

Claims

INDEPENDENT CLAIMS		
<p>1. A stable aqueous liquid preparation consisting essentially of: (a) a first component; (b) a second component;</p> <p>wherein the first component is 2-amino-3-(4-bromobenzoyl) phenylacetic acid or a pharmacologically acceptable salt thereof or a hydrate thereof;</p> <p>(c) boric acid; (d) sodium tetraborate; and (e) water;</p> <p>wherein the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate, and 3/2 hydrate;</p> <p>the first component is the sole pharmaceutical active ingredient contained in the preparation and is present in the preparation at a concentration from about 0.05 w/v % to about 0.2 w/v %;</p> <p>the second component is tyloxapol and is present in said liquid preparation in an amount sufficient to stabilize said first component; and</p> <p>wherein said stable liquid preparation is formulated for ophthalmic administration.</p>	<p>7. A stable aqueous liquid preparation consisting essentially of: (a) a first component; (b) a second component;</p> <p>wherein the first component is 2-amino-3-(4-bromobenzoyl) phenylacetic acid or a pharmacologically acceptable salt thereof or a hydrate thereof;</p> <p>(c) boric acid; (d) sodium tetraborate; and (e) water;</p> <p>wherein the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate, and 3/2 hydrate;</p> <p>the first component is the sole pharmaceutical active ingredient contained in the preparation and is present in the preparation at a concentration from about 0.05 w/v % to about 0.2 w/v %;</p> <p>the second component is tyloxapol;</p> <p>wherein said stable liquid preparation is formulated for ophthalmic administration; and</p> <p>wherein the stable aqueous liquid preparation is characterized in that greater than about 90% of the original amount of the first component remains in the preparation after storage at about 60°C. for 4 weeks.</p>	<p>13. A stable aqueous liquid preparation consisting essentially of: (a) a first component; and (b) a second component;</p> <p>wherein the first component is 2-amino-3-(4-bromobenzoyl) phenylacetic acid or a pharmacologically acceptable salt thereof or a hydrate thereof;</p> <p>(c) boric acid; (d) sodium tetraborate; and (e) water;</p> <p>wherein the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate, and 3/2 hydrate;</p> <p>the first component is the sole pharmaceutical active ingredient contained in the preparation and is present in the preparation at a concentration from about 0.05 w/v % to about 0.2 w/v %;</p> <p>the second component is tyloxapol;</p> <p>wherein said stable liquid preparation is formulated for ophthalmic administration;</p> <p>provided that the liquid preparation does not include mannitol.</p>

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STABILITY
9. The stable aqueous liquid preparation of claim 7; wherein the stable aqueous liquid preparation is characterized in that greater than about 92% of the original amount of the first component remains in the preparation after storage at about 60°C. for 4 weeks.
19. The stable aqueous liquid preparation of claim 13; wherein the stable aqueous liquid preparation is characterized in that greater than about 90% of the original amount of the first component remains in the preparation after storage at about 60°C. for 4 weeks.
20. The stable aqueous liquid preparation of claim 19; wherein the stable aqueous liquid preparation is characterized in that greater than about 92% of the original amount of the first component remains in the preparation after storage at about 60°C. for 4 weeks.
PHARMACOLOGICALLY ACCEPTABLE SALTS
2. The aqueous liquid preparation according to claim 1, wherein the aqueous liquid preparation further consists of sodium sulfite.
3. The aqueous liquid preparation according to claim 1, wherein the first component is a 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt.
8. The aqueous liquid preparation according to claim 7, wherein the aqueous liquid preparation further consists of sodium sulfite.
14. The aqueous liquid preparation according to claim 13, wherein the aqueous liquid preparation further consists of sodium sulfite.
15. The aqueous liquid preparation according to claim 13, wherein the first component is a 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt.
pH
5. The aqueous liquid preparation according to claim 1, wherein the pH of the aqueous liquid preparation is from about 7.5 to about 8.5.
11. The aqueous liquid preparation according to claim 10, wherein the pH is from about 7.5 to about 8.5.
17. The aqueous liquid preparation according to claim 13, wherein the pH is from about 7.5 to about 8.5.
22. The aqueous liquid preparation according to claim 21, wherein the pH of the aqueous liquid preparation is from about 7.5 to about 8.5.

