the currently used products are below the maximum allowed level as determined by the Federal Drug Administration (FDA) (Fig. 2), the aluminum amounts are known to be toxic in impaired patients.

[0008] Furthermore, while there are a few reported potassium phosphate compositions having decreased concentrations of aluminum—e.g., US 10,632,150 and CN106265499—these compositions include varying amounts of potassium in the form of potassium dihydrogen phosphate and potassium hydrogen phosphate and do not provide a ratio of these critical components together with a tonicity agent in a solution for injection.

[0009] Thus, there is still a need for less toxic potassium phosphates in sodium chloride solution for phosphorous replacement therapy that can be prepared and administered more efficiently and effectively for any of the concentrations and infusion rates that may be needed for patients.

Summary of The Invention

[0010] The inventive subject matter provides compositions and methods of ready-to-use (RTU) potassium phosphate solutions for intravenous administration to patients in need of phosphorous replacement therapy.

[0011] More specifically, aspects and embodiments of the contemplated composition include a sterile ready-to-use (RTU) aqueous potassium phosphates in sodium chloride solution made of potassium phosphate and sodium chloride, wherein the solution comprises 15 mmol/100 ml Phosphorus and less than 100 mcg/L aluminum. The sterile RTU aqueous potassium phosphates

in sodium chloride solution may be packaged in a flexible container. Preferably, the potassium phosphates comprise potassium dihydrogen phosphate and potassium hydrogen phosphate. More preferably, the potassium dihydrogen phosphate is at an amount of about 1120 mg/100 ml (or 8.2 mmol/100 ml of phosphorus) and the potassium hydrogen phosphate is at an amount of about 1180 mg/100 ml (or 6.8 mmol/100 ml 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.

[0012] In exemplary embodiments, the RTU potassium phosphates in sodium chloride solution has undergone sterilization selected from terminal sterilization in the flexible container and/or filter sterilization into a sterile flexible container.

[0013] In further embodiments, the sterile RTU aqueous potassium phosphates in sodium chloride solution is packaged in a flexible container at a fixed volume. Preferably, the fixed volume is 100 ml of the aqueous potassium phosphates in sodium chloride solution.

[0014] The inventive subject matter includes a ready-to-use (RTU) premixed pharmaceutical product stored in an autoclavable flexible container, wherein the pharmaceutical product comprises a potassium phosphates in sodium chloride solution having less than 100 mcg/L aluminum and comprising 15 mmol/100 ml Phosphorus. The potassium phosphates in sodium chloride solution may be at a fixed volume of 100 ml in the autoclavable flexible container. The autoclavable flexible container may be made of a PVC plastic or a non-PVC plastic. The autoclavable flexible container with the potassium phosphates in sodium chloride solution therein may be stored in an aluminum pouch.

[0015] The contemplated subject matter also includes methods of making an aqueous potassium phosphates in sodium chloride solution for phosphorous replacement therapy, wherein the method includes 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 in sodium chloride. The method may also include filter sterilizing a fixed volume of the aqueous potassium phosphates in sodium chloride solution into a flexible container.

[0016] In additional embodiments, a ready-to-use (RTU) premixed pharmaceutical product is stored in an autoclavable flexible container, wherein the pharmaceutical product includes potassium phosphates in sodium chloride solution having 4.65 mg/mL of Phosphorus (0.15 mmol/mL), 8.50 mg/mL of Potassium (0.22 mEq/mL), 3.57 mg/mL of Sodium and 5.43 mg/mL of Chloride.

[0017] Advantageously, the inventive subject matter includes methods of administering phosphates to a patient in need of phosphorous replacement therapy, the method including administering a sterile ready-to-use (RTU) potassium phosphates in 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 phosphorous replacement, wherein the flexible container comprises a fixed volume of the sterile RTU potassium phosphates in sodium chloride solution includes 15 mmol/100 ml Phosphorus and less than 100 mcg/L aluminum. Typically, the fixed volume of the sterile RTU potassium phosphates in sodium chloride solution is 100 ml.

[0018] 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 maximum daily 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.

[0019] 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 maximum daily 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.

[0020] 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

[0021] Fig. 1A is a table of the maximum recommended concentration of potassium phosphates injection by age and route of administration (peripheral versus central).

[0022] Fig. 1B is a table of the maximum recommended infusion rate of potassium phosphates injection for adults and pediatric patients 12 years of age and older.

[0023] Fig. 2 is a table showing the aluminum content in admixture NDA based on the calculated limit per the NDA approved product after admixture dilution.

[0024] Fig. 3 is a flow chart of the contemplated method of preparing potassium phosphates in sodium chloride injection, according to exemplary embodiments of the present invention.

[0025] Figs. 4A to 4E are chromatograms from an anion assay using ion chromatography (IC) to assay the phosphorus and chloride anions in the Blank, Standard, and Sample Solutions as indicated and disclosed herein.

[0026] Figs. 5A to 5D are chromatograms from a cation assay using ion chromatography (IC) to assay the potassium and sodium cations in the Blank, Standard, and Sample Solutions as indicated and disclosed herein.

Detailed Description

[0027] Advantageously, the inventors have contemplated a ready-to-use (RTU) potassium phosphates in sodium chloride solution having a concentration of 15 mmol/100 ml Phosphorus and less than 100 micrograms/liter (mcg/L or $\mu\text{g/L}$) aluminum. As contemplated herein, the RTU potassium phosphates in sodium chloride solution at 15 mmol/100 ml concentration is provided in a fixed volume (e.g., 100 ml) in a flexible container (e.g., a plastic intravenous (IV)

bag) for efficient administration to both adult and pediatric patients in need of phosphorus replacement therapy. Different rates of infusion from using the RTU potassium phosphates in sodium chloride solution may be programmed using the 15 mmol/100 ml phosphates solution for peripheral venous administration or central venous administration. Most advantageously, the rates of infusion may also be programmed in order to effectively and safely administer lower doses of the potassium phosphates in sodium chloride solution to pediatric and adult patients.

[0028] 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 has less than 100 mcg/L aluminum. Typically, the potassium phosphates in sodium chloride solution has 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 typically, the potassium phosphates in sodium chloride solution has not 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 aluminum. Most typically, the contemplated potassium phosphates in sodium chloride solution has less than 50 mcg/L aluminum.

[0029] As used herein the term “ready-to-use (RTU) potassium phosphates in sodium chloride solution,” ready-to-use (RTU) solution” and “premixed pharmaceutical product” are used interchangeably to refer to the aqueous solution of potassium phosphates in sodium chloride that does not require further dilution or admixtures prior to administration to a patient.

[0030] In exemplary embodiments, the RTU potassium phosphates in sodium chloride solution includes potassium dihydrogen phosphate and potassium hydrogen phosphate. 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 (15 mmol/100 ml).

[0031] The inventive subject matter includes a ready-to-use (RTU) premixed pharmaceutical product stored in an autoclavable flexible container, wherein the pharmaceutical product comprises a potassium phosphates in sodium chloride solution having less than 100 mcg/L aluminum and comprising 15 mmol/100 ml Phosphorus. The potassium phosphates in sodium chloride solution may be at a fixed volume of 100 ml in the autoclavable flexible container. The autoclavable flexible container may be made of a PVC plastic or a non-PVC plastic. The autoclavable flexible container with the potassium phosphates in sodium chloride solution therein may be stored in an aluminum pouch.

