~~Claims~~

CLAIMS

1. A tablet comprising:

a ~~fimasartan granule portion~~first layer comprising granules comprising fimasartan, pharmaceutically acceptable salt thereof, hydrate thereof or solvate thereof, and pharmaceutically acceptable additive; and

~~an atorvastatin granule portion~~a second layer comprising granules comprising atorvastatin, pharmaceutically acceptable salt thereof, hydrate thereof or solvate thereof, and pharmaceutically acceptable additive,

~~wherein, the fimasartan granule portion and the atorvastatin granule portion are present while being separate from each other.~~

wherein, the granules of the second layer exhibit a particle size distribution with a D_{50} of 80 to 260 μm.

2. A tablet comprising:

a first layer comprising granules comprising fimasartan, pharmaceutically acceptable salt thereof, hydrate thereof or solvate thereof, and pharmaceutically acceptable additive; and

a second layer comprising granules comprising atorvastatin, pharmaceutically acceptable salt thereof, hydrate thereof or solvate thereof, and pharmaceutically acceptable additive,

wherein the granules of the second layer exhibit a particle size distribution with a D_{50} of 80 μm ~~or more.~~to 260 μm,

the additive of the second layer comprises a mixture of lactose hydrate and microcrystalline cellulose, and

the mixture of lactose hydrate and microcrystalline cellulose exhibits a particle size

distribution with a D_{50} of 75 μm to 200 μm.

3. The tablet of claim ~~2~~1, wherein the granules of the second layer exhibit a particle size distribution with a D_{10} of 14 to 70 μm.

4. The tablet of claim ~~2~~1, wherein the granules of the second layer exhibit a particle size distribution with a D_{90} of 290 to 600 μm.

5. The tablet of claim ~~2~~1, wherein the tablet is a bilayer tablet.

6. The tablet of claim ~~2~~1, wherein the fimasartan, pharmaceutically acceptable salt thereof, hydrate thereof or solvate thereof is comprised in an amount of 0.5 to 240.0 mg per unit dosage form.

7. The tablet of claim ~~2~~1, wherein the atorvastatin, pharmaceutically acceptable salt thereof, hydrate thereof or solvate thereof is comprised in an amount of 1.0 to 100.0 mg per unit dosage form.

8. The tablet of claim ~~2~~1, wherein the additives of the first and second layers are any one selected from the group consisting of excipient, solubilizing agent, disintegrant, binder, lubricant and mixture thereof.

9. The tablet of claim ~~2~~1, wherein the granules of the second layer comprise a mixture of lactose hydrate and microcrystalline cellulose, and wherein the mixture is comprised in an amount of 40 to 50 wt% based on the total weight of the granules of the second layer.

10. The tablet of claim 9, wherein the granules of the second layer further comprise precipitated calcium carbonate.

11. The tablet of claim 9, wherein the mixture of lactose hydrate and microcrystalline cellulose exhibits a particle size distribution with a D_{50} of 75 μm ~~or more~~to 200 μm.

12. The tablet of claim ~~2~~1, wherein the granules of the second layer comprise 1 to 10 parts by weight of atorvastatin, pharmaceutically acceptable salt thereof, hydrate thereof or solvate thereof, 50 to 99.9 parts by weight of excipient, 0.1 to 2 parts by weight of solubilizing agent, 0.5 to 15 parts by weight of disintegrant, 0.1 to 10 parts by weight of binder, and 0.1 to 5 parts by weight of lubricant.

13. The tablet of claim 12, wherein the excipient is any one of precipitated calcium carbonate, lactose hydrate, microcrystalline cellulose, or a mixture thereof.

14. The tablet of claim 13, wherein the mixture comprises 30 to 50 parts by weight of precipitated calcium carbonate, 20 to 40 parts by weight of lactose hydrate, and 15 to 35 parts by weight of microcrystalline cellulose.

15. The tablet of claim ~~2~~1, wherein the tablet further comprises a coating layer.

16. The tablet of claim ~~2~~1, wherein the granules of the first and second layers are wet granules.

17. A method of preparing a tablet, the method comprising:

(S1) preparing a first layer comprising granules which comprise fimasartan, pharmaceutically acceptable salt thereof, hydrate thereof or solvate thereof, and pharmaceutically acceptable additive;

(S2) preparing a second layer comprising granules which comprise atorvastatin, pharmaceutically acceptable salt thereof, hydrate thereof or solvate thereof, and pharmaceutically acceptable additive; and

(S3) preparing a bilayer tablet by tableting the first and the second layers~~.~~,

wherein the granules of the second layer exhibit a particle size distribution with a D_{50} of 80 to 260 μm.

18. The method of claim 17, wherein the tableting of the ~~fimasartan granule portion~~first and ~~the atorvastatin granule portion~~second layers is performed by applying a tableting pressure of 5 to 15 KN.

19. The tablet of claim ~~2~~1, wherein the tablet is for treating cardiovascular diseases.

20. ~~A method of preventing or treating cardiovascular diseases, the method comprising administering a therapeutically effective~~ The tablet of claim 2, wherein the mixture of lactose hydrate and microcrystalline cellulose is comprised in an amount of ~~the tablet of claim 2, to mammals including human.~~

~~21. Use of~~ 40 to 50 wt% based on the ~~tablet~~total weight of ~~claim 2 in~~ the ~~manufacture of a formulation for preventing or treating cardiovascular diseases.~~

~~22. Use~~granules of the second layer.

21. The tablet of claim ~~2 for preventing or treating cardiovascular diseases.~~

~~23. The tablet of any one of claims~~ 19 ~~to 22~~, wherein the cardiovascular disease is any one selected from hypertension, diabetes, obesity, hyperlipidemia, coronary artery disease, chronic stable angina, vasospastic angina, stroke, myocardial infarction, temporary ischemic attack, congestive heart failure, insulin resistance, impaired glucose tolerance, prediabetes, type 2 diabetes mellitus, diabetic nephropathy, dyslipidemia, cognitive decline, dementia, and combinations thereof.

22. The tablet of claim 1, wherein the additive of the second layer comprises a mixture of lactose hydrate and microcrystalline cellulose.