

INDEPENDENT CLAIMS		
<p>1. A stable aqueous liquid preparation comprising:</p> <p>(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, 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;</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>8. A stable aqueous liquid preparation comprising:</p> <p>(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, 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;</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>14. A stable aqueous liquid preparation comprising:</p> <p>(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, 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;</p> <p>the second component is tyloxapol;</p> <p>wherein said stable liquid preparation is formulated for ophthalmic administration; provided that the liquid preparation does not include mannitol.</p>
STABILITY		
<p>10. The stable aqueous liquid preparation of claim 8, 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.</p>		

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20. The stable aqueous liquid preparation of claim 14, 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.
22. The stable aqueous liquid preparation of claim 20; 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, further comprising a quaternary ammonium salt.
9. The aqueous liquid preparation according to claim 8, further comprising a quaternary ammonium salt.
15. The aqueous liquid preparation according to claim 14, further comprising a quaternary ammonium salt.
21. The aqueous liquid preparation according to claim 20, further comprising a quaternary ammonium salt.
3. The aqueous liquid preparation according to claim 1, wherein the first component is a 2-amino-3-(4-bromobenzoyl) phenylacetic acid sodium salt.
16. The aqueous liquid preparation according to claim 14, wherein the first component is a 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt.
pH
6. The aqueous liquid preparation according to claim 1, wherein the pH is from about 7.5 to about 8.5.
12. The aqueous liquid preparation according to claim 11, wherein the pH is from about 7.5 to about 8.5.
18. The aqueous liquid preparation according to claim 17, wherein the pH is from about 7.5 to about 8.5.
24. The aqueous liquid preparation according to claim 23, wherein the pH 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 %; 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 0.01 to about 0.2 w/v %.

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

7. The stable aqueous liquid preparation of claim 1, wherein the stable aqueous liquid preparation consists essentially of:

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

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 0.02 w/v % to about 0.1 w/v %.

11. The aqueous liquid preparation according to claim 8,

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 0.01 to about 0.2 w/v %.

13. The stable aqueous liquid preparation of claim 8, wherein the stable aqueous liquid preparation consists essentially 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) benzalkonium chloride;
- (g) polyvinylpyrrolidone; and
- (h) sodium sulfite; and

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 %.

17. The aqueous liquid preparation according to claim 16, 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 0.2 w/v %.

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19. The stable aqueous liquid preparation of claim 14; wherein the stable aqueous liquid preparation consists essentially 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) benzalkonium chloride;
- (g) polyvinylpyrrolidone; and
- (h) sodium sulfite;

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 %.

23. The 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 0.01 to about 0.2 w/v %.

25. The stable aqueous liquid preparation of claim 20, wherein the stable aqueous liquid preparation consists essentially 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) benzalkonium chloride;
- (g) polyvinylpyrrolidone; and
- (h) sodium sulfite;

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 0.02 w/v % to about 0.1 w/v %.

PRESERVATIVE EFFICACY STANDARD OF EP-CRITERIA B

26. The aqueous liquid preparation of claim 1, wherein the aqueous liquid preparation further satisfies the preservative efficacy standard of EP-criteria B of the European Pharmacopoeia as follows:

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viable cell counts of bacteria (*S. aureus*, *P. aeruginosa*) 24 hours and 7 days after inoculation decrease to not more than 1/10 and not more than 1/1000, respectively, and thereafter, the cell count levels off or decreases; and viable cell count of fungi (*C. albicans*, *A. niger*) 14 days after inoculation decreases to not more than 1/10, and thereafter, the cell count keeps the same level as that of 14 days after inoculation.

27. The aqueous liquid preparation of claim 8, wherein the aqueous liquid preparation further satisfies the preservative efficacy standard of EP-criteria B of the European Pharmacopoeia as follows:

viable cell counts of bacteria (*S. aureus*, *P. aeruginosa*) 24 hours and 7 days after inoculation decrease to not more than 1/10 and not more than 1/1000, respectively, and thereafter, the cell count levels off or decreases; and viable cell count of fungi (*C. albicans*, *A. niger*) 14 days after inoculation decreases to not more than 1/10, and thereafter, the cell count keeps the same level as that of 14 days after inoculation.

28. The aqueous liquid preparation of claim 14, wherein the aqueous liquid preparation further satisfies the preservative efficacy standard of EP-criteria B of the European Pharmacopoeia as follows:

viable cell counts of bacteria (*S. aureus*, *P. aeruginosa*) 24 hours and 7 days after inoculation decrease to not more than 1/10 and not more than 1/1000, respectively, and thereafter, the cell count levels off or decreases; and viable cell count of fungi (*C. albicans*, *A. niger*) 14 days after inoculation decreases to not more than 1/10, and thereafter, the cell count keeps the same level as that of 14 days after inoculation.

29. The aqueous liquid preparation of claim 20, wherein the aqueous liquid preparation further satisfies the preservative efficacy standard of EP-criteria B of the European Pharmacopoeia as follows:

viable cell counts of bacteria (*S. aureus*, *P. aeruginosa*) 24 hours and 7 days after inoculation decrease to not more than 1/10 and not more than 1/1000, respectively, and thereafter, the cell count levels off or decreases; and viable cell count of fungi (*C. albicans*, *A. niger*) 14 days after inoculation decreases to not more than 1/10, and thereafter, the cell count keeps the same level as that of 14 days after inoculation.

30. The aqueous liquid preparation of claim 22, wherein the aqueous liquid preparation further satisfies the preservative efficacy standard of EP-criteria B of the European Pharmacopoeia as follows:

viable cell counts of bacteria (*S. aureus*, *P. aeruginosa*) 24 hours and 7 days after inoculation decrease to not more than 1/10 and not more than 1/1000, respectively, and thereafter, the cell count levels off or decreases; and viable cell count of fungi (*C. albicans*, *A. niger*) 14 days after inoculation decreases to not more than 1/10, and thereafter, the cell count keeps the same level as that of 14 days after inoculation.