[0032] The inventors advantageously contemplated the specific components for preparing the disclosed aqueous potassium phosphates in sodium chloride solution. In particular, with reference to Tables 3, 4, and 5, the contemplated methods of making an aqueous potassium phosphates in sodium chloride solution for phosphorous 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 2 part per million (ppm) or approximately 0.7 mmol/100 ml aluminum. Accordingly, in contrast to the currently available products, the aluminum is reduced from the starting materials thereby avoiding any further compounding of the aluminum levels and decreasing the levels of aluminum in the disclosed potassium phosphates in sodium chloride solution at 15 mmol/100ml.

[0033] With reference to Fig. 3 and Tables 1 and 2, exemplary methods of making an aqueous potassium phosphates in sodium chloride solution for phosphorous replacement therapy, include 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.

[0034] In additional 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 autoclave sterilization. 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.

[0035] Notably, the inventive RTU aqueous potassium phosphates in sodium chloride solution may be efficiently administered to a patient in need of phosphorous 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 phosphorous 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.

[0036] 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 maximum daily 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.

[0037] 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 maximum daily 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.

[0038] In additional embodiments, a flexible container is modified ports and a closure system suitable for storing a premixed solution of potassium phosphates in sodium chloride solution for injection as disclosed herein. The potassium phosphates in sodium chloride solution in the flexible container may be sterilized by steam sterilization (autoclaving, 121°C for about 15 minutes) without altering the thermal properties of the film layers, ports and closure system as well as maintaining the integrity of the flexible container. The primary polymeric materials in the flexible container may 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, AN-copolymer etc. 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 modified 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.

[0039] Within these embodiments, it is preferred that the autoclaving temperature range 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, or 120°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. Exemplary ranges for the autoclaving temperature include from 110 to 130°C, or from 115 to 125°C.

[0040] 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.

EXAMPLES

[0041] Formulation of ingredients for potassium phosphates in sodium chloride injection 15 mmol/100 ml solution. As set forth in Table 1 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 having a IIG limit of 0.9% weight/volume (w/v). Accordingly, for a 100 ml solution, 900 mg of NaCl is added.

[0042] **Table 1.** Formulation of 15 mmol/100 ml potassium phosphates in sodium chloride injection solution.

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

[0043] **Table 2.** Batch formulation of 15 mmol/100 ml potassium phosphates injection solution in 1 liter (1000 ml).

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 3. Specification of Monobasic Potassium Phosphate API

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

[0044] Table 4. Specification of Dibasic Potassium Phosphate API

Sr. No.	Test	Specification	Reference
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

[0045] Table 5. Specification of Sodium Chloride

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

[0046] Table 6. Specification of Potassium Phosphates in Sodium Chloride Injection, RTU

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 100 µg/L	Not more than 100 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>

[0047] Table 7. Ion Chromatography (IC) Analysis of Potassium Phosphates in Sodium Chloride Injection

Sample Details	Description	pH of solution	Conductivity (mS/cm)	LPC		Assay of Anions		Assay of Cations	
				10 µm	25 µm	% Phosphorus	% Chloride	% Potassium	% Sodium
NPO23012 Initial Autoclave 121°C for 15 min, Technoflex 17 PP Bag	A Clear colorless solution, free from visible foreign particles.	6.543	576	237	58	101.8	102.8	102.1	99.8
NPO23012 Initial Autoclave 121°C for 15 min, Technoflex 17 PP Bag		6.553	589	533	13	101.8	101.8	102.8	99.7
NPO23012 Initial Autoclave 121°C for 15 min, Certeis 17 PP Bag		6.548	579	187	8	100.8	101.9	101.8	99.4
NPO23012 Initial Autoclave 121°C for 15 min, Technoflex 17 PP Bag		6.548	579	287	27	101.8	102.8	102.1	100.1
NPO23012 Initial Autoclave 121°C for 15 min, Biontech 17 PP Bag		6.555	572	153	13	101.8	100.6	102.4	100.2
NPO23012 Initial Autoclave 121°C for 15 min, Technoflex 17 PP Bag		6.558	573	133	13	101.9	100.1	102.3	100.1

Materials and Methods.

[0048] Assay of Anions. With reference to Table 7 and the chromatograms of Figs. 4A-4E, ion chromatography was used to assay anions in the prepared solutions. Instruments and Apparatus for assaying anions include ion chromatography (IC) with conductivity detector, an analytical balance, sonicator, plastic volumetric flasks (Class-A), plastic beakers, pipettes (polyethylene). Reagents, solvents, and standards for assaying anions include deionized water (WFI), phosphorous IC standard, and chloride IC standard. Mobile phase solutions were prepared as follows: 4.5 mM sodium carbonate and 1.4 mM sodium bicarbonate solution; 20 to 30 mM KOH Solution or NaOH Solution. The mobile phase bottle was tightly capped with para-film and aluminum foil to avoid evaporation or exposure. The diluent is deionized water (WFI).

[0049] The chromatographic conditions for assaying anions are provided in Table 8 below. The liquid chromatography apparatus was equipped with a conductivity detector, an injector, and a data processor.

[0050] Table 8. Chromatographic Conditions: Anion Assay

Parameters	Conditions
Column	: 1. IonPac AG22 (4 ×50 mm) + AS22 (4 × 250 mm) 2. IonPac AG18 (2 ×50 mm) + AS18 (2 × 250 mm)
Flow rate	: 0.35 mL/min to 1.5 mL /min.
Detection Wavelength	: Suppressed conductivity
Injection volume	: 5 µL to 25 µL
Run time	: 20 Minutes
Cell Temperature	: 30°C to 40°C
Sample Cooler Temperature	: 25°C
Suppressor	: 1. AERS 500e 4 mm (constant voltage & recycle mode) 2. ADRS 600 2 mm (constant voltage & recycle mode)

[0051] The Blank was deionized water (WFI) (Fig. 4A).

[0052] The Standard Solution (Figs. 4B-4C) was prepared as follows: 1. 0.00140 mg/mL to 0.0698 mg/mL of Phosphorus Standard Solution. 2. 0.0163 mg/mL to 0.0815 mg/mL of Chloride Standard Solution.

[0053] The Sample Solution (Figs. 4D-4E) was prepared as follows: 1. 0.00233 mg/mL to 0.0698 of Phosphorus in Sample Solution. 2. 0.0272 mg/mL to 0.0815 mg/mL of Chloride in Sample Solution.

[0054] Both the Standard and Sample solutions are stable when stored at 25 °C for 7 days.

[0055] The Injection Sequence for the anion assay is set forth in Table 9 below.

[0056] Table 9. Injection Sequence

Sr. No.	Solution Name	:	Number of Injection
1.	Blank	:	1
2.	Standard solution	:	5
3.	Test solution	:	12
4.	Bracketing standard solution	:	1

[0057] The system suitability requirements include: 1. The relative standard deviation of Phosphorus peak for five replicate injections in standard solution should not be more than 5.0%. 2. The relative standard deviation of Chloride peak for five replicate injections in standard solution should not be more than 5.0%. 3. Tailing factor for the Phosphorus and Chloride is not more than 2.0. 4. USP Plate count for the Phosphorus and Chloride is not less than 2500. The

IC column should be washed properly with the mobile phase solution after the completion of the sample sequence.

