Claims

1. A solid oral dosage form comprising a plurality of particles, each particle comprising a core comprising an active agent susceptible to abuse, wherein the cores are

(i) dispersed in a matrix comprising a controlled release material or

(ii) coated with a controlled release material,

wherein the dosage form further comprises from about 0.05% to about 15% (w/w) of an internal adhesion promoter to promote the adhesion of the active agent and the controlled release material, and

wherein the amount of active agent released from the dosage form after crushing is within 30% of the amount of active agent released from the dosage form before crushing when measured at 4 hours using a USP Type 2, Paddle Method at 50 rpm in 900 ml simulated gastric fluid without enzymes (SGF) with 0% ethanol at 37°C.

2. The solid oral dosage form of claim 1, wherein the core further comprises a dissolution enhancer.

3. The solid oral dosage form of claim 1, wherein the coating or matrix further comprises a pore former.

4. The solid oral dosage form of claim 1, further comprising an alcohol resistant material.

5. The solid oral dosage form of claim 1, further comprising an external adhesion promoter.

6. The solid oral dosage form of claim 1, wherein the controlled release material is a polymer.

7. The solid oral dosage form of claim 5, wherein the internal adhesion promoter and external adhesion promoter are selected from the group consisting of a cellulosic material, a surfactant, a carbomer and a mixture thereof.

8. The solid oral dosage form of claim 2, wherein the dissolution enhancer is selected from the group consisting of a cellulosic material, a sugar, a starch and a polymer.

9. The solid oral dosage form of claim 3, wherein the pore former is selected from the group consisting of sodium chloride, a polysaccharide, a polymer, an organic solvent and an inorganic material.

10. The solid oral dosage form of claim 1, wherein the plurality of particles are compressed into a tablet having a breaking strength of less than 400N.

11. The solid oral dosage form of claim 1, wherein the weight ratio of the active agent to the controlled release material is from about 2:1 to about 1:100.

12. The solid oral dosage form of claim 1, wherein the particles have a mean diameter from about 0.01 mm to about 3 mm.

13. The solid oral dosage form of claim 1, comprising from about 0.1% to about 80% (w/w) active agent.

14. The solid oral dosage form of claim 1, comprising from about 10% to about 90% (w/w) controlled release material.

15. The solid oral dosage form of claim 1, comprising from about 0.1% to about 5% (w/w) internal adhesion promoter.

16. The solid oral dosage form of claim 1, comprising from about 1% to about 40% (w/w) dissolution enhancer.

17. The solid oral dosage form of claim 1, comprising from about 0.5% to about 25% (w/w) pore former.

18. The solid oral dosage form of claim 1, comprising from about 1% to about 50% (w/w) alcohol resistant material.

19. The oral dosage form of claim 1, which provides a dissolution release rate in-vitro of the active agent, when measured by the USP Type 2, Paddle Method at 50 rpm in 900 ml

Simulated Gastric Fluid (SGF) without enzymes at 37°C of at least about 15% by weight of the active agent released at 1 hour, from about 25% to about 65% by weight of the active agent released at 2 hours, from about 45% to about 85% by weight of the active agent released at 4 hours, and at least about 60% by weight of the active agent released at 8 hours.

20. The oral dosage form of claim 1, wherein the amount of active agent released at 0.5 hour, 1 hour, 2 hours or 4 hours when measured in a USP Type 2, Paddle Method at 50 rpm in 900 ml simulated gastric fluid (SGF) without enzymes with 40% ethanol at 37°C, is within 30% of the amount of active agent released at the same time period when measured in a USP Type 2, Paddle Method at 50 rpm in 900 ml simulated gastric fluid without enzymes (SGF) with 0% ethanol at 37°.

21. The oral dosage form of claim 1, wherein the amount of active agent released at 0.5 hour, 1 hour, 2 hours or 4 hours when measured in a USP Type 2, Paddle Method at 50 rpm in 900 ml simulated gastric fluid (SGF) without enzymes with 40% ethanol at 37°C, is less than the amount of active agent released at the same time period when measured in a USP Type 2, Paddle Method at 50 rpm in 900 ml simulated gastric fluid without enzymes (SGF) with 0% ethanol at 37°.

