

CLAIMS

1. A solid pharmaceutical composition in the form of an immediate release tablet, comprising:
 - 5 i. pregabalin particles having a particle size distribution with a D(50) from 100 μm to 420 μm , and/or pregabalin particles having a particle size distribution with a D(90) from 300 μm to 850 μm ,
 - ii. at least one filler, and
 - iii. at least one lubricant,
- 10 wherein the immediate release tablet is prepared by direct compression.
2. The solid pharmaceutical composition according to claim 1, wherein the pregabalin particles (i) are characterized by having a particle size distribution with a D(50) from 120 μm to 400 μm .
- 15 3. The solid pharmaceutical composition according to any of the preceding claims, wherein the pregabalin particles (i) are characterised by having a particle size distribution with D(90) from 320 μm to 800 μm .
- 20 4. The solid pharmaceutical composition according to any of the preceding claims, wherein the filler (ii) is a cellulose derivative, preferably characterized by having particles size distribution of D(50) below 200 μm .
- 25 5. The solid pharmaceutical composition according to claim 4, wherein the cellulose derivative is selected from methyl cellulose, microcrystalline cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, and mixtures thereof, preferably the cellulose derivate is microcrystalline cellulose.
- 30 6. The solid pharmaceutical composition according to any of the preceding claims, wherein the filler is not lactose or an alkaline earth phosphate.

7. The solid pharmaceutical composition according to any the preceding claims, wherein the lubricant (iii) is an alkaline stearate.
- 5 8. The solid pharmaceutical composition according to claim 7, wherein the alkaline stearate is selected from magnesium stearate, calcium stearate and mixtures thereof, preferably the alkaline stearate is magnesium stearate.
- 10 9. The solid pharmaceutical composition according to any of the preceding claims, wherein the lubricant (iii) is not an α -amino acid.
- 15 10. The solid pharmaceutical composition according to anyone of the preceding claims, wherein the filler (ii) is present in an amount from 45% to 80% by weight, based on the total weight of the composition, preferably in an amount from 45% to 70%, based on the total weight of the composition.
- 20 11. The solid pharmaceutical composition according to any of the preceding claims, wherein the pregabalin particles (i) are present in amount from 15% to 50% by weight, based on the total weight of the composition, preferably from 25% to 45% by weight, based on the total weight of the composition.
- 25 12. The solid pharmaceutical composition according to any of the preceding claims, wherein the tablets are coated with a functional polymer, which acts as a filmogenic agent.
- 30 13. The solid pharmaceutical composition according to any of the preceding claims, wherein the content of degradation products is less than 0.20% by weight, preferably less than 0.10% by weight based on the total weight of the composition.

14. A process for preparing the solid pharmaceutical composition according to any of the preceding claims, comprising at least the following steps:
- 5 a) Providing pregabalin particles having a particle size distribution with a D(50) from 100 to 420 μm and/or a D(90) from 300 μm to 850 μm , and at least one filler;
 - b) Mixing the ingredients of step a) in a suitable mixer to achieve a homogeneous mixture; and
 - c) Mixing the blend of step b) with at least one lubricant, until a homogeneous powder is obtained;
 - 10 d) Compressing the powder mixture of step c) into tablets
 - e) Optionally, coating the tablets of step d), with a functional polymer which acts as a filmogenic agent.
15. A process for preparing according to claim 14, wherein the pregabalin particles of step a) have a D(50) from 120 to 400 μm and/or a D(90) from 320 μm to 800 μm