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.

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.

In a third aspect, the present disclosure provides a composition as disclosed herein for use as a medicament. In embodiments, the present disclosure provides medical uses of the compositions according to the present disclosure. Products according to the present disclosure can be advantageously used to administer at the same time ibuprofen and paracetamol. The problem of managing the two drugs separately is overcome.

In a fourth aspect, the present disclosure provides a device comprising a composition as disclosed herein for delivering said aqueous composition by means of injection or infusion. In an embodiment, the present disclosure provides for delivery of an aqueous solution of ibuprofen and paracetamol at pH 6.3-7.3 in accordance with the present disclosure.

In a fifth aspect, the present disclosure provides the use of a composition as disclosed herein 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.

The present disclosure thereto provides a device (1) comprising a composition according to an embodiment of the present disclosure for delivering said aqueous composition by means of injection or infusion. This device can be a syringe or infusion bag.

This device can be ready for use, i.e. comprising said aqueous solution of ibuprofen and paracetamol at pH 6.3-7.3. It can also be equipped for mixing of separate components of the solution prior to administration.

In a preferred embodiment said device comprises

-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 an embodiment of the present disclosure.

Description of figures

Figure 1 depicts several different embodiments a-e of an infusion bag 1, as examples of delivery devices according to the invention.

Detailed description of the invention

Unless otherwise defined, all terms used in disclosing the invention, including technical and scientific terms, have the meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. By means of further guidance, term definitions are included to better appreciate the teaching of the present invention.

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 storage stability of at least 6 months, preferably 12 months, more preferably 18 months, most preferably 18 months.

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

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

13. Use of a composition according to any one of claims 7-12 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.

14. A device (1) comprising a composition according to any of claims 8-13 for delivering said aqueous composition by means of injection or infusion.

15. Device (1) according to claim 14, 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 8-13.

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

17. Device (1) according to claim 14 or 15, in the form of an infusion bag, preferably a multi-chamber infusion bag.