[0058] Assay of Cations. With reference to Table 7 and the chromatograms of Figs. 5A-5D, ion chromatography was used to assay cations in the prepared solutions. Instruments and Apparatus for assaying anions include ion chromatography (IC) with conductivity detector, an analytical balance, sonicator, plastic volumetric flasks (Class-A), plastic beakers, pipettes (polyethylene). Reagents, solvents, and standards for assaying cations include deionized water (WFI), potassium IC standard, and sodium IC standard. Mobile phase solutions were prepared as follows: 16 to 20 mM methane sulfonic acid (MSA) solution. The mobile phase bottle was tightly capped with para-film and aluminum foil to avoid evaporation or exposure. The diluent is deionized water (WFI).

[0059] The chromatographic conditions for assaying anions are provided in Table 10 below. The liquid chromatography apparatus was equipped with a conductivity detector, an injector, and a data processor.

[0060] Table 10. Chromatographic Conditions: Cation Assay

Parameters	Conditions
Column	: 1. IonPac CG12A (4 ×50 mm) + CS12A (4 × 250 mm) 2. IonPac CG12A (2 ×50 mm) + CS12A (2 × 250 mm)
Flow rate	: 0.35 mL/min to 1.0 mL /min.
Detection Wavelength	: Suppressed conductivity
Injection volume	: 5 µL to 25 µL
Run time	: 15 Minutes
Cell Temperature	: 30°C to 40°C
Sample Cooler Temperature	: 25°C
Suppressor	: 1. CERS 500e 4 mm (constant voltage & recycle mode) 2. ADRS 600 2 mm (constant voltage & recycle mode)

[0001] The Blank was deionized water (WFI) (Fig. 5A).

[0002] The Standard Solution (Fig. 5B) was prepared as follows: 1. 0.00255 mg/mL to 0.1275 mg/mL of Potassium Standard Solution. 2. 0.0107 mg/mL to 0.0536 mg/mL of Sodium Standard Solution.

[0003] The Sample Solution (Figs. 5C-5D) was prepared as follows: 1. 0.00425 mg/mL to 0.1275 mg/mL of Potassium in Sample Solution. 2. 0.0179 mg/mL to 0.0536 mg/mL of Sodium in Sample Solution.

[0004] Both the Standard and Sample solutions are stable when stored at 25 °C for 7 days.

[0005] The Injection Sequence for the anion assay is set forth in Table 11 below.

[0006] Table 11. Injection Sequence

Sr. No.	Solution Name	:	Number of Injection
1.	Blank	:	1
2.	Standard solution	:	5
3.	Test solution	:	12
4.	Bracketing standard solution	:	1

[0007] The system suitability requirements include: 1. The relative standard deviation of Potassium peak for five replicate injections in standard solution should not be more than 5.0%. 2. The relative standard deviation of Sodium peak for five replicate injections in standard solution should not be more than 5.0%. 3. Tailing factor for the Potassium and Sodium is not more than 2.0. 4. USP Plate count for the Potassium and Sodium is not less than 2500. The IC column should be washed properly with the mobile phase solution after the completion of the sample sequence.

[0008] As 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.

[0009] 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. In some embodiments, the

numerical parameters should be construed in light of the number of reported significant digits and by applying ordinary rounding techniques. Notwithstanding that the numerical ranges and parameters setting forth the broad scope of some embodiments of the invention are approximations, the numerical values set forth in the specific examples are reported as precisely as practicable. The numerical values presented in some embodiments of the invention may contain certain errors necessarily resulting from the standard deviation found in their respective testing measurements.

[0010] Unless the context dictates the contrary, all ranges set forth herein should be interpreted as being inclusive of their endpoints and open-ended ranges should be interpreted to include only commercially practical values. Similarly, all lists of values should be considered as inclusive of intermediate values unless the context indicates the contrary.

[0011] 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.

[0012] 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 with a range is incorporated into the specification as if it were individually recited herein. 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.

[0013] Groupings of alternative elements or embodiments of the invention disclosed herein are not to be construed as limitations. Each group member can be referred to and claimed individually or in any combination with other members of the group or other elements found herein. One or more members of a group can be included in, or deleted from, a group for reasons

of convenience and/or patentability. When any such inclusion or deletion occurs, the specification is herein deemed to contain the group as modified thus fulfilling the written description of all Markush groups used in the appended claims.

[0014] 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 spirit 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.

Fig. 1A

Maximum Recommended Daily Concentration of Potassium Phosphates Injection By Age and Route of Administration (Peripheral vs. Central)

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)

Fig. 1B

Maximum Recommended Infusion Rate of Potassium Phosphates Injection For Adults and Pediatric Patients 12 Years of Age and Older

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)

Fig. 2

Route	Conc.	Aluminum Content in Admixture NDA *As per NDA Approved Product
Peripheral	6.8 mmol/100 mL	45 mcg/L
	6.8 mmol/Hour	
Central	18 mmol/100 mL	120 mcg/L
	15 mmol/Hour	100 mcg/L

