CLAIMS

1. Immediate release, oral pharmaceutical formulation comprising nalbuphine or a pharmaceutically acceptable salt thereof, and at least one hydrophilic granulation carrier, one hydrophilic binder and one lubricant.

2. Formulation according to claim 1, characterized in that it only contains nalbuphine or one of the pharmaceutically acceptable salts thereof, preferably nalbuphine hydrochloride as an active ingredient.

3. The pharmaceutical formulation according to claim 1 or 2, wherein the hydrophilic granulation carrier is selected from the group comprising mannitol, polyvinyl pyrrolidone or a derivative thereof, a polyol, lactose, a cellulose derivative, polyethylene glycol or a derivative thereof and a silica derivative.

4. The pharmaceutical formulation according to any of claims 1 to 3, wherein the hydrophilic granulation carrier is lactose.

5. The pharmaceutical formulation according to any of claims 1 to 4, wherein the hydrophilic binder is selected from the group comprising polyvinyl pyrrolidone or a derivative thereof, a polyol, lactose, a cellulose derivative, polyethylene glycol or a derivative thereof, gums and carbomers.

6. The pharmaceutical formulation according to any of claims 1 to 5, wherein the hydrophilic binder is polyvinylpyrrolidone.

7. The pharmaceutical formulation according to any of claims 1 to 6, wherein the lubricant is selected from the group comprising silicon dioxide, magnesium stearate, anhydrous colloidal silica, sodium stearyl fumarate and talcum.

8. The pharmaceutical formulation according to any of claims 1 to 7, wherein it comprises at least 45% by weight of hydrophilic granulation carrier, preferably from 45 to 70% by weight, and still more preferably from 55 to 65% by weight of granulation carrier, relative to the total weight of the formulation.

9. The pharmaceutical formulation according to any of claims 1 to 8, wherein it comprises less than 10% by weight of hydrophilic binder, preferably from 2 to 10% by weight, and still more preferably from 4 to 8% by weight of binder, relative to the total weight of the formulation.

10. The pharmaceutical formulation according to any of claims 1 to 9, wherein it comprises less than 10% by weight of lubricant, preferably from 0.9 to 7% by weight, and still more preferably from 2 to 3% by weight of lubricant, relative to the total weight of the formulation.

11. The pharmaceutical formulation according to any of claims 1 to 10, wherein it comprises less than 30% by weight of nalbuphine, preferably from 4 to 30% by weight of nalbuphine, and still more preferably from 18 to 22% by weight of nalbuphine, relative to the total weight of the formulation.

12. The pharmaceutical formulation according to any of claims 1 to 11, wherein it further comprises:

- at least one disintegrating agent; and optionally
- at least one excipient.

13. The pharmaceutical formulation according to any of claims 1 to 11, wherein it comprises:

- from 4 to 30% by weight of nalbuphine;
- from 45 to 70% by weight of lactose;
- from 2 to 10% by weight of PVP; and
- from 0.9 to 7% by weight of at least one lubricant.

14. The pharmaceutical formulation according to any of claims 1 to 13, wherein it is in solid form.

15. The pharmaceutical formulation according to claim 14, wherein it is in a form selected from the group comprising tablets, granules, pellets, micro-granules, capsules and lozenges.

16. Use of the pharmaceutical formulation according to any of claims 1 to 15 in the manufacture of a medicament for the treatment of pain.

17. The use of the pharmaceutical formulation according to claim 16, wherein pain is generated by a treatment for opioid addiction.

18. Use of the pharmaceutical formulation according to any of claims 1 to 15 in the manufacture of a medicament for the treatment of opioid addiction.

CLAIMS

1. Immediate release, oral pharmaceutical formulation, wherein it comprises:
- from 15 to 30% by weight of nalbuphine;
- from 50 to 70% by weight of an hydrophilic granulation carrier;
- from 2 to 10% by weight of an hydrophilic binder; and
- from 1 to 5% by weight of at least one lubricant.

2. The pharmaceutical formulation according to claim 1, wherein it comprises:
- from 18 to 22% by weight of nalbuphine;
- from 55 to 65% by weight of an hydrophilic granulation carrier;
- from 4 to 8% by weight of an hydrophilic binder; and
- from 2 to 3% by weight of at least one lubricant.

3. The pharmaceutical formulation according to claim 1 or 2 wherein the nalbuphine is under the form of its hydrochloride.

4. The pharmaceutical formulation according to any of claims 1 to 3, wherein the the hydrophilic granulation carrier is selected from the group comprising mannitol, polyvinyl pyrrolidone or a derivative thereof, a polyol, lactose, a cellulose derivative, polyethylene glycol or a derivative thereof and a silica derivative.

5. The pharmaceutical formulation according to any of claims 1 to 4, wherein the hydrophilic binder is selected from the group comprising polyvinyl pyrrolidone or a derivative thereof, a polyol, lactose, a cellulose derivative, polyethylene glycol or a derivative thereof, gums and carbomers.

6. The pharmaceutical formulation according to any of claims 1 to 5, wherein the lubricant is selected from the group comprising silicon dioxide, magnesium stearate, anhydrous colloidal silica, sodium stearyl fumarate and talcum.

7. The pharmaceutical formulation according to any of claims 1 to 6, wherein it further comprises:
- at least one disintegrating agent; and optionally
- at least one excipient.

8. A pharmaceutical formulation, wherein it comprises:
- from 15 to 30% by weight of nalbuphine;
- from 50 to 70% by weight of lactose;
- from 2 to 10% by weight of PVP; and
- from 1 to 5% by weight of at least one lubricant.

9. The pharmaceutical formulation according to any of claims 1 to 8, wherein it is in solid form.

10. The pharmaceutical formulation according to claim 9, wherein it is in a form selected from the group comprising tablets, granules, pellets, micro-granules, capsules and lozenges.

11. The pharmaceutical formulation according to any of claims 1 to 10, for its use in the treatment of pain.

12. The pharmaceutical formulation for use according to claim 11, wherein pain is generated by a treatment for opioid addiction.