Claims

1. An extrudable polyvinyl alcohol (PVA) powder with improved flowability, consisting of particles consisting of PVA, which has been cryo-milled, and which has d_{50} particle sizes in the range of 45 to 1400 µm.

2. An extrudable polyvinyl alcohol (PVA) powder with improved flowability, consisting of particles consisting of PVA, which has been cryo-milled, and which has a particle size distribution of d_{10}=20±10 µm, d_{20}=30±10 µm, d_{50}=70±10 µm, d_{90}=200±30 µm, and d_{99}=300±30 µm.

3. The polyvinyl alcohol according to claim 1, which has been extruded.

4. The polyvinyl alcohol according to claim 1 having a viscosity ≤ 40 mPa.s, the viscosity being measured on 4 % w/v aqueous solution at 20°C DIN 53015.

5. The polyvinyl alcohol according to claim 1, which is selected from the group consisting of PVA 3-88, PVA 4 -88, PVA 5-74, PVA 5-88, PVA 8-88, and PVA 18-88.

6. The polyvinyl alcohol according to claim 1, which is capable of providing uninterrupted feeding and dosing during processing.

7. A powdery composition for the preparation of pharmaceutical formulations, comprising the polyvinyl alcohol according to claim 1 homogeneously mixed with at least one active pharmaceutical ingredient (API).

8. The powdery composition according to claim 7, comprising at least one additive selected from the group consisting of plasticizers, surface active materials, antioxidants, stabilizing agents, solubility-enhancing agents, pH control agents and flow regulators.

9. The powdery composition according to claim 7, which is a pharmaceutical grade powder comprising one or more further excipient(s) with d_{50} particle sizes in the range of 45 µm to 1400 µm.

10. The powdery composition according to claim 7, which is a pharmaceutical grade powder comprising one or more further excipient(s) having a particle size distribution of d_{10}=20±10 µm, d_{20}=30±10 µm, d_{50}=70±10 µm, d_{90}=200±30 µm, d_{99}=300±30 µm.

11. A process for producing a solid pharmaceutical dosage form, comprising extruding or forming a homogeneous melt of a mixture of ingredients comprising the cryo-milled powdered polyvinyl alcohol according to claim 1 and at least one active pharmaceutical ingredient (API), and forming a powder or a molded form.

12. The process according to claim 11, comprising continuously and evenly feeding the mixture of ingredients into a feeder line of an extruder, processing said mixture to a homogeneous melt, and then shaping the melt.

13. A process for producing a solid pharmaceutical dosage form according to claim 11, comprising

a) cryo-milling the polyvinyl alcohol (PVA) to a powder having d_{50} particle sizes in the range of 45 to 1400 µm, and

b) homogeneously mixing the resultant powder with at least one active pharmaceutical ingredient, and optionally with at least one additive selected from the group consisting of plasticizers, surface active materials, antioxidants, stabilizing agents, solubility-enhancing agents, pH control agents and flow regulators, thereby forming a powdery composition, and

c) evenly feeding said composition into a feeder line of an extruder followed by processing to a homogeneous melt, and shaping.

14. A process according to claim 11, wherein the polyvinyl alcohol (PVA) is cryo-milled to a powder having a particle size distribution of d_{10}=20±10 µm, d_{20}=30±10 µm,

d_{50}=70±10 µm, d_{90}=200±30 µm, and d_{99}=300±30 µm.

15. A process according to claim 11, wherein the polyvinyl alcohol (PVA) has a viscosity ≤40 mPa.s, the viscosity being measured on 4 % w/v aqueous solution at 20°C DIN 53015, and which is cryo-milled to a powder having a particle size distribution of d_{10}=20±10 µm, d_{20}=30±10 µm, d_{50}=70±10 µm, d_{90}=200±30 µm, and d_{99}=300±30 µm, and wherein optionally the particle size distribution is adjusted by combining respective sieve fractions.

16. A process according to claim 11, wherein the polyvinyl alcohol (PVA) is selected from the group consisting of PVA 3-88, PVA 4 -88, PVA 5-74, PVA 5-88, PVA 8-88, and PVA 18-88, and which is cryo-milled to a powder having a particle size distribution of d_{10}=20±10 µm, d_{20}=30±10 µm, d_{50}=70±10 µm, d_{90}=200±30 µm, and d_{99}=300±30 µm, and wherein optionally the particle size distribution is adjusted by combining respective sieve fractions.

17. A solid pharmaceutical dosage form that has been obtained by the process according to claim 11.

18. A process for producing a solid pharmaceutical dosage form according to claim 12, comprising
a) cryo-milling the polyvinyl alcohol (PVA) to a powder having d_{50} particle sizes in the range of 45 to 1400 µm, and
b) homogeneously mixing the resultant powder with at least one active pharmaceutical ingredient, and optionally with at least one additive selected from the group consisting of plasticizers, surface active materials, antioxidants, stabilizing agents, solubility-enhancing agents, pH control agents and flow regulators, thereby forming a powdery composition, and
c) evenly feeding said composition into a feeder line of an extruder followed by processing to a homogeneous melt, and shaping.

19. The polyvinyl alcohol according to claim 1, which has particle sizes in the range of 50 to 300 µm.

20. The polyvinyl alcohol according to claim 1, which has a particle size distribution of d_{10}=20±10 µm, d_{50}=70±10 µm and d_{90}=200±30 µm.

21. The polyvinyl alcohol according to claim 1, which has a particle size distribution of d_{10}=17.25±10 µm, d_{50}=63.74±10 µm and d_{90}=169.91±30 µm.