Summary

The current disclosure provides a solution for at least one of the above mentioned problems by providing a composition combining ibuprofen and paracetamol with improved compatibility.

In a first aspect, the present disclosure provides a process for manufacturing an aqueous composition comprising ibuprofen and paracetamol in combination, comprising the steps of:

a) providing an aqueous solvent of pH 6.0-8.0, preferably 6.2-7.5, more preferably 6.3-7.3,
b) dissolving in said aqueous solvent ibuprofen and paracetamol,
c) if required adjusting the pH to 6.3-7.3,
d) thereby obtaining said aqueous composition comprising ibuprofen and paracetamol in combination at pH 6.3-7.3.

In another aspect, the present disclosure provides a process for manufacturing an aqueous composition comprising ibuprofen and paracetamol in combination, comprising the steps of:

a) providing an aqueous solvent of pH 6.0-8.0, preferably 6.2-7.5, more preferably 6.3-7.3,
b) dissolving in said aqueous solvent ibuprofen and paracetamol,
c) ensuring that the final composition comprising ibuprofen and paracetamol has a pH of 6.3-7.3.

More specifically, a process for manufacturing an aqueous composition comprising ibuprofen and paracetamol in combination, comprising in order the steps of: providing an aqueous solvent of pH 6.0-8.0, preferably 6.2-7.5, more preferably 6.3-7.3, and dissolving in said aqueous solvent 2.8 to 3.2 mg ibuprofen and 9.8 to 10.2 mg paracetamol expressed per ml of said composition. The pH of the final composition obtained should be between pH 6.3-7.3. Thus, if required, the pH is adjusted.

This method has the advantages that conditions are used which at the same time overcome poor ibuprofen solubility and paracetamol sensitivity to degradation. The resulting product has long term storage stability.

In embodiments, the present disclosure provides aqueous compositions, preferably obtained by a method of the present disclosure.

In a second aspect, the present disclosure provides an aqueous composition, comprising ibuprofen and paracetamol, wherein the pH of said composition is 6.3 to 7.3.

Products according to an embodiment of the present disclosure are characterized in that they provide a stable combination of ibuprofen and paracetamol at a physiologically acceptable pH.

Claims

1. A process for manufacturing an aqueous composition comprising ibuprofen and paracetamol in combination, comprising the steps of:
   a) providing an aqueous solvent of pH 6.0-8.0, preferably 6.2-7.5, more preferably 6.3-7.3,
   b) dissolving in said aqueous solvent ibuprofen and paracetamol,
   c) ensuring that the final composition comprising ibuprofen and paracetamol has a pH of 6.3-7.3.

2. Process according to claim 1, wherein said aqueous solvent has a dissolved oxygen content below 2 ppm.

3. Process according to any of the above claims 1-2, wherein the pH of the aqueous solvent in step a) is 6.3 to 6.5.

4. Process according to any of the above claims 1-3, wherein the composition comprises 2.8-3.2 mg ibuprofen and 9.8-10.2 mg paracetamol per ml of said composition.

5. Process according to any of the above claims 1-4, wherein the composition comprises an anti-oxidant; preferably said anti-oxidant is cysteine or acetyl cysteine.

6. Process according to any one of claims 1 to 5, wherein the aqueous solvent comprises an isotonic agent, preferably mannitol.

7. An aqueous composition, comprising ibuprofen and paracetamol, characterized in that, the pH of said composition is 6.3 to 7.3.

8. Composition according to claim 7, comprising 2.8 to 3.2 mg ibuprofen and 9.8 to 10.2 mg paracetamol expressed per ml of said composition; preferably 3 mg ibuprofen and 10 mg paracetamol expressed per ml of said composition.

9. Composition according to any one of claims 7-8, comprising an isotonic agent, preferably said isotonic agent is mannitol.

10. Composition according to any one of claims 7-9, wherein said composition has a dissolved oxygen content below 2 ppm.

11. Composition according to any one of claims 7-10, for use as a medicament.

12. Use of a composition according to any one of claims 7-11 in the manufacture of a medicament, for the treatment of pain and/or inflammation; wherein the composition is to be administered preferably by intravenous injection or infusion.

13. A device (1) comprising a composition according to any of claims 7-12 for delivering said aqueous composition by means of injection or infusion.

14. Device (1) according to claim 13, comprising
-at least a first and a second reservoir (2,3), wherein ibuprofen is comprised in a first reservoir (2) and paracetamol is comprised in a second reservoir (3), and
-a mixing zone (9) for combining said paracetamol and said ibuprofen prior to delivery,
characterized in that, said combination is a composition according to any of claims 7-12.

15. Device (1) according to claim 13 or 14, in the form of a pre-filled syringe, preferably a multi-chamber pre-filled syringe.

16. Device (1) according to claim 13 or 14, in the form of an infusion bag, preferably a multi-chamber infusion bag.