Claims

1. Extrudable polyvinyl alcohol (PVA) powder with improved flowability, which is milled and which has particle sizes in the range of 45 to 1400 µm, preferably in the range of 45 to 1000 µm, most preferred in the range of 50 to 300 µm and which is hot melt extrudable or melt extrudable.

2. Polyvinyl alcohol (PVA) according to claim 1, 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, and wherein optionally the particle size distribution is adjusted by combining respective sieve fractions.

3. Polyvinyl alcohol according to claim 1 or 2 having a viscosity ≤ 40 mPa.s, the viscosity being measured on 4 % w/v aqueous solution at 20°C DIN 53015.

4. Polyvinyl alcohol according to one or more of the claims 1 to 3, which is selected from the group PVA 3-88, PVA 4 -88, PVA 5-74, PVA 5-88, PVA 8-88, and PVA 18-88.

5. Powdered polyvinyl alcohol according to one or more of the claims 1 to 4, which is a suitable carrier for the preparation of pharmaceutical formulations and which is a milled powder showing an improved flowability enabling an uninterrupted feeding and dosing during processing.

6. A powdery composition for the preparation of pharmaceutical formulations, comprising polyvinyl alcohol according to one or more of the claims 1 to 5 as carrier, which is homogeneously mixed with at least one active pharmaceutical ingredient (API), whereby this mixture is storage and transport-stable, showing an improved flowability, and leading to an uninterrupted feeding and dosing during processing.

7. A powdery composition according to claim 6, comprising at least one additive selected from the group plasticizer, surface active material,

antioxidant, stabilizing agent, solubility-enhancing agents, pH control agents and flow regulators.

8. A powdery composition according to claim 6 or 7, which is a milled pharmaceutical grade powder comprising polyvinyl alcohol and optionally one or more further excipient(s) with particle sizes in the range of 45 µm to 1400 µm, preferably in the range of 45 to 1000 µm, most preferred in the range of 50 to 300 µm.

9. A powdery composition according to claim 6 or 7, which is a milled pharmaceutical grade powder comprising polyvinyl alcohol, comprising optionally 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.

10. A process for producing a solid pharmaceutical dosage form, characterized in that the mixture of ingredients including the powdered polyvinyl alcohol according to claims 1 to 5 or including the powdery composition according to claims 6 to 9 is processed in an extruder to a homogeneous melt, and then shaping the feeds either to a powder or molded forms.

11. A process according to claim 10 characterized in that the mixture of ingredients including the powdered polyvinyl alcohol according to claims 1 to 4 or including the powdery composition according to claims 5 to 8 is continuously and evenly fed into the feeder line of the extruder and that it is processed to a homogeneous melt, and that the feed is then shaped.

12. A process for producing a solid pharmaceutical dosage form according to claim 10 and/or claim 11, characterized in that
a) polyvinyl alcohol (PVA) having pharmaceutical grade is milled to a powder having particle sizes in the range of 45 to 1400 µm, preferably in the range of 45 to 1000 µm, most preferred in the range of 50 – 300 µm, and
b) that this powder is homogeneously mixed with at least one active

pharmaceutical ingredient, and optionally with at least one additive selected from the group plasticizer, surface active material, antioxidant, stabilizing agent, solubility-enhancing agents, pH control agents and flow regulators and

c) that this powdery composition is evenly fed into the feeder line of the extruder followed by processing to a homogeneous melt, and shaping this feed.

13. A process according to one or more of the claims 10 to 12, characterized in that polyvinyl alcohol (PVA) having pharmaceutical grade is 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, d_{99}=300±30 µm.

14. A process according to one or more of the claims 10 to 13, characterized in that solid polyvinyl alcohol (PVA) having pharmaceutical grade, and which is characterized having a viscosity ≤40 mPa.s, the viscosity being measured on 4 % w/v aqueous solution at 20°C DIN 53015, is 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, d_{99}=300±30 µm, and wherein optionally the particle size distribution is adjusted by combining respective sieve fractions.

15. A process according to one or more of the claims 10 to 14, characterized in that polyvinyl alcohol (PVA) having pharmaceutical grade, selected from the group PVA 3-88, PVA 4 -88, PVA 5-74, PVA 5-88, PVA 8-88, and PVA 18-88, is 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, d_{99}=300±30 µm, and wherein optionally the particle size distribution is adjusted by combining respective sieve fractions.

16. Solid pharmaceutical dosage form obtainable by a process according to the claims 10 to 15.