Fig. 3

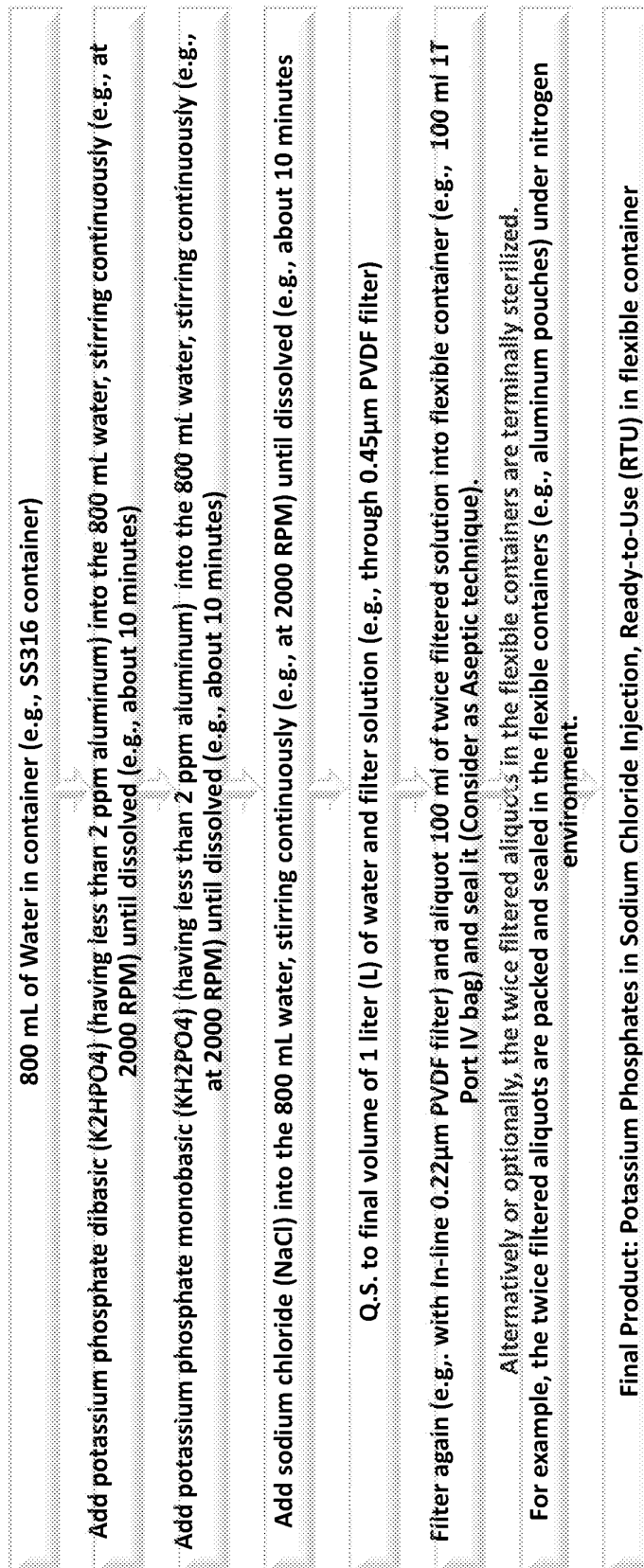


Fig. 4A

Phosphorus Chloride

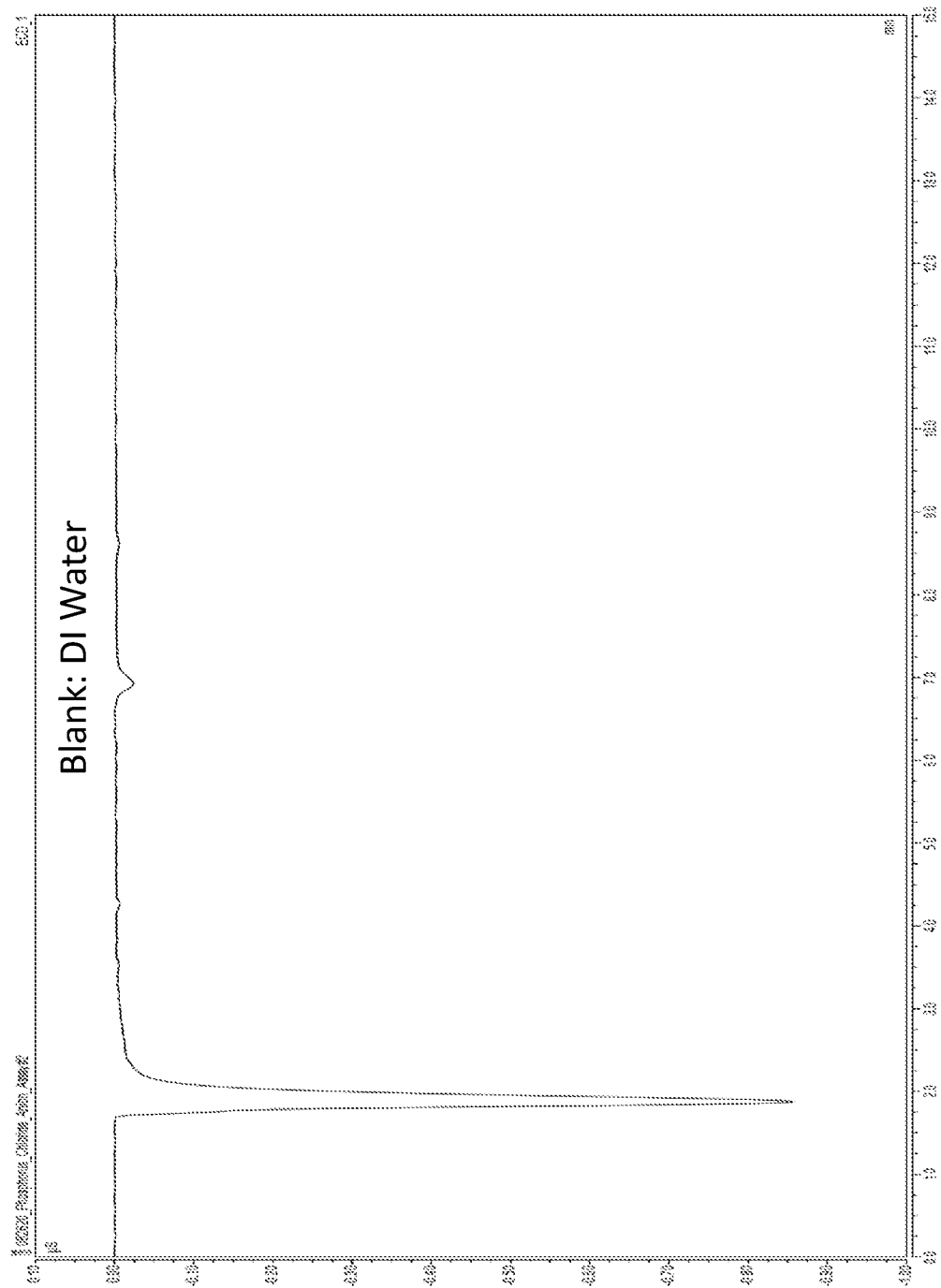


