

WHAT IS CLAIMED IS:

1. A method of stabilizing a composition comprising aceclidine comprising storing the composition in a container having a headspace at a temperature from about 2 degrees Celsius to about 8 degrees Celsius.
2. The method of claim 1, wherein the composition is filled into the container under an inert gas overlay.
3. The method of claim 2, wherein the headspace is purged with an inert gas.
4. The method of claim 1, wherein the container comprises a closure and a vessel wherein a portion of the closure and a portion of the vessel are sealed with an anti-leaching material selected from the group consisting of biaxially-oriented polyethylene terephthalate, polytetrafluorethylene and aluminum foil.
5. The method of claim 1, wherein the container is disposed in a second container that is formed with or lined with an anti-leaching material selected from the group consisting of biaxially-oriented polyethylene terephthalate, polytetrafluorethylene and aluminum foil.
6. The method of claim 1, wherein aceclidine is at a concentration from about 0.25% to about 4.0% w/v aceclidine, wherein w/v denotes weight by total volume of the composition.
7. The method of claim 1, wherein the method provides at least 90% stability of aceclidine for at least 7 months.
8. The method of claim 5, wherein the method provides at least 90% stability of aceclidine for at least 12 months.
9. The method of claim 1, wherein the composition further comprises a viscosity agent, a polysorbate, a cryoprotectant and a preservative.
10. The method of claim 9, wherein the method provides at least 90% stability of aceclidine for at least 18 months.
11. The method of claim 9, wherein the viscosity agent provides a viscosity of at least 50 centipoise.
12. The method of claim 9, wherein the cryoprotectant is selected from the group consisting of a polyol, a sugar, an alcohol, a lower alkanol, a lipophilic solvent, a hydrophilic solvent, a bulking agent, a solubilizer, a surfactant, an antioxidant, a cyclodextrin, a maltodextrin, colloidal silicon dioxide, polyvinyl alcohol, 2-methyl-2,4-pentanediol, cellobiose, gelatin, polyethylene

glycol (PEG), dimethyl sulfoxide (DMSO), formamide, antifreeze protein 752 or a combination thereof.

13. The method of claim 9, wherein the preservative is selected from the group consisting of benzalkonium chloride, sorbate, an antioxidant and a combination thereof.

14. The method of claim 11, wherein the antioxidant is selected from the group consisting of sodium ascorbate, sodium bisulfate, sodium metabisulfite, n-acetyl cysteine and a combination thereof.

15. A method of stabilizing a composition comprising aceclidine, a viscosity agent, and a nonionic surfactant comprising storing the composition in a container having a headspace at a temperature from about 2 degrees Celsius to about 8 degrees Celsius, wherein the composition is filled into the container under a nitrogen overlay and the headspace is purged with nitrogen and wherein the composition provides a low shear (1/sec) viscosity from about 50 to about 1000 centipoise and a high shear (1:1000/sec) of about 0.5 or less centipoise.

16. A method of stabilizing a composition comprising aceclidine, hydroxypropylmethyl cellulose, polysorbate 80, mannitol, sorbate and an antioxidant selected from the group consisting of sodium ascorbate, sodium bisulfate, sodium metabisulfite, n-acetyl cysteine or a combination thereof comprising storing the composition in a container having a headspace at a temperature from about 2 degrees Celsius to about 8 degrees Celsius, wherein the composition is filled into the container under a nitrogen overlay and the headspace is purged with nitrogen.

17. The method of claim 16, wherein the aceclidine is at a concentration from about 0.25% to about 4.00% w/v, the hydroxypropylmethyl cellulose is at a concentration from about 0.75% to about 1.25% w/v, polysorbate 80 is at a concentration from about 2% to about 4% w/v, mannitol is at a concentration from about 2% to about 4% w/v, sorbate is at a concentration from about 0.10% to about 0.12% w/v and the antioxidant is at a concentration from about 0.10% to about 0.25% w/v, wherein w/v denotes weight by total volume of the composition.

18. The method of claim 17, wherein the method provides at least 90% stability of aceclidine for at least 20 months.

19. The method of claim 18, wherein the method provides at least 90% stability of aceclidine for at least 22 months.

20. A container comprising aceclidine prepared by the process comprising the steps of:

a) providing a container;

- b) filling the container with a composition comprising aceclidine under an inert gas overlay;
- c) purging a headspace created during the filling step b) with an inert gas;
- d) capping the container.

21. The container of claim 20, wherein the process further comprises the step of storing the container at a temperature from about 2 to about 8 degrees Celsius.

22. The container of claim 20, wherein the composition further comprises a preservative selected from the group consisting of sorbate, benzalkonium chloride, sodium ascorbate, sodium bisulfate, sodium metabisulfite, n-acetyl cysteine and a combination thereof.

23. The container of claim 20, wherein the composition has a viscosity of at least 50 centipoise.

24. A composition comprising from about 0.25% to about 4.0% w/v aceclidine and one or more means of stabilizing the composition selected from the group consisting of filling the composition into a container under an inert gas overlay and purging a headspace created during filling with an inert gas, having a total viscosity of the composition of at least 50 centipoise or more, adding a preservative to the composition selected from the group consisting of sorbate, benzalkonium chloride, sodium ascorbate, sodium bisulfate, sodium metabisulfite, n-acetyl cysteine and a combination thereof,

wherein the composition is stored at a temperature from about 2 to about 8 degrees Celsius and wherein w/v denotes weight by total volume of the composition.

25. A method of stabilizing a composition comprising aceclidine comprising storing the composition in a container having a headspace at a temperature from about 22 degrees Celsius to about 25 degrees Celsius, wherein the container comprises a closure and a vessel wherein a portion of the closure and a portion of the vessel are sealed with an anti-leaching material selected from the group consisting of biaxially-oriented polyethylene terephthalate, polytetrafluorethylene and aluminum foil and/or the container is disposed in a second container that is formed with or lined with biaxially-oriented polyethylene terephthalate, polytetrafluorethylene and aluminum foil.

26. The method of claim 25, wherein the second container comprises a second closure, wherein the second closure provides an airtight seal.

27. The method of claim 26, wherein the airtight seal is resealable.