WHAT IS CLAIMED IS:

1. A process of manufacturing a multi-phasic, fast-dissolving dosage form for the delivery of a pharmaceutically active ingredient comprising the sequential steps of:

(a) dosing a formulation comprising a non-gelling matrix forming agent into a preformed mold;

(b) dosing a formulation comprising a gelling matrix forming agent into the preformed mold; and

(c) freeze drying the formulations dosed in steps (a) and (b) to form the multi-phasic, fast-dissolving dosage form.

2. The process according to claim 1, wherein the formulation of step (a) comprises a non-gelling matrix forming agent, mannitol and water.

3. The process according to claim 1, wherein the non-gelling matrix forming agent is selected from the group consisting of non-gelling gelatins, modified starches, and combinations thereof.

4. The process according to claim 3, wherein the at least one non-gelling gelatin is pullulan.

5. The process according to claim 1, wherein the non-gelling matrix forming agent is present in an amount ranging from about 1% to about 20% based on weight of the formulation of step (a).

6. The process according to claim 2, wherein the mannitol is present in an amount ranging from about 0% to about 10% based on weight of the formulation of step (a).

7. The process according to claim 2, wherein the water is present in an amount ranging from about 50% to about 98% based on weight of the formulation of step (a).

8. The process according to claim 1, wherein step (a) is conducted at a temperature ranging from about 2°C to about 20°C.

9. The process according to claim 1, wherein the formulation of step (b) comprises a gelling matrix forming agent, mannitol and water.

10. The process according to claim 1, wherein the gelling matrix forming agent is selected from the group consisting of gelling gelatins, or gelling polymers having a ratio of viscosity at 5°C over viscosity at 25°C of 4 or less, and combinations thereof.

11. The process according to claim 1, wherein the gelling matrix forming agent is present in an amount ranging from about 0.2% to about 15% based on weight of the formulation of step (b).

12. The process according to claim 8, wherein the mannitol is present in an amount ranging from about 1% to about 10% based on weight of the formulation of step (b).

13. The process according to claim 8, wherein the water is present in an amount ranging from about 50% to about 98% based on weight of the formulation of step (b).

14. The process according to claim 1, wherein step (b) is conducted at a temperature ranging from about 15°C to about 30°C.

15. The process according to claim 1, wherein step (c) comprises the sub-steps of (c1) freezing the formulations dosed in steps (a) and (b) within the

preformed molds; and (c2) freeze drying the formulations dosed in steps (a) and (b).

16. The process according to claim 1 further comprising repeating step (a) at least once prior to step (b).

17. The process according to claim 1 further comprising repeating step (b) at least once prior to step (c).

18. The process according to claim 15 further comprising repeating step (b) at least once prior to step (c).

19. A multi-phasic, fast-dissolving dosage form made according to the process of claim 1.

20. A multi-phasic, lyophilized, fast-dissolving dosage form for the delivery of a pharmaceutically active ingredient comprising:

(a) at least one gelled matrix layer; and

(b) at least one non-gelled matrix layer.

21. The multi-phasic, lyophilized, fast-dissolving dosage form according to claim 19, wherein the weight ratio of gelled matrix layer to non-gelled matrix layer is about 1:1.

CLAIMS

1. A process of manufacturing a multi-phasic, fast-dissolving dosage form for the delivery of a pharmaceutically active ingredient comprising, in the following order, the steps of:

(a) dosing a formulation comprising a non-gelling matrix forming agent into a preformed mold;

(b) dosing a formulation comprising a gelling matrix forming agent into the preformed mold; and

(c) freeze drying the formulations dosed in steps (a) and (b) to form the multi-phasic, fast-dissolving dosage form.

2. The process according to claim 1, wherein the formulation of step (a) comprises a non-gelling matrix forming agent, mannitol and water.

3. The process according to claim 1, wherein the non-gelling matrix forming agent is selected from the group consisting of non-gelling gelatins, modified starches, and combination thereof.

4. The process according to claim 3, wherein the at least one non-gelling gelatin is pullulan.

5. The process according to claim 1, wherein the non-gelling matrix forming agent is present in an amount ranging from 1% to 20% based on weight of the formulation of step (a).

6. The process according to claim 2, wherein the mannitol is present in an amount ranging from 0% to 10% based on weight of the formulation of step (a).

7. The process according to claim 2, wherein the water is present in an amount ranging from 50% to 98% based on weight of the formulation of step (a).

8. The process according to claim 1, wherein step (a) is conducted at a temperature ranging from 2°C to 20°C.

9. The process according to claim 1, wherein the formulation of step (b) comprises a gelling matrix forming agent, mannitol and water.

10. The process according to claim 1, wherein the gelling matrix forming agent is selected from the group consisting of gelling gelatines, gelling polymers having a ratio of bulk viscosity at 5°C over bulk viscosity at 25°C of at least 5, and combinations thereof.

11. The process according to claim 1, wherein the gelling matrix forming agent is present in an amount ranging from 0.2% to 15% based on weight of the formulation of step (b).

12. The process according to claim 9, wherein the mannitol is present in an amount ranging from 1% to 10% based on weight of the formulation of step (b).

13. The process according to claim 9, wherein the water is present in an amount ranging from 50% to 98% based on weight of the formulation of step (b).

14. The process according to claim 1, wherein step (b) is conducted at a temperature ranging from 15°C to 30°C.

15. The process according to claim 1, wherein step (c) comprises the sub-steps of (c1) freezing the formulations dosed in steps (a) and (b) within the preformed molds; and (c2) freeze drying the formulations dosed in steps (a) and (b).

16. The process according to claim 1 further comprising repeating step (a) at least once prior to step (b).

17. The process according to claim 1 further comprising repeating step (b) at least once prior to step (c).

18. The process according to claim 15 further comprising repeating step (b) at least once prior to step (c).

19. A multi-phasic, fast-dissolving dosage form made according to the process of claim 1.

20. A multi-phasic, lyophilized, fast-dissolving dosage form for the delivery of a pharmaceutically active ingredient, produced by the process of Claim 1, comprising:

(a) at least one gelled matrix layer; and

(b) at least one non-gelled matrix layer.

21. The multi-phasic, lyophilized, fast-dissolving dosage form according to claim 20, wherein the weight ration of gelled matrix later to non-gelled matrix layer is 1:1.