22. The oral dosage form of claim 1, wherein the amount of active agent released from a crushed dosage form at 0.5 hour, 1 hour, 2 hours or 4 hours when measured in a USP Type 2, Paddle Method at 50 rpm in 900 ml simulated gastric fluid (SGF) without enzymes at 37°C, is within 50%, 40%, 30% or 20% of the amount of active agent released from an intact dosage

form at the same time period when measured in a USP Type 2, Paddle Method at 50 rpm in 900 ml simulated gastric fluid without enzymes (SGF) with 0% ethanol at 37°.

23. The solid oral dosage form of claim 1, wherein the recovery of the active agent is less than about 50% based on a syringability test whereby the dosage form is crushed and mixed with 5 or 10 mL solvent and the resultant solution is aspirated with a 18, 22, 25, or 27 gauge needle.

24. The solid oral dosage form of claim 1, wherein the active agent is selected from the group consisting of opioid agonists, tranquilizers, CNS depressants, CNS stimulants, sedative hypnotics, and mixtures thereof.

25. The solid oral dosage form of claim 1, further comprising an aversive agent.

26. The solid oral dosage form of claim 25, wherein the aversive agent is selected from the group consisting of emetics, antagonists, bittering agents, irritants, gelling agents and mixtures thereof.

27. A solid oral dosage form comprising a plurality of particles, each particle comprising a core comprising an opioid agonist and a carbomer, wherein the cores are (i) dispersed in a matrix comprising a neutral acrylic polymer and a pore former (ii) coated with a neutral acrylic polymer and a pore former; wherein the carbomer is present in the solid oral dosage

form at a concentration ranging from about 0.05% to about 15% (w/w), and wherein the dosage form further comprises a dissolution enhancer.

28. A process for preparing a solid oral dosage form comprising preparing a plurality of particles by

(i) granulating an opioid agonist and a carbomer to form core granules;

(ii) coating or granulating the core granules with a neutral acrylic polymer and lactose to obtain controlled release particles or granules;

(iii) coating or granulating the controlled release particles or granules with methylcellulose and a carbomer to obtain alcohol resistant controlled release particles or granules; and

(iv) compressing the alcohol resistant controlled release particles or granules into a tablet,

wherein the carbomer is present in the solid oral dosage form at a concentration ranging from about 0.05% to about 15% (w/w)

wherein the amount of opioid agonist released from the solid dosage form after crushing is within 30% of the amount of opioid agonist released from the solid dosage form before crushing when measured at 4 hours using a USP Type 2, Paddle Method at 50 rpm in 900 ml simulated gastric fluid without enzymes (SGF) with 0% ethanol at 37°C.

~~29. A method of management of both acute and chronic conditions comprising~~

~~administering a solid oral dosage form comprising a plurality of particles, each particle comprising a core comprising an active agent susceptible to abuse, wherein the cores are~~

~~(i) dispersed in a matrix comprising a controlled release material or~~

~~(ii) coated with a controlled release material,~~

~~wherein the dosage form further comprises from about 0.05% to about 15% (w/w) of an internal adhesion promoter to promote the adhesion of the active agent and the controlled release material,~~

~~wherein the internal adhesion promoter is selected from the group consisting of a cellulosic material, a surfactant, a carbomer and a mixture thereof, and~~

~~wherein the amount of active agent released from the solid dosage form after crushing is within 30% of the amount of active agent released from the solid dosage form before crushing when measured at 4 hours using a USP Type 2, Paddle Method at 50 rpm in 900 ml simulated gastric fluid without enzymes (SGF) with 0% ethanol at 37°C.~~

~~30~~ 29. The solid oral dosage form of claim 1, wherein the extraction at 60 minutes is less than about 90% based on both heated and unheated extraction tests, whereby the dosage form is mixed or crushed and mixed with 30 mL of a solvent selected from a group consisting of water, pH 3 buffer, pH 10 buffer, 40% ethanol, and cooking oil.