

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 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 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 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 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 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>

Claims

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.
21. 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, 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.
8. The aqueous liquid preparation according to claim 7, further comprising a quaternary ammonium salt.
14. The aqueous liquid preparation according to claim 13, further comprising a quaternary ammonium salt.
15. The aqueous liquid preparation according to claim 13, wherein the first component is a 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt.
20. The stable aqueous liquid preparation according to claim 19, further comprising a quaternary ammonium salt.
pH
5. The aqueous liquid preparation according to claim 1, wherein the pH 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.
23. The aqueous liquid preparation according to claim 22, 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 %.

6. 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,

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 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 0.05 w/v % to about 0.1 w/v %, and

Claims

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

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 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 %, and

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

22. The stable aqueous liquid preparation according to claim 21, 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 %.

24. The stable aqueous liquid preparation of claim 13; 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 0.05 w/v % to about 0.1 w/v %.

US Pharmacopoeia Preservative Efficacy Standard

25. The aqueous liquid preparation of claim 1, wherein the aqueous liquid preparation further satisfies the preservative efficacy standard of US 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.

26. The aqueous liquid preparation of claim 4, wherein the aqueous liquid preparation further satisfies the preservative efficacy standard of US 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.

27. The aqueous liquid preparation of claim 7, wherein the aqueous liquid preparation further satisfies the preservative efficacy standard of US 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 9, wherein the aqueous liquid preparation further satisfies the preservative efficacy standard of US 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 13, wherein the aqueous liquid preparation further satisfies the preservative efficacy standard of US 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.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.