

INDEPENDENT CLAIMS		
<p>1. A method for treating an inflammatory disease of an eye, the method comprising administering to said eye a stable aqueous liquid preparation that comprises:</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;</p> <p>wherein said stable liquid preparation is formulated for ophthalmic administration; and</p> <p>wherein said liquid preparation is administered to said eye at a dose and a frequency effective to treat said inflammatory disease.</p>	<p>11. A method for treating an inflammatory disease of an eye, the method comprising administering to said eye a stable aqueous liquid preparation that comprises:</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;</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; and</p> <p>wherein said liquid preparation is administered to said eye at a dose and a frequency effective to treat said inflammatory disease.</p>	<p>19. A method for treating an inflammatory disease of an eye, the method comprising administering to said eye a stable aqueous liquid preparation that comprises:</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;</p> <p>provided that the liquid preparation does not include mannitol; and</p> <p>wherein said liquid preparation is administered to said eye at a dose and a frequency effective to treat said inflammatory disease.</p>

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DISEASE INDICATIONS
2. The method according to claim 1, wherein said inflammatory disease is a disease of an anterior or posterior segment of said eye.
3. The method according to claim 2, wherein said disease is postoperative inflammation.
13. The method according to claim 11, wherein said inflammatory disease is a disease of an anterior or posterior segment of said eye.
14. The method according to claim 13, wherein said disease is postoperative inflammation.
20. The method according to claim 19, wherein said inflammatory disease is a disease of an anterior or posterior segment of said eye.
21. The method according to claim 20, wherein said disease is postoperative inflammation.
DOSAGE INFORMATION
10. The method according to claim 1, wherein said dose comprises one or two drops.
STABILITY
12. The method according to claim 11, 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.
26. The method according to claim 20, 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.
PHARMACOLOGICALLY ACCEPTABLE SALTS
4. The method according to claim 1, wherein the first component is a 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt.
7. The method according to claim 5, wherein the aqueous liquid preparation further comprises a quaternary ammonium salt.
17. The method according to claim 11, further comprising a quaternary ammonium salt.
22. The method according to claim 19, wherein the first component is a 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt.
CONCENTRATION OF COMPONENTS
5. The method according to claim 1, wherein the concentration of tyloxapol is from about 0.01

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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 %.

6. The method according to claim 5, 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 %.

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

9. The method according to claim 1, wherein the stable aqueous liquid preparation consists essentially of:

- (a) 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt,
- (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 %.

15. The method according to claim 11, 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 %.

16. The method according to claim 15, 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 %.

18. The method according to claim 11, 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

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(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 %.

23. The method according to claim 22, 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 %.

24. The method according to claim 22, 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 %.

25. The method according to 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 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 %.

27. The method 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 0.02 to about 0.1 w/v %.

EP-criteria B

28. The method according to claim 1, 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.

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29. The method according to claim 11, 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 method according to claim 19, 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.