CONCENTRATION OF COMPONENTS

4. The aqueous liquid preparation according to claim 1, wherein the concentration of tyloxapol is from about 0.01 w/v % to about 0.05 w/v %.

6. The stable aqueous liquid preparation of claim 1; wherein the stable aqueous liquid preparation consists of:

- (a) 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt;
- (b) tyloxapol;
- (c) boric acid;
- (d) sodium tetraborate;
- (e) EDTA sodium salt;
- (f) polyvinylpyrrolidone;
- (g) sodium sulfite; and
- (h) water;

wherein said liquid preparation is formulated for ophthalmic administration,

wherein the concentration of the 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt is from about 0.02 w/v % to about 0.1 w/v %, and

wherein the concentration of tyloxapol is from about 0.01 w/v % to about 0.05 w/v %.

10. The aqueous liquid preparation according to claim 7;

wherein the concentration of tyloxapol is from about 0.01 w/v % to about 0.05 w/v %; and

wherein the first component is a 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt,

wherein the concentration of the 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt is from about 0.05 w/v % to about 0.1 w/v %.

12. The stable aqueous liquid preparation of claim 7; wherein the stable aqueous liquid preparation consists of:

- (a) 2-amino-3-(4-bromobenzoyl)phenylacetic acid or a pharmacologically acceptable salt thereof or a hydrate thereof, wherein the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate, and 3/2 hydrate;
- (b) tyloxapol;
- (c) boric acid;
- (d) sodium tetraborate;
- (e) EDTA sodium salt;
- (f) polyvinylpyrrolidone;
- (g) sodium sulfite; and
- (h) water; and

wherein the concentration of the 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt is from about 0.05 w/v % to about 0.1 w/v %, and

the concentration of tyloxapol is about 0.02 w/v %.

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16. The aqueous liquid preparation according to claim 13, wherein the concentration of tyloxapol is from about 0.01 w/v % to about 0.05 w/v % and the concentration of the 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt is from about 0.05 to about 0.1 w/v %.

18. The stable aqueous liquid preparation of claim 13; wherein the stable aqueous liquid preparation consists of:

- (a) 2-amino-3-(4-bromobenzoyl)phenylacetic acid or a pharmacologically acceptable salt thereof or a hydrate thereof, wherein the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate, and 3/2 hydrate;
- (b) tyloxapol;
- (c) boric acid;
- (d) sodium tetraborate;
- (e) EDTA sodium salt;
- (f) polyvinylpyrrolidone;
- (g) sodium sulfite; and
- (h) water;

wherein the concentration of the 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt is from about 0.02 w/v % to about 0.1 w/v %, and

the concentration of tyloxapol is from about 0.02 w/v % to about 0.05 w/v %.

21. The stable aqueous liquid preparation according to claim 20,

wherein the concentration of tyloxapol is from about 0.01 w/v % to about 0.05 w/v %; and

wherein the first component is a 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt,

wherein the concentration of the 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt is from about 0.05 w/v % to about 0.1 w/v %.

23. The stable aqueous liquid preparation of claim 13; wherein the stable aqueous liquid preparation consists of:

- (a) 2-amino-3-(4-bromobenzoyl)phenylacetic acid or a pharmacologically acceptable salt thereof or a hydrate thereof, wherein the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate, and 3/2 hydrate;
- (b) tyloxapol;
- (c) boric acid;
- (d) sodium tetraborate;
- (e) EDTA sodium salt;
- (f) polyvinylpyrrolidone;
- (g) sodium sulfite; and
- (h) water;

wherein said liquid preparation is formulated for ophthalmic administration; and

wherein the concentration of the 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt is from about 0.05 w/v % to about 0.1 w/v %.

NO PRESERVATIVES

24. The aqueous liquid preparation of claim 1, wherein the aqueous liquid preparation does not include any preservative.

25. The aqueous liquid preparation of claim 7, wherein the aqueous liquid preparation does not include any preservative.

26. The aqueous liquid preparation of claim 13, wherein the aqueous liquid preparation does not include any preservative.

ADDITIVES

27. The aqueous liquid preparation according to claim 1, optionally further consisting of one or more additives selected from the group consisting of buffers, thickeners, stabilizers, chelating agents, and pH controlling agents.