CLAIMS

1. A combination formulation comprising:

a first sustained-release composition, which comprises granules comprising metformin or a pharmaceutically acceptable salt thereof and a swellable polymer, and a water-insoluble polymer film for coating the granules; and

a second immediate-release composition comprising an HMG-CoA reductase inhibitor.

2. The combination formulation of claim 1, wherein the swellable polymer is at least one selected from the group consisting of hydroxypropyl methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, polyethylene oxide, carrageenan, natural gum, guar gum, tragacanth, acacia gum, locust bean gum, xanthan gum, polyvinyl alcohol, and polyvinylpyrrolidone.

3. The combination formulation of claim 1 or 2, wherein the swellable polymer has a viscosity of 100 cps or higher.

4. The combination formulation of any one of claims 1 to 3, wherein the water-insoluble polymer is at least one selected from the group consisting of methacrylic acid copolymer, ethylcellulose, cellulose acetate succinate, cellulose acetate phthalate, fatty acids, fatty acid esters, fatty acid alcohols, and waxes.

5. The combination formulation of claim 4, wherein the fatty acid and fatty acid ester are at least one selected from the group consisting of glyceryl palmitostearate, glyceryl stearate, glyceryl behenate, cetyl palmitate, glyceryl monooleate, stearic acid, and a mixture thereof;
the fatty acid alcohol is at least one selected from the group consisting of cetostearyl alcohol, cetyl alcohol, stearyl alcohol, and a mixture thereof; and
the wax is at least one selected from the group consisting of carnauba wax, beeswax, microcrystalline wax, and a mixture thereof.

6. The combination formulation of any one of claims 1 to 5, wherein metformin or a pharmaceutically acceptable salt thereof is contained in an amount from 250 mg to 1000 mg.

7. The combination formulation of any one of claims 1 to 6, wherein the water-insoluble polymer is contained in an amount from 1 wt% to 20 wt% based on the total weight of the first sustained-release composition.

8. The combination formulation of any one of claims 1 to 7, wherein the swellable polymer is contained in an amount from 1 wt% to 40 wt% based on the total weight of the first sustained-release composition.

9. The combination formulation of any one of claims 1 to 8, wherein the HMG-CoA reductase inhibitor is at least one selected from the group consisting of rosuvastatin, atorvastatin, pitavastatin, lovastatin, simvastatin, pravastatin, and fluvastatin.

10. The combination formulation of any one of claims 1 to 9, wherein the HMG-CoA reductase inhibitor is contained in an amount from 5 mg to 160 mg.

11. The combination formulation of any one of claims 1 to 10, wherein the second immediate-release composition is completely disintegrated in distilled water at 37°C within 5 minutes.

12. The combination formulation of any one of claims 1 to 11, the combination formulation is formulated so that physical contact or chemical reaction between the swellable polymer in the first sustained-release composition and the HMG-CoA reductase inhibitor is inhibited by the water-insoluble polymer film.

13. The combination formulation of any one of claims 1 to 12, wherein the combination formulation is an uncoated tablet, a film-coated tablet, a double-layer

tablet, a multi-layer tablet, or a core tablet and/or, wherein the first sustained-release composition and the second immediate-release composition are in a form of a double-layer tablet.

14. A method of preparing the combination formulation of any one of claims 1 to 13, comprising:

preparing the first sustained-release composition by preparing granules comprising metformin or a pharmaceutically acceptable salt thereof, and a swellable polymer, followed by forming a water-insoluble polymer film on the granules;

preparing the second immediate-release composition comprising an HMG-CoA reductase inhibitor; and

formulating the first sustained-release composition and the second immediate-release composition into a unit formulation.

15. The method of claim 14, further comprising forming a film layer on the external surface of the combination formulation.