

<u>Claims of 8,895,546</u>	<u>Claims of 9,763,876 Found Unpatentable in IPR 2019-00451</u>
1. A pharmaceutical solution for nasal administration consisting of: (a) a benzodiazepine drug; (b) one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, in an amount from about 30% to about 95% (w/w); (c) ethanol and benzyl alcohol in a combined amount from about 10% to about 70% (w/w); and (d) an alkyl glycoside.	1. A method of treating a patient with a disorder which is treatable with a benzodiazepine drug, comprising: administering to one or more nasal mucosal membranes of a patient a pharmaceutical solution for nasal administration consisting of a benzodiazepine drug, one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, in an amount from about 30% to about 95% (w/w); ethanol and benzyl alcohol in a combined amount from about 10% to about 70% (w/w); and an alkyl glycoside.
2. The pharmaceutical solution of claim 1, wherein the benzodiazepine drug is selected from the group consisting of: alprazolam, brotizolam, chlordiazepoxide, clobazam, clonazepam, clorazepam, demoxazepam, diazepam, flumazenil, flurazepam, halazepam, midazolam, nordazepam, medazepam, nitrazepam, oxazepam, lorazepam, prazepam, quazepam, triazolam, temazepam, loprazolam, any pharmaceutically-acceptable salts thereof, and any combinations thereof.	3. The method of claim 1, wherein the benzodiazepine drug is selected from the group consisting of: alprazolam, brotizolam, chlordiazepoxide, clobazam, clonazepam, clorazepam, demoxazepam, diazepam, flumazenil, flurazepam, halazepam, midazolam, nordazepam, medazepam, nitrazepam, oxazepam, lorazepam, prazepam, quazepam, triazolam, temazepam, loprazolam, or any pharmaceutically-acceptable salts thereof, and any combinations thereof.

3. The pharmaceutical solution of claim 2, wherein the benzodiazepine drug is diazepam, or a pharmaceutically-acceptable salt thereof.	4. The method of claim 3, wherein the benzodiazepine drug is diazepam, or a pharmaceutically-acceptable salt thereof.
4. The pharmaceutical solution of claim 1, wherein said benzodiazepine is present in the pharmaceutical solution in a concentration from about 1 to about 20% (w/v).	5. The method of claim 1, wherein the solution contains about 1 to about 20% (w/v) of benzodiazepine.
5. The pharmaceutical solution of claim 4, wherein said benzodiazepine is diazepam.	6. The method of claim 5, wherein the solution contains about 1 to about 20% (w/v) of diazepam.
6. The pharmaceutical solution of claim 1, wherein the one or more natural or synthetic tocopherols or tocotrienols are selected from the group consisting of: α -tocopherol, β -tocopherol, γ -tocopherol, δ -tocopherol, α -tocotrienol, β -tocotrienol, γ -tocotrienol, δ -tocotrienol, tocophersolan, any isomers thereof, any esters thereof, any analogs or derivatives thereof, and any combinations thereof.	7. The method of claim 1, wherein the one or more natural or synthetic tocopherols or tocotrienols are selected from the group consisting of: α -tocopherol, β -tocopherol, γ -tocopherol, δ -tocopherol, α -tocotrienol, β -tocotrienol, γ -tocotrienol, δ -tocotrienol, tocophersolan, any isomers thereof, any esters thereof, any analogs or derivatives thereof, and any combinations thereof.
7. The pharmaceutical solution of claim 1, wherein the ethanol is present in the pharmaceutical solution in a concentration of from 1 to 25% (w/v) and the benzyl alcohol is present in the pharmaceutical solution in a concentration from 1 to 25% (w/v).	8. The method of claim 1, wherein the solution contains ethanol from 1 to 25% (w/v) and benzyl alcohol from 1 to 25% (w/v).
8. The pharmaceutical solution of claim 1, wherein the ethanol is present in the	15. The method of claim 1, wherein the solution comprises ethanol from 10 to 22.5% (w/v) and

solution in a concentration of from 10 to 22.5% (w/v) and the benzyl alcohol is present in the solution in a concentration of from 7.5 to 12.5% (w/v).	benzyl alcohol from 7.5 to 12.5% (w/v).
9. The pharmaceutical solution of claim 8, wherein the benzodiazepine is present in the pharmaceutical solution in a concentration from about 20 mg/mL to about 200 mg/mL.	10. The method of claim 9, wherein the benzodiazepine drug is present in the pharmaceutical solution in a concentration of from about 20 mg/mL to about 50 mg/mL. *Claim language is not identical, however, a finding that the more narrow benzodiazepine drug concentration of from about 20 mg/mL to about 50 mg/ml would also render obvious the broader benzodiazepine concentration of from about 20 mg/ml to about 200 mg/ml
10. The pharmaceutical solution of claim 1, wherein the one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, is in an amount from about 45% to about 85% (w/w).	11. The method of claim 1, wherein the one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, is in an amount from about 45% to about 85% (w/w).
11. The pharmaceutical solution of claim 10, wherein the one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, is in an amount from about 50% to about 75% (w/w).	12. The method claim 11, wherein the one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, is in an amount from about 60% to about 75% (w/w). *Claim language is not identical, however, a finding that the more narrow concentration range of from about 60% to about 75% (w/w) would also render

