CLAIMS

1. An oral composite tablet comprising:

an ezetimibe wet granule portion including ezetimibe; and

a rosuvastatin mixture portion including rosuvastatin or a pharmaceutically acceptable salt thereof,

wherein the ezetimibe wet granule portion includes, as a binder, povidone having a weight average molecular weight of 30,000 to 50,000 Da,

wherein the rosuvastatin mixture portion includes a diluent including a water-soluble diluent and a water-insoluble diluent, the water-insoluble diluent having a particle size (d90) of 98 μm to 229 μm corresponding to 90% in a cumulative particle size distribution of total particles,

wherein an amount of the water-insoluble diluent is from 2 parts to 10 parts by weight with respect to 1 part by weight of the rosuvastatin,

wherein the water-insoluble diluent is microcrystalline cellulose,

wherein an amount of the ezetimibe is in a range of 5 mg to 20 mg in a unit dosage form,

wherein an amount of the rosuvastatin or a pharmaceutically acceptable salt thereof is in a range of 2.5 mg to 40 mg as a free base in a unit dosage form, and

wherein the rosuvastatin mixture portion is in the form of a simple mixture or dry granules.

2. The oral composite tablet of claim 1, wherein the ezetimibe wet granule portion and the rosuvastatin mixture portion each further include a pharmaceutically acceptable additive selected from a diluent, a binder, a disintegrant, a glidant, and any combination thereof.

3. The oral composite tablet of claim 2, wherein

the diluent is selected from the group consisting of lactose, starch, mannitol, carboxymethyl cellulose, and any combination thereof,

the binder is selected from the group consisting of povidone,

hypromellose, hydroxypropyl cellulose, copovidone, and any combination thereof,

the disintegrant is selected from the group consisting of crospovidone, croscarmellose sodium, sodium starch glycolate, low-substituted hydroxypropyl cellulose, and any combination thereof, and

the glidant is selected from the group consisting of magnesium stearate, talc, light anhydrous silicic acid, sodium stearyl fumarate, and any combination thereof.

4. The oral composite tablet of claim 1, wherein the oral composite tablet is in the form of a single-layered tablet, a double-layered tablet, or a press-coated tablet.

5. The oral composite tablet of claim 1, wherein a dissolution rate of the ezetimibe is 90% or greater in 30 minutes at a temperature of 37.5°C in a sodium acetate buffer solution of a pH of 4.5 containing 0.45%(w/v) sodium lauryl sulfate, as measured at a paddle rotation speed of 75 rpm in a dissolution test of the oral composite tablet performed according to Dissolution method II in the Korean Pharmacopoeia.

6. The oral composite tablet of claim 1, wherein a dissolution rate of the ezetimibe is 20% or greater in 30 minutes at a temperature of 37.5°C in simulated gastric fluid (SGF) of a pH of 1.2, as measured at a paddle rotation speed of 50 rpm in a dissolution test of the oral composite tablet performed according to Dissolution method II in the Korean Pharmacopoeia.

7. The oral composite tablet of claim 1, wherein a total amount of rosuvastatin lactone-related compounds is less than 1.5%, as measured in a stress testing of the oral composite tablet under stressed conditions at a temperature of 60°C for 2 weeks.

8. A method of preparing the oral composite tablet according to any

one of claims 1 to 4 and 10, the method comprising:

preparing the ezetimibe wet granule portion by wet-granulating the ezetimibe together with a pharmaceutically acceptable additive including, as a binder, povidone having a weight average molecular weight of 30,000 to 50,000 Da; and

tableting the ezetimibe wet granule portion together with the rosuvastatin mixture portion including the rosuvastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable additive, wherein the pharmaceutically acceptable additive comprises a diluent including the water-soluble diluent and the water-insoluble diluent, the water-insoluble diluent having a particle size (d90) of 98 μm to 229 μm corresponding to 90% in a cumulative particle size distribution of total particles.