IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Attorney Docket No. 2014-0075
Shirou SAWA	:	
Serial No. NEW	:	
Filed January 28, 2014	:	

AQUEOUS LIQUID PREPARATION CONTAINING 2-AMINO-3-(4-BROMOBENZOYL)PHENYLACETIC ACID
(Rule 1.53(b) Divisional of Serial No. 13/687,242, Filed November 28, 2012)

PRELIMINARY AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir/Madam:

Prior to examination, please amend the above-identified application as follows:

The USPTO is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17, and 1.492, which may be required by this paper to Deposit Account No. 23-0975, except fees for multiple dependent claims.

AMENDMENTS TO THE CLAIMS

1-18. (Cancelled)

19. (New) A stable aqueous liquid preparation comprising: (a) a first component; and (b) a second component; 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; 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 %; the second component is tyloxapol and is present in said liquid preparation in an amount sufficient to stabilize said first component; and wherein said stable liquid preparation is formulated for ophthalmic administration.

20. (New) The aqueous liquid preparation according to claim 19, further comprising a quaternary ammonium salt.

21. (New) The aqueous liquid preparation according to claim 19, wherein the first component is a 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt.

22. (New) The aqueous liquid preparation according to claim 19, wherein the concentration of tyloxapol is from about 0.01 w/v % to about 0.05 w/v %.

23. (New) The aqueous liquid preparation according to claim 19, wherein the pH is from about 7.5 to about 8.5.

24. (New) The stable aqueous liquid preparation of claim 19; 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 %.

25. (New) A stable aqueous liquid preparation comprising: (a) a first component; and (b) a second component; 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; 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 %; the second component is tyloxapol; wherein said stable liquid preparation is formulated for ophthalmic administration; and 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.

26. (New) The aqueous liquid preparation according to claim 25, further comprising a quaternary ammonium salt.

27. (New) The stable aqueous liquid preparation of claim 25; 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.

28. (New) The aqueous liquid preparation according to claim 25; 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 %.

29. (New) The aqueous liquid preparation according to claim 28, wherein the pH is from about 7.5 to about 8.5.

30. (New) The stable aqueous liquid preparation of claim 25; 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 the concentration of tyloxapol is about 0.02 w/v%.

31. (New) A stable aqueous liquid preparation comprising: (a) a first component; and (b) a second component; 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; 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 %; the second component is tyloxapol; wherein said stable liquid preparation is formulated for ophthalmic administration; provided that the liquid preparation does not include mannitol.

32. (New) The aqueous liquid preparation according to claim 31, further comprising a quaternary ammonium salt.

33. (New) The aqueous liquid preparation according to claim 31, wherein the first component is a 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt.

34. (New) The aqueous liquid preparation according to claim 31, 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 %.

35. (New) The aqueous liquid preparation according to claim 31, wherein the pH is from about 7.5 to about 8.5.

36. (New) The stable aqueous liquid preparation of claim 31; 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 %.

37. (New) The stable aqueous liquid preparation of claim 31; 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.

38. (New) The stable aqueous liquid preparation according to claim 37, further comprising a quaternary ammonium salt.

39. (New) The stable aqueous liquid preparation of claim 37; 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.

40. (New) The stable aqueous liquid preparation according to claim 39, 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 %.

41. (New) The aqueous liquid preparation according to claim 40, wherein the pH is from about 7.5 to about 8.5.

42. (New) The stable aqueous liquid preparation of claim 31; 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 %.

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