	obvious the broader concentration range of from about 50% to about 75% (w/w)
12. The pharmaceutical solution of claim 1, wherein the ethanol and benzyl alcohol are present in the pharmaceutical solution in a combined amount from about 15% to about 55% (w/w).	13. The method of claim 1, wherein the ethanol and benzyl alcohol is in a combined amount from about 15% to about 55% (w/w).
13. The pharmaceutical solution of claim 12, wherein the ethanol and benzyl alcohol are present in the pharmaceutical solution in a combined amount from about 25% to about 40% (w/w).	14. The method of claim 13, wherein the ethanol and benzyl alcohol is in a combined amount from about 25% to about 40% (w/w).
14. The pharmaceutical solution of claim 1, consisting of 5-15% (w/v) diazepam, 0.01-1% (w/v) alkyl glycoside, 45-65% (w/v) vitamin E, 10-25% (w/v) ethanol and 5-15% (w/v) benzyl alcohol.	30. The method of claim 1, wherein the solution consists of diazepam from 5 to 15% (w/v), dodecyl maltoside from about 0.01 to 1% (w/v), vitamin E from 45 to 65% (w/v), ethanol from 10 to 25% (w/v) and benzyl alcohol from 5 to 15% (w/v). *Claim language is not identical, however, a finding that the more narrow dodecyl maltoside species compound is rendered obvious would also render obvious the "alkyl glycoside" genus
15. The pharmaceutical solution of claim 1, wherein the alkyl glycoside is present in pharmaceutical solution in	24. The method of claim 1, wherein the solution contains at least about 0.01% (w/w) of an alkyl glycoside.

a concentration of at least about 0.01% (w/w).	
16. The pharmaceutical solution of claim 15, wherein the alkyl glycoside is present in the pharmaceutical solution in an amount of 0.01% to 1% (w/w).	25. The method of claim 24, wherein the solution contains about 0.01% to 1% (w/w) of an alkyl glycoside.
17. The solution of claim 1, consisting of diazepam, vitamin E, ethanol, benzyl alcohol and dodecyl maltoside.	27. The method of claim 1, wherein the solution consists of diazepam, vitamin E, ethanol, benzyl alcohol and dodecyl maltoside.
18. The solution of claim 17, consisting of about 56.47% (w/v) vitamin E, about 10.5% (w/v) benzyl alcohol, about 10% (w/v) diazepam, about 0.25% (w/v) dodecyl maltoside, q.s. dehydrated ethanol.	28. The method of claim 1, wherein the solution consists of about 56.47% (w/v) vitamin E, about 10.5% (w/v) benzyl alcohol, about 10% (w/v) diazepam, about 0.25% (w/v) dodecyl maltoside, q.s. dehydrated ethanol.
19. The pharmaceutical solution of claim 14, consisting of 5-15% (w/v) diazepam, 0.01-1% (w/v) dodecyl maltoside, 45-65% (w/v) vitamin E, 10-25% (w/v) ethanol and 5-15% (w/v) benzyl alcohol.	30. The method of claim 1, wherein the solution consists of diazepam from 5 to 15% (w/v), dodecyl maltoside from about 0.01 to 1% (w/v), vitamin E from 45 to 65% (w/v), ethanol from 10 to 25% (w/v) and benzyl alcohol from 5 to 15% (w/v).

20. The pharmaceutical solution of claim 14, consisting of 9-11% (w/v) diazepam, 0.1-0.5% (w/v) dodecyl maltoside, 50-60% (w/v) vitamin E, 15-22.5% (w/v) ethanol and 7.5-12.5 (w/v) benzyl alcohol.	32. The method of claim 1, wherein the solution consists of diazepam from 9 to 11% (w/v), dodecyl maltoside from 0.1 to 0.5% (w/v), vitamin E from 50 to 60% (w/v), ethanol from 15 to 22.5% (w/v) and benzyl alcohol from 7.5 to 12.5% (w/v).
21. The pharmaceutical solution of claim 14, consisting of 10% (w/v) diazepam, 0.15-0.3% (w/v) dodecyl maltoside, 50-60 (w/v) vitamin E, 17-20% (w/v) ethanol and 10-12% (w/v) benzyl alcohol.	33. The method of claim 1, wherein the solution consists of diazepam 10% (w/v), dodecyl maltoside from 0.15 to 0.3% (w/v), vitamin E from 50 to 60% (w/v), ethanol from 17 to 20% (w/v) and benzyl alcohol from 10 to 12% (w/v).
22. The solution of claim 16, wherein the alkyl glycoside is dodecyl maltoside.	26. The method of claim 25, wherein the solution contains about 0.01% to 1% (w/w) of dodecyl maltoside.