Claims

1. An orally dispersible taste masking composition, which is tablet, granule or dry suspension, wherein the orally dispersible taste masking composition comprises vortioxetine hemihydrobromide and pharmaceutically acceptable taste masking excipients comprise alkaline excipients, the weight ratio of the vortioxetine hemihydrobromide to the taste masking excipients is 1:0.1-1:5..

2. The orally dispersible taste masking composition according to claim 1, further comprising granules in which the vortioxetine hemihydrobromide is coated with the taste masking excipients.

3. The orally dispersible taste masking composition according to claim 1, further comprising a solid dispersion in which the vortioxetine hemihydrobromide is dispersed in the taste masking excipients.

4. The orally dispersible taste masking composition according to claim 1, wherein the alkaline excipients selected from the group consisting of trisodium phosphate, disodium hydrogen phosphate, dipotassiumhydrogen phosphate, potassium carbonate, sodium carbonate, sodium bicarbonate, potassium citrate, sodium acetate, calcium hydroxide, sodium hydroxide, potassium hydroxide, and meglumine.

5. The orally dispersible taste masking composition according to claim 2, wherein the weight ratio of the vortioxetine hemihydrobromide to the alkaline excipient is 1:0.01-1:1.1.

6. The orally dispersible taste masking composition according to claim 3, wherein the weight ratio of the vortioxetine hemihydrobromide to the alkaline excipient is 1:0.01-1:1.1.

7. The orally dispersible taste masking composition according to claim 4, wherein the weight ratio of the vortioxetine hemihydrobromide to the alkaline

excipients is 1:0.01-1:1.1.

8. The orally dispersible taste masking composition according to claim 5, further comprising a solid dispersion in which the granules are dispersed in the taste masking excipients.

9. The orally dispersible taste masking composition according to claim 6, further comprising granules in which the solid dispersion is coated with the taste masking excipient.

10. The orally dispersible taste masking composition according to claim 1, wherein the orally dispersible taste masking composition has a crystalline form, and wherein the crystalline form has characteristic peaks at 4.2±0.2°, 14.5±0.2°, 17.4±0.2°, 19.2±0.2°, and 22.6±0.2°, when Cu-Kα radiation is used and the X-ray powder diffraction pattern is expressed at 2θ angles, the pharmaceutically acceptable taste masking excipients comprise polyacrylic resin IV.

11. The orally dispersible taste masking composition according to claim 1, further comprising a filler, a flavoring agent, a release regulator agent, a plasticizer, an anticaking agent, and/or a disintegrant agent.

12. A method for preparing the orally dispersible taste masking composition according to claim 1, wherein the composition comprising coated granules of vortioxetine hemihydrobromide, comprising:

(1) milling vortioxetine hemihydrobromide to obtain vortioxetine hemihydrobromide powder;

(2a) dispersing the taste masking excipients in a solvent; coating the vortioxetine hemihydrobromide powder with the taste masking excipients in the solvent through a fluid bed, whereby a mixture is formed; and removing the solvent from the mixture, whereby vortioxetine hemihydrobromide coated with the taste masking excipients is obtained; or

(2b) adding the vortioxetine hemihydrobromide powder and the taste

masking excipients to a solvent to form a suspension; and removing the solvent from the suspension through a fluid bed, spray drying or evaporation, whereby vortioxetine hemihydrobromide coated with the taste masking excipients is obtained;

whereby a composition comprising the coated vortioxetine hemihydrobromide is prepared.

13. A method for preparing the orally dispersible taste masking composition according to claim 1, wherein the composition comprising a solid dispersion of the vortioxetine hemihydrobromide, comprising:

(1) milling vortioxetine hemihydrobromide to obtain vortioxetine hemihydrobromide powder;

(2a) mixing the vortioxetine hemihydrobromide powder with the taste masking excipients, whereby a combination is formed; heating the combination at 50-150°C, whereby a softened or liquefied mixture is formed; cooling the softened or liquefied mixture, whereby a solidified mixture is formed; and milling the solidified mixture to obtain powder; or

(2b) dissolving the vortioxetine hemihydrobromide powder and taste masking excipients in a solvent, whereby a solution is formed; and removing the solvent from the solution by distillation, fluid bed or spray drying to obtain powder;

whereby a composition comprising the the powder obtained in step (2a) or (2b).

14. A method for preparing the orally dispersible taste masking composition according to claim 1, wherein the taste masking excipients comprise alkaline excipients, comprising:

(1) milling vortioxetine hemihydrobromide to obtain vortioxetine hemihydrobromide powder;

(2) mixing the vortioxetine hemihydrobromide powder with the alkaline excipients, whereby a taste masking combination is obtained; and

(3) preparing the taste masking combination as a composition.

15. The preparation method according to claim 12, wherein the weight ratio of vortioxetine hemihydrobromide to alkaline excipient is 1:0.01-1:1.1.

16. The preparation method according to claim 13, wherein the weight ratio of vortioxetine hemihydrobromide to alkaline excipient is 1:0.01-1:1.1.

17. The preparation method according to claim 14, wherein the weight ratio of vortioxetine hemihydrobromide to alkaline excipient is 1:0.01-1:1.1.

18. The orally dispersible taste masking composition according to claim 3, wherein the taste masking excipients comprise polyacrylic resin IV, wherein the orally dispersible taste masking composition has a crystalline form, and wherein the crystalline form has characteristic peaks at 4.2±0.2°, 14.5±0.2°, 17.4±0.2°, and 22.6±0.2° when Cu-Kα radiation is used and the X-ray powder diffraction pattern is expressed at 2θ angles.

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Use of vortioxetine hemihydrobromide in the manufacture of orally dispersible taste masking composition for treating depression disorder.

20. An orally dispersible taste masking composition, comprising vortioxetine hydrobromide and alkaline excipients, wherein the weight ratio of the vortioxetine hydrobromide to the alkaline excipient is 1:0.01-1:1.1, wherein the orally dispersible taste masking composition has a crystalline form, and wherein the crystalline form has characteristic peaks at 4.2±0.2°, 14.5±0.2°,17.4±0.2°, 19.2±0.2°, and 22.6±0.2°, when Cu-Kα radiation is used and the X-ray powder diffraction pattern is expressed at 2θ angles, the pharmaceutically acceptable taste masking excipients comprise polyacrylic resin IV.