WHAT IS CLAIMED IS:

1. A hard capsule composite formulation comprising two or more pharmaceutically active ingredients, wherein each pharmaceutically active ingredient is contained in a multi-unit spheroidal tablet (MUST) having a diameter in a range of 1 to 4 mm and 4 to 40 MUSTs per each pharmaceutically active ingredient are encapsulated in the hard capsule.

2. The hard capsule composite formulation of claim 1, wherein each MUST has a diameter to thickness ratio in a range of 1:0.7 to 1:1.3.

3. The hard capsule composite formulation of claim 1, wherein the diameter of each MUST is less than or equal to 1/2 of the internal diameter of the hard capsule.

4. (Deleted)

5. The hard capsule composite formulation of claim 1, wherein each MUST has a thickness to cylinder height ratio in a range of 1:0.3 to 1:0.9.

6. The hard capsule composite formulation of claim 5, wherein the thickness to cylinder height ratio is in a range of 1:0.5 to 1:0.8.

7. (Deleted)

8. The hard capsule composite formulation of claim 1, wherein the hard capsule is hard capsule No. 0, hard capsule No. 1, hard capsule No. 2, hard capsule No. 3, or hard capsule No. 4.

9. The hard capsule composite formulation of claim 1, wherein each pharmaceutically active ingredient is selected from the group consisting of levocetirizine, montelukast, ambroxol, levodropropizine, losartan, ibersartan, amlodipine, rosuvastatin, atorvastatin, aspirin,

clopidogrel, aceclofenac, eperison, esomeprazole, naproxen, and pharmaceutically acceptable salts thereof.

10. The hard capsule composite formulation of claim 1, wherein each MUST comprises a pharmaceutically acceptable additive.

11. The hard capsule composite formulation of claim 10, wherein the pharmaceutically acceptable additive is selected from the group consisting of a pharmaceutically acceptable diluent, disintegrating agent, binder, stabilizer, lubricant, coloring agent, and a mixture thereof.

12. The hard capsule composite formulation of claim 1, wherein each MUST is coated with a polymer film coating layer.

13. The hard capsule composite formulation of claim 1, wherein one or more of the pharmaceutically active ingredients are immediately released.

14. The hard capsule composite formulation of claim 13, wherein one or more of the pharmaceutically active ingredients has an *in vitro* initial dissolution rate of 30% or more within 5 minutes from administration and an *in vitro* initial dissolution rate of 80% or more within 10 minutes from administration.

15. A method for preparing the hard capsule composite formulation of claim 1, which comprises:

(1) preparing a MUST having a diameter in a range of 1 to 4 mm which comprises a pharmaceutically active ingredient; and

(2) encapsulating 4 to 40 MUSTs in the hard capsule such that the hard capsule composite formulation comprises two or more pharmaceutically active ingredients.

16. The method of claim 15, which further comprises coating each MUST with a polymer film during step (1).

Claims

1. A hard capsule composite formulation comprising two or more pharmaceutically active ingredients selected from the group consisting of levocetirizine, montelukast, ambroxol, levodropropizine, losartan, amlodipine, rosuvastatin, aspirin, clopidogrel, and pharmaceutically acceptable salts thereof, wherein each pharmaceutically active ingredient is contained in a multi-unit spheroidal tablet (MUST) having a diameter to thickness ratio in a range of 1:0.7 to 1:1.3 and a plurality of the MUSTs per each pharmaceutically active ingredient are encapsulated in the hard capsule.

2. The hard capsule composite formulation of claim 1, wherein the diameter of each MUST is less than or equal to 1/2 of the internal diameter of the hard capsule.

3. The hard capsule composite formulation of claim 1, wherein each MUST has a diameter in a range of 1 mm to 4 mm.

4. The hard capsule composite formulation of claim 1, wherein each MUST has a thickness to cylinder height ratio in a range of 1:0.3 to 1:0.9.

5. The hard capsule composite formulation of claim 4, wherein the thickness to cylinder height ratio is in a range of 1:0.5 to 1:0.8.

6. The hard capsule composite formulation of claim 1, comprising 4 to 40 MUSTs per each pharmaceutically active ingredient.

7. The hard capsule composite formulation of claim 1, wherein the hard capsule is hard capsule No. 0, hard capsule No. 1, hard capsule No. 2, hard capsule No. 3, or hard capsule No. 4.

8. The hard capsule composite formulation of claim 1, wherein each MUST comprises a pharmaceutically acceptable additive.

9. The hard capsule composite formulation of claim 8, wherein the pharmaceutically acceptable additive is selected from the group consisting of a pharmaceutically acceptable diluent, disintegrating agent, binder, stabilizer, lubricant, coloring agent, and a mixture thereof.

10. The hard capsule composite formulation of claim 1, wherein each MUST is coated with a polymer film coating layer.

11. The hard capsule composite formulation of claim 1, wherein one or more of the pharmaceutically active ingredients are immediately released.

12. The hard capsule composite formulation of claim 11, wherein one or more of the pharmaceutically active ingredients has an *in vitro* initial dissolution rate of 30% or more within 5 minutes from administration and an *in vitro* initial dissolution rate of 80% or more within 10 minutes from administration.

13. A method for preparing the hard capsule composite formulation of claim 1, which comprises:

    (1) preparing a multi-unit spheroidal tablet (MUST) which has a diameter to thickness ratio in a range of 1:0.7 to 1:1.3 and comprises a pharmaceutically active ingredient selected from the group consisting of levocetirizine, montelukast, ambroxol, levodropropizine, losartan, amlodipine, rosuvastatin, aspirin, clopidogrel, and pharmaceutically acceptable salts thereof; and

    (2) encapsulating a plurality of the MUSTs in the hard capsule such that the hard capsule composite formulation comprises two or more pharmaceutically active ingredients.

14. The method of claim 13, which further comprises coating each MUST with a polymer film during step (1).