【CLAIMS】

【Claim 1】

A pharmaceutical combination preparation comprising ezetimibe or a pharmaceutically acceptable salt thereof, and losartan or a pharmaceutically acceptable salt thereof,

wherein when the pharmaceutical combination preparation is dissolved in a solution of pH 4.0 to 5.0 without surfactant for 10 minutes, the dissolved amount of the losartan is 5,700 μg or less, and the dissolved amount of the ezetimibe is 270 μg or more,

the dissolution in a solution of pH 4.0 to 5.0 is carried out under the conditions of a temperature of 37 °C and a paddle method of 50 rpm in 500 mL of acetate buffer according to United States Pharmacopoeia for the pharmaceutical combination preparation comprising 20 mg of ezetimibe and 183 mg of losartan,

the ezetimibe or a pharmaceutically acceptable salt thereof and the losartan or a pharmaceutically acceptable salt thereof are each present in a granular form,

the granule comprising the ezetimibe or a pharmaceutically acceptable salt thereof has a content of 15% by weight or less of granule having a diameter of more than 250 μm,

the granule comprising the losartan or a pharmaceutically acceptable salt thereof has a content of 35 to 55% by weight of granule having a diameter of more than 250 μm, and has a content of 10 to 30% by weight of granule having a diameter of more than 500 μm, and

the granule comprising the losartan or a pharmaceutically acceptable salt thereof further comprises 10 to 25 parts by weight of disintegrant, based on 100 parts by weight of losartan.

~~【Claim 2】~~

~~The pharmaceutical combination preparation according to claim 1, wherein the dissolution in a solution of pH 4.0 to 5.0 is carried out under the conditions of a temperature of 37 °C and a paddle method of 50 rpm in 500 mL of acetate buffer according to United States Pharmacopoeia for the pharmaceutical combination preparation comprising 20 mg of ezetimibe and 183 mg of losartan.~~

【Claim ~~3~~2】

The pharmaceutical combination preparation according to claim 1, wherein when the pharmaceutical combination preparation is dissolved in a solution of pH 4.0 to 5.0 for 10 minutes, the dissolved amount of losartan is 5,200 μg or less, and the dissolved amount of the ezetimibe is 300 μg or more.

~~【Claim 4】~~

~~The pharmaceutical combination preparation according to claim 1, wherein the ezetimibe or a pharmaceutically acceptable salt thereof and the losartan or a pharmaceutically acceptable salt thereof are physically separated from each other.~~

~~【Claim 5】~~

~~The pharmaceutical combination preparation according to claim 4, wherein the ezetimibe or a pharmaceutically acceptable salt thereof and the losartan or a pharmaceutically acceptable salt thereof are each present in a granular form.~~

~~【Claim 6】~~

~~The pharmaceutical combination preparation according to claim 5, wherein the granule comprising the ezetimibe or a pharmaceutically acceptable salt thereof has a content of 15% by weight or less of granule having a diameter of more than 250 μm.~~

~~【Claim 7】~~

~~The pharmaceutical combination preparation according to claim 5, wherein the granule comprising the losartan or a pharmaceutically acceptable salt thereof has a content of 35 to 55% by weight of granule having a diameter of more than 250 μm, and has a content of 10 to 30% by weight of granule having a diameter of more than 500 μm.~~

【Claim ~~8~~3】

The pharmaceutical combination preparation according to claim 1, wherein the pharmaceutical combination preparation includes 5 to 10 mg of the ezetimibe or a pharmaceutically acceptable salt thereof as converted into the form of ezetimibe free acid, and includes 40 to 100 mg of the losartan or a pharmaceutically acceptable salt thereof as converted into the form of losartan free acid.

【Claim ~~9~~4】

The pharmaceutical combination preparation according to claim ~~5~~1, wherein the granule comprising the ezetimibe or a pharmaceutically acceptable salt thereof further comprises a solubilizing agent.

【Claim ~~10~~5】

The pharmaceutical combination preparation according to claim ~~9~~4, wherein the solubilizing agent is sodium lauryl sulfate.

【Claim ~~11~~6】

The pharmaceutical combination preparation according to claim ~~9~~4, wherein the solubilizing agent is included in the granule comprising the ezetimibe or a pharmaceutically acceptable salt thereof, in an amount of 5 to 50 parts by weight, based on 100 parts by weight of ezetimibe.

~~【Claim 12】~~

~~The pharmaceutical combination preparation according to claim 5, wherein the granule comprising the losartan or a pharmaceutically acceptable salt thereof further comprises 1 to 30 parts by weight of disintegrant, based on 100 parts by weight of losartan.~~

【Claim ~~13~~7】

The pharmaceutical combination preparation according to claim 1, wherein the pharmaceutical combination preparation is present in the form of a bilayer tablet consisting of:

a first layer comprising the ezetimibe or a pharmaceutically acceptable salt thereof; and

a second layer comprising the losartan or a pharmaceutically acceptable salt thereof.

【Claim ~~14~~8】

The pharmaceutical combination preparation according to claim 1, wherein the pharmaceutical combination preparation further comprises amlodipine or a pharmaceutically acceptable salt thereof, and rosuvastatin or a pharmaceutically acceptable salt thereof,

~~A~~the pharmaceutical combination preparation ~~having~~is present in the form of a bilayer tablet consisting of:

a first layer comprising ezetimibe or a pharmaceutically acceptable salt thereof, amlodipine or a pharmaceutically acceptable salt thereof, and rosuvastatin or a pharmaceutically acceptable salt thereof; and

a second layer comprising losartan or a pharmaceutically acceptable salt thereof,

wherein when the pharmaceutical combination preparation is dissolved in a solution of pH 4.0 to 5.0 without surfactant for 10 minutes, the dissolved amount of the losartan is 5,700 μg or less, and the dissolved amount of the ezetimibe is 270 μg or more,

the ezetimibe or a pharmaceutically acceptable salt thereof is included in a granular form in the first layer, and the losartan or a pharmaceutically acceptable salt thereof is included in a granular form in the second layer,

the granule comprising the ezetimibe or a pharmaceutically acceptable salt thereof has a content of 15% by weight or less of granule having a diameter of more than 250 μm,

the granule comprising the losartan or a pharmaceutically acceptable salt thereof has a content of 35 to 55% by weight of granule having a diameter of more than 250 μm, and has a content of 10 to 30% by weight of granule having a diameter of more than 500 μm, and

the granule comprising the losartan or a pharmaceutically acceptable salt thereof further comprises 10 to 25 parts by weight of disintegrant, based on 100 parts by weight of losartan.

~~【Claim 15】~~

~~The pharmaceutical combination preparation according to claim 14, wherein the ezetimibe or a pharmaceutically acceptable salt thereof is included in a granular form in the first layer, and the losartan or a pharmaceutically acceptable salt thereof is included in a granular form in the second layer.~~