Fig. 4B

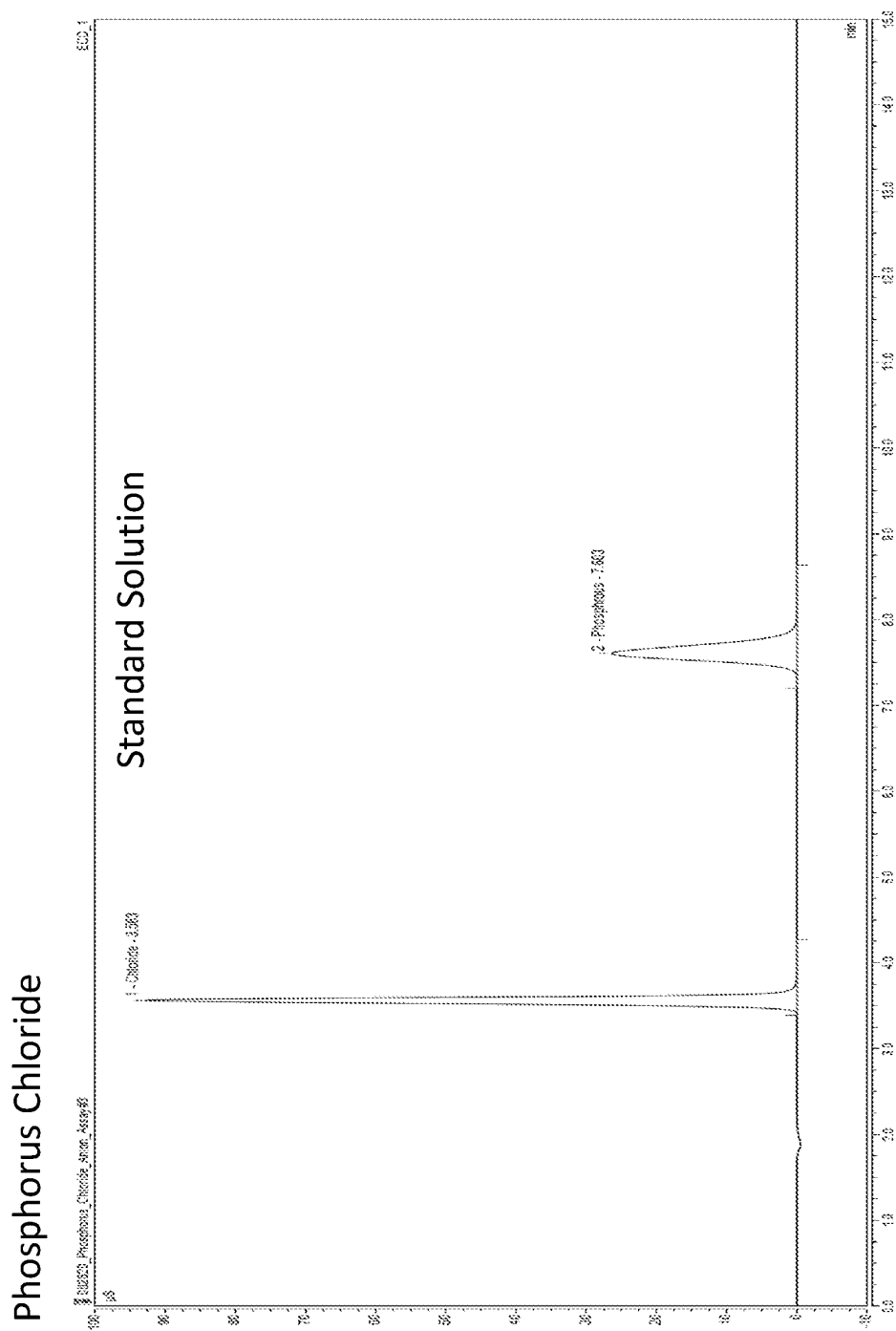


Fig. 4C

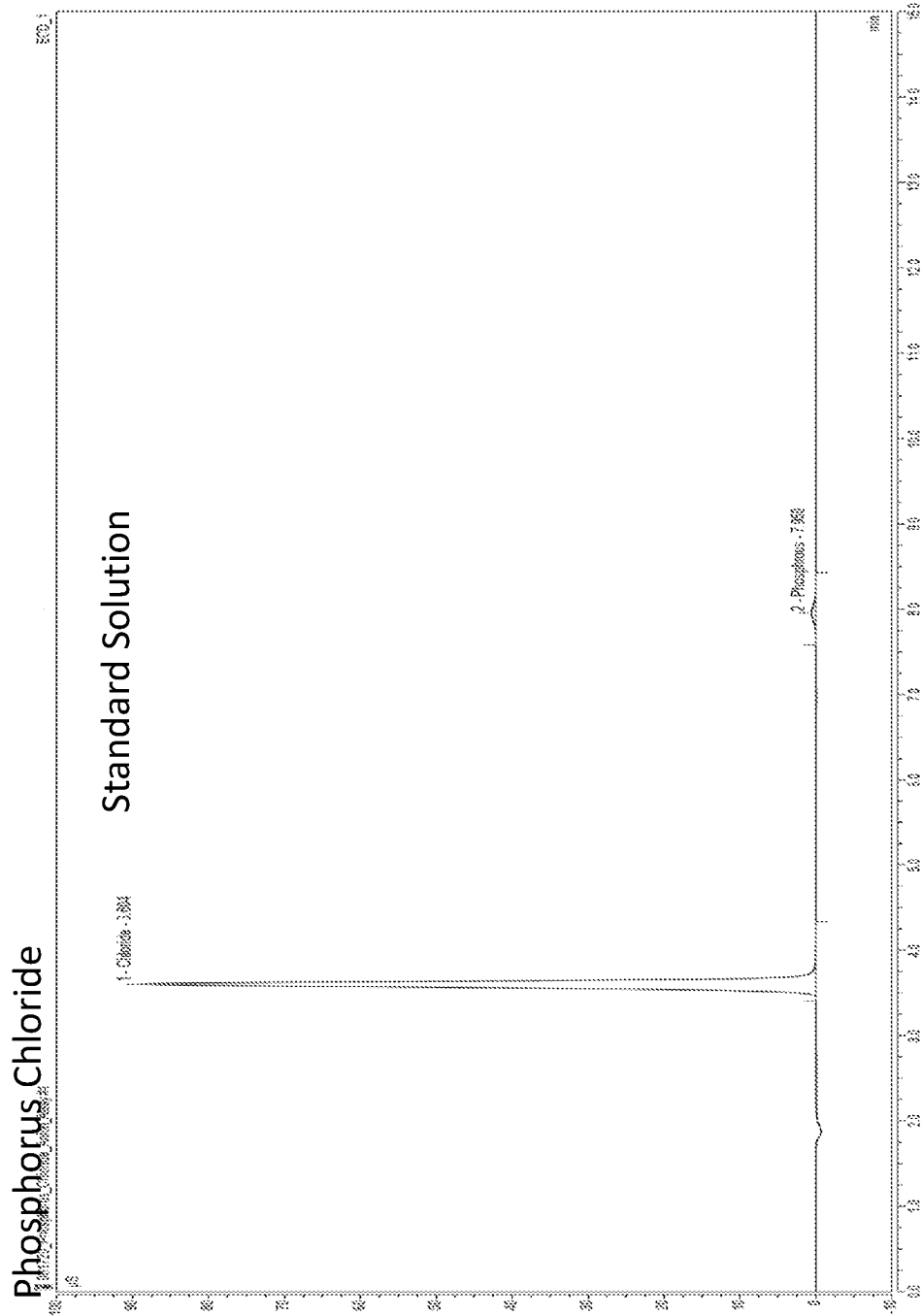


Fig. 4D

