【CLAIMS】

【Claim 1】

Bitter taste-masked granules comprising besifovir dipivoxil or a pharmaceutically acceptable salt thereof, and being coated with a lipid excipient, wherein the lipid excipient is at least one fatty acid ester selected from the group consisting of glycerol distearate, glyceryl stearate, glyceryl oleate, glyceryl myristate, cetyl palmitate, cetyl caprate, stearyl palmitate, and stearyl stearate.

【Claim 2】

The bitter taste-masked granules according to claim 1, wherein the lipid excipient is present in an amount of 10 parts by weight to 70 parts by weight relative to 100 parts by weight of the besifovir dipivoxil or the pharmaceutically acceptable salt thereof.

【Claim 3】

The bitter taste-masked granules according to claim 1, wherein the lipid excipient is at least one fatty acid ester selected from the group consisting of glycerol distearate, glyceryl stearate, glyceryl oleate, and glyceryl myristate.

【Claim 4】

The bitter taste-masked granules according to claim 1, wherein intrinsic bitter taste of the besifovir dipivoxil or the pharmaceutically acceptable salt thereof is not sensed until more than 10 seconds have elapsed after putting an agent containing the besifovir dipivoxil or the pharmaceutically acceptable salt thereof in the mouth without any beverage or water.

【Claim 5】

A method of preparing bitter taste-masked granules comprising besifovir dipivoxil or a pharmaceutically acceptable salt thereof, and being coated with a lipid excipient, the method comprising:

melting the lipid excipient through heating to a temperature higher than or equal to a melting point of the lipid excipient, wherein the lipid excipient is at least one fatty acid ester

selected from the group consisting of glycerol distearate, glyceryl stearate, glyceryl oleate, glyceryl myristate, cetyl palmitate, cetyl caprate, stearyl palmitate, and stearyl stearate;

mixing the melt with the besifovir dipivoxil or the pharmaceutically acceptable salt thereof in a solid state; and

cooling the mixture.

【Claim 6】

The method according to claim 5, wherein cooling the mixture comprises cooling the mixture to a temperature of 10℃ to 40℃.

【Claim 7】

The method according to claim 5, further comprising:

sieving the cooled mixture after cooling the mixture.

【Claim 8】

A pharmaceutical composition comprising:

the bitter taste-masked granules according to any one of claims 1 to 4; and

a pharmaceutically acceptable additive.

【Claim 9】

The pharmaceutical composition according to claim 8, wherein the bitter taste-masked granules are present in an amount of 20 wt% to 70 wt% based on the total weight of the pharmaceutical composition.

【Claim 10】

The pharmaceutical composition according to claim 8, wherein the pharmaceutical composition is a tablet obtained by directly tableting a mixture of the bitter taste-masked granules and the pharmaceutically acceptable additive.

【Claim 11】

A method of preparing a pharmaceutical agent, comprising:

mixing a pharmaceutically acceptable additive with bitter taste-masked granules comprising besifovir dipivoxil or a pharmaceutically acceptable salt thereof and being coated with a lipid excipient, wherein the lipid excipient is at least one fatty acid ester selected from the group consisting of glycerol distearate, glyceryl stearate, glyceryl oleate, glyceryl myristate, cetyl palmitate, cetyl caprate, stearyl palmitate, and stearyl stearate; and

forming the mixture into an oral pharmaceutical agent.

【Claim 12】

The method according to claim 11, wherein the pharmaceutical agent is prepared by directly tableting the mixture.