Claims

1. An oral pharmaceutical composition comprising a first population of beads and a second population of beads; said first bead population comprising a pharmaceutically active ingredient selected from the group consisting of hydrocodone and pharmaceutically acceptable salts thereof, wherein said first bead population is substantially free of polyethylene oxide; and said second bead population comprising polyethylene oxide and a permeable or semi-permeable coating selected from the group consisting of an ammonio methacrylate copolymer, a methacrylic acid copolymer and a mixture thereof, wherein said second bead population is substantially free of any pharmaceutically active ingredient.

2. The composition according to claim 1, wherein said second bead population further comprises povidone.

3. The composition according to claim 2, wherein the polyethylene oxide is present in particulate form.

4. The composition according claim 1, wherein the pharmaceutically active ingredient is hydrocodone bitartrate.

5. The composition according to claim 4, wherein the hydrocodone bitartrate is present in an amount of from 5 to 250 mg.

6. An oral pharmaceutical composition comprising a population of immediate release hydrocodone bitartrate beads that is substantially free of polyethylene oxide, a population of controlled release hydrocodone bitartrate beads that is substantially free of polyethylene oxide, and a population of gelling agent-containing beads; said gelling agent-containing beads comprising polyethylene oxide, povidone and a permeable or semi-permeable coating selected from the group consisting of an ammonio methacrylate copolymer, a methacrylic acid copolymer and a mixture thereof.

7. The composition according to claim 6, wherein the immediate release beads contain from 1 to 75% w/w of the total amount of hydrocodone bitartrate in the composition and the controlled release beads contain from 25 to 99% w/w of the total amount of hydrocodone bitartrate in the composition.

8. A unit dosage form comprising a composition according to claim 1 presented in the form of a capsule or in the form of a tablet.

9. The unit dosage form according to claim 8, presented in the form of a capsule, said unit dosage form comprising at least about 20 mg of gelling agent per capsule.

10. The unit dosage form comprising a composition according to claim 6, presented in the form of a capsule or in the form of a tablet.

11. The unit dosage form according to claim 10, presented in the form of a capsule, said unit dosage form comprising at least about 20 mg of gelling agent per capsule.

12. An oral capsule containing a composition made up of hydrocodone bitartrate beads that are substantially free of polyethylene oxide, and gelling agent-containing beads; said gelling agent-containing beads consisting essentially of sugar spheres, polyethylene oxide, povidone and a semi-permeable coating comprising a polymer selected from the group consisting of an ammonio methacrylate copolymer, a methacrylic acid copolymer and a combination thereof.

13. An oral capsule according to claim 12 wherein the gelling agent-containing beads consist essentially of

(i) sugar spheres 25.0-35.0% w/w

(ii) polyethylene oxide 40.0-50.0% w/w (

(iii) povidone 2.5-7.5% w/w

(iv) ammonio methacrylate copolymer 5.0-20.0% w/w

(v) silicon dioxide 1.0-7.5% w/w

(vi) talc 1.0-7.5% w/w.

14. The oral capsule according to claim 12 wherein the hydrocodone bitartrate beads consist of hydrocodone bitartrate immediate release beads and hydrocodone bitartrate controlled release beads.

15. The oral capsule according to claim 14 wherein the composition consists essentially of

(i) hydrocodone bitartrate 5.0-50.0 mg/capsule

(ii) sugar spheres 65.0-250.0 mg/capsule

(iii) hypromellose 2.0-15.0 mg/capsule

(iv) ammonio methacrylate copolymer 7.5-40.0 mg/capsule

(v) silicon dioxide 2.5-25.0 mg/capsule

(vi) talc 1.0-7.5 mg/capsule

(vii) polyethylene oxide 30.0-100.0 mg/capsule

(viii) povidone 2.5-12.5 mg/capsule

and wherein 20% of the hydrocodone bitartrate are present in the immediate release beads and 80% of the hydrocodone bitartrate are present in the controlled release beads.