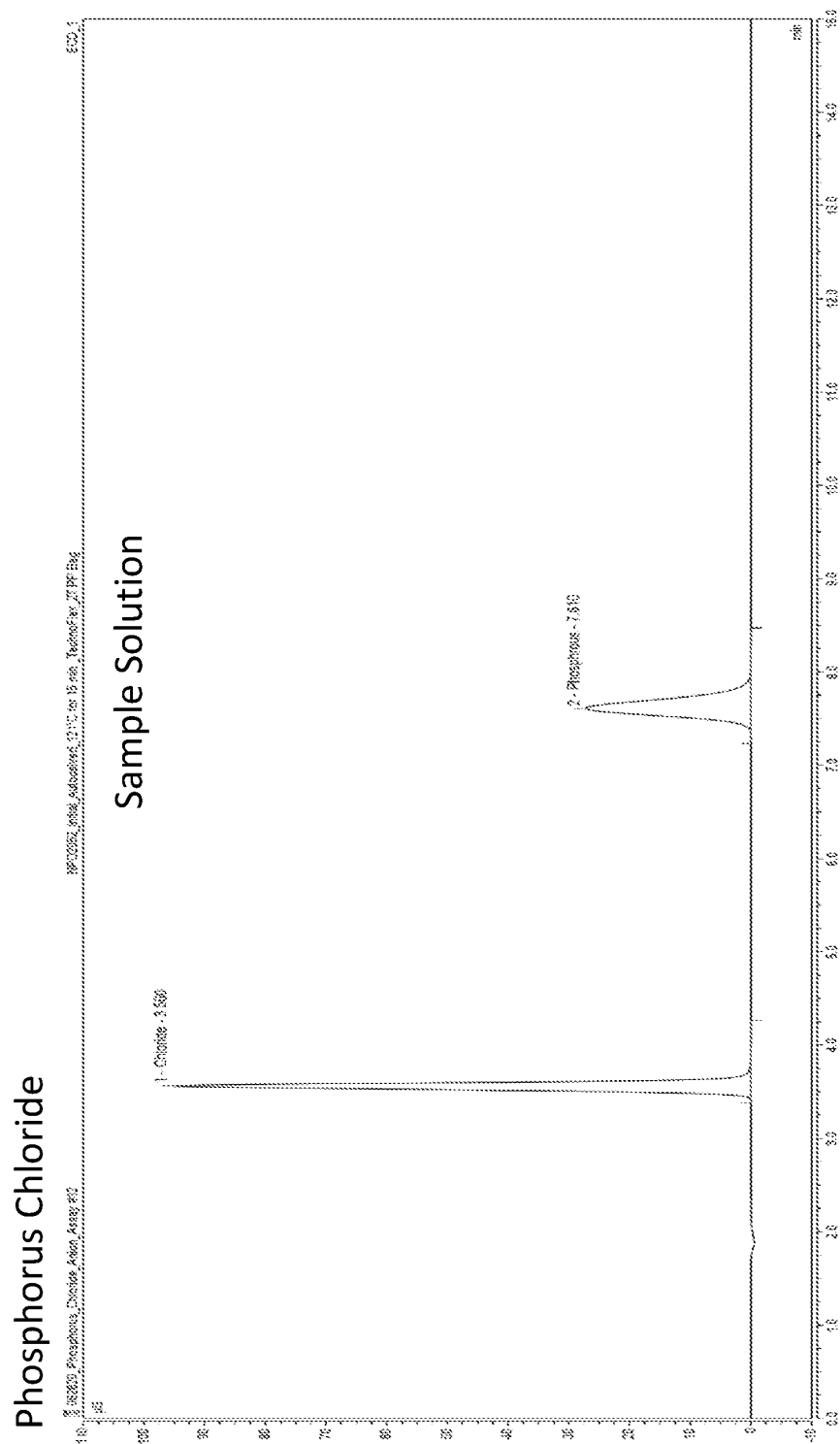


Fig. 4E

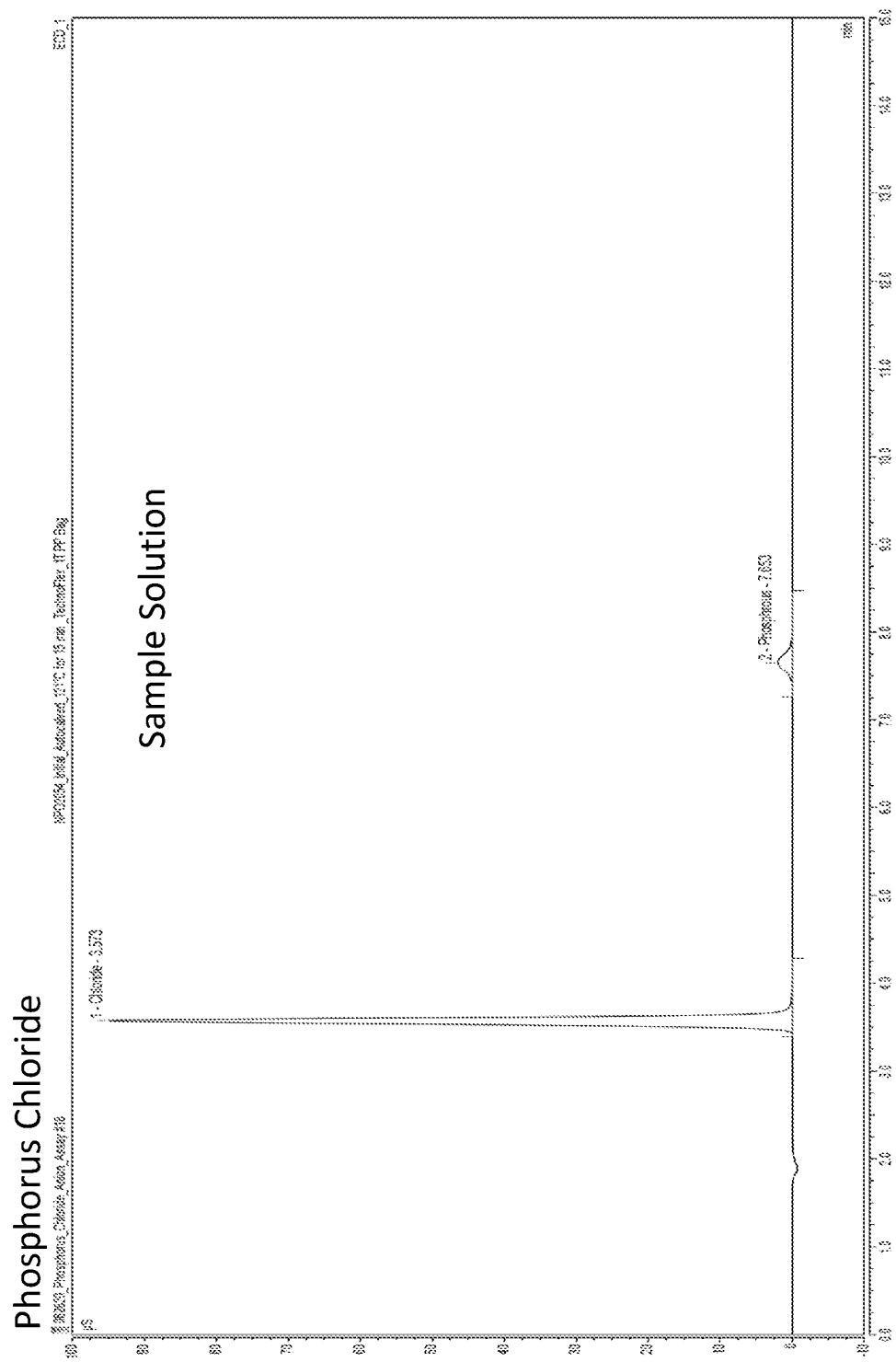
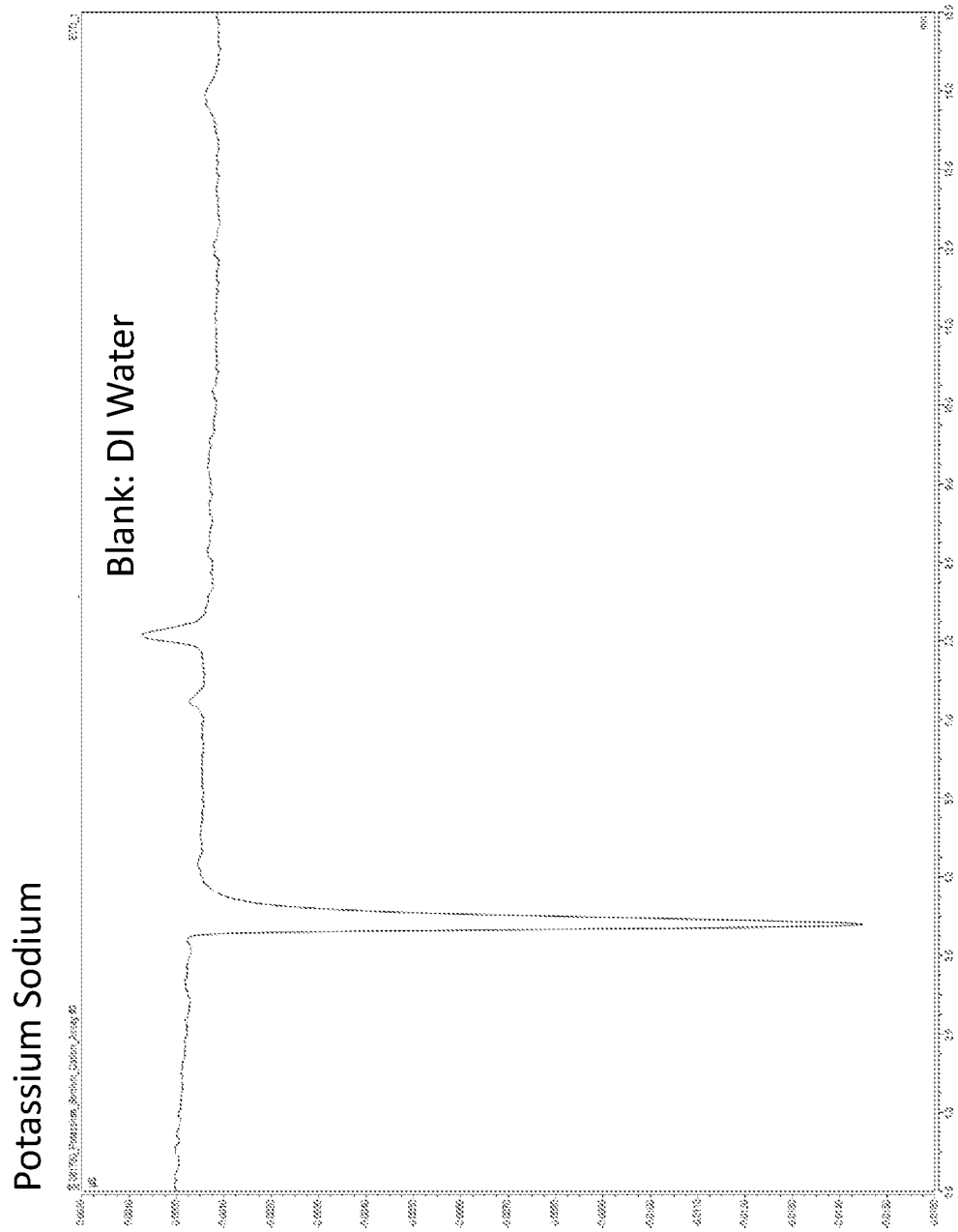


