Patent claims

1. A pharmaceutical composition comprising a granulate comprising brexpiprazole, wherein the granulate is obtained by wet-granulation of a carrier using a granulation liquid that is a solution of brexpiprazole in a solvent system.

2. A pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises 0.20 wt.% – 15 wt.% brexpiprazole.

3. The pharmaceutical composition of any one of the preceding claims, wherein the granulate is obtained using fluid-bed granulation.

4. The pharmaceutical composition of any one of the preceding claims, wherein the solution of brexpiprazole comprises brexpiprazole, a solvent system, a binder, and a optional surfactant.

5. The pharmaceutical composition of claim 4, wherein the solvent system is a mixture of acetone, ethanol, and water.

6. The pharmaceutical composition of claim 5, wherein acetone, ethanol, and water are used in a mass ratio 7.7:1:1.

7. The pharmaceutical composition of claim 4, wherein the surfactant is selected from polysorbate 80, poloxamer 188, sorbitan monooleate, polysorbate 60, or polyethylene glycol.

8. The pharmaceutical composition of claim 4, wherein the binder is selected from polyvinyl caprolactam-polyvinyl acetate-polyethylene glycol copolymer, polyvinylpyrrolidone, hydroxypropyl methylcellulose, hydroxypropylcellulose, or Arabic gum.

9. The pharmaceutical composition of claims 1–8, wherein the carrier is selected from lactose monohydate, magnesium aluminum silicate, microcrystalline cellulose, isomalt, mannitol, dibasic calcium phosphate, or a mixture thereof, or a pellet.

10. Granulate comprising brexpiprazole obtained by wet-granulation of a carrier using a granulation liquid, wherein the granulation liquid comprises a solution of brexpiprazole in a solvent system.

11. The granulate of claim 10, wherein the carrier, solution of brexpiprazole, and solvent system are as defined in claims 1–9.

12. Unit dosage form comprising the pharmaceutical composition as defined in claims 1–9.

13. Method for manufacturing a pharmaceutical composition comprising brexpiprazole with the following steps:

a) Preparation of a solution of binder, brexpiprazole and optional surfactant in a solvent system.

b) Wet-granulation of a carrier with the solution obtained in a).

14. Method of claim 13, wherein the solvent system is a mixture of acetone, ethanol, and water.

15. Method of claims 13 or 14, wherein the carrier, binder and surfactant are as defined in any one of the preceding claims.

16. Method of claims 13–15, wherein the wet-granulation is fluid-bed granulation.

17. Use of a wet-granulation process with a solution of brexpiprazole as the granulation liquid, in preparation of a pharmaceutical composition comprising brexpiprazole.