Fig. 5A



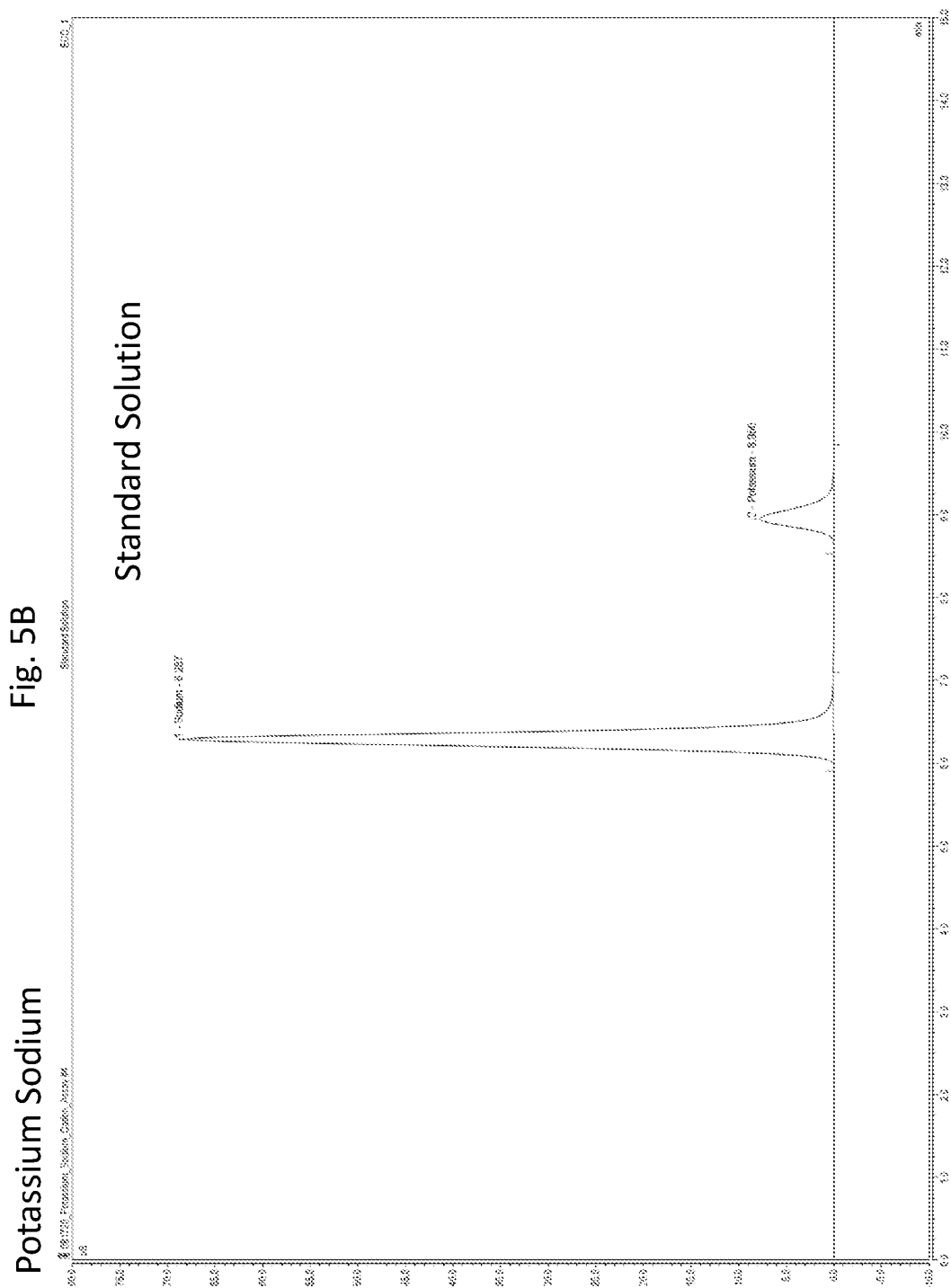


Fig. 5C

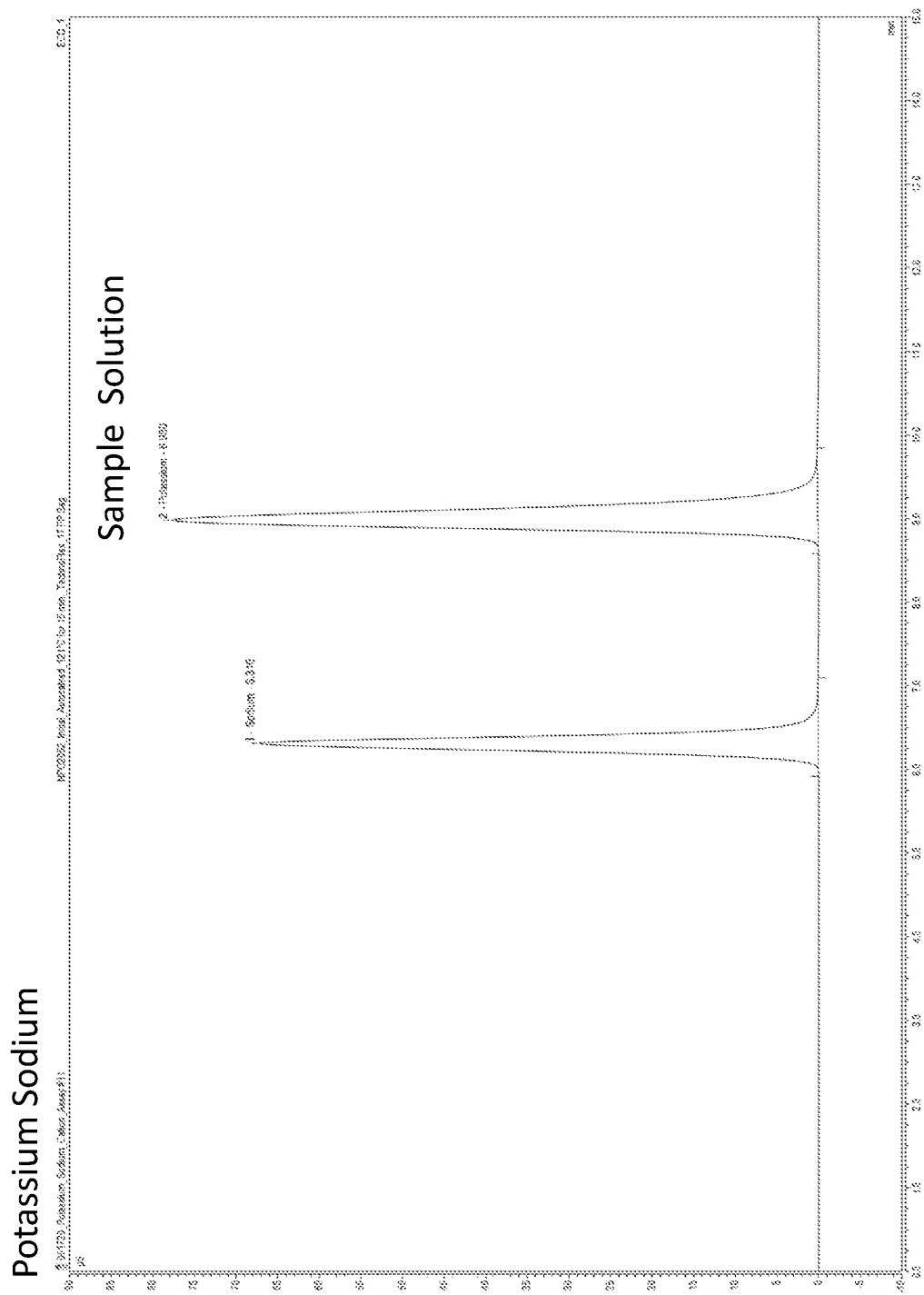
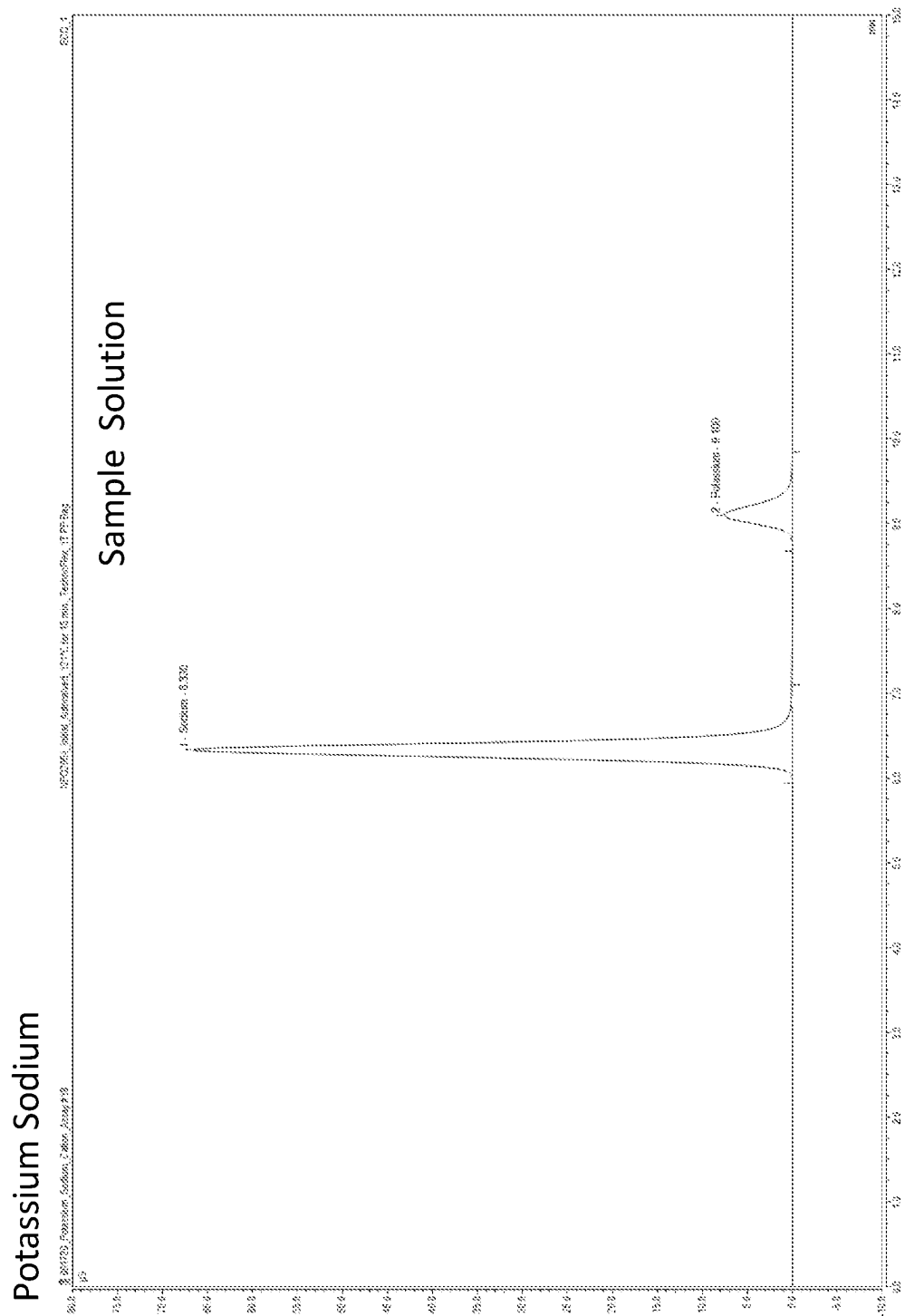


Fig. 5D



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:		Nicole Ballew Chang/Danielle Moroz		
Attorney Docket Number:		104078.0005PRO		
Filed as Small Entity				
Filing Fees for Provisional				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
PROVISIONAL APPLICATION FILING FEE	2005	1	150	150
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				150

Electronic Acknowledgement Receipt	
EFS ID:	40819996
Application Number:	63090518
International Application Number:	
Confirmation Number:	4961
Title of Invention:	Ready-To-Use Potassium Phosphates In Sodium Chloride Solutions
First Named Inventor/Applicant Name:	Brijeshkumar B. Pandya
Customer Number:	149344
Filer:	Nicole Ballew Chang/Danielle Moroz
Filer Authorized By:	Nicole Ballew Chang
Attorney Docket Number:	104078.0005PRO
Receipt Date:	12-OCT-2020
Filing Date:	
Time Stamp:	16:49:23
Application Type:	Provisional

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 150
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File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Provisional Cover Sheet (SB16)	ProvisionalSB.pdf	2032478	no	4
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Warnings:					
Information:					
2	Application Data Sheet	ADS.pdf	1874159	no	10
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3		2020_10_12_FINALPROVAPPLN_104078_0005PRO.pdf	1140312	yes	29
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	Multipart Description/PDF files in .zip description				
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	Abstract		29	29	
	Claims		24	28	
	Specification		1	23	
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4	Drawings-only black and white line drawings	2020_10_12_FINALDRAWINGS_104078_0005PRO.pdf	1358495	no	12
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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
63/090,518	10/12/2020		150	104078.0005PRO		

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

CONFIRMATION NO. 4961
FILING RECEIPT



CC000000120982689

Date Mailed: 10/29/2020

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Power of Attorney:

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page 1 of 3

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

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: No

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