Claims

1. Use of spray-dried sorbitol as plasticizer in polyvinyl alcohol (PVA) containing compositions for hot melt extrusion (HME) or melt extrusion processes.

2. Use of spray-dried sorbitol as plasticizer in polyvinyl alcohol (PVA) containing compositions for the production of pharmaceutical formulations in form of amorphous solid dispersions of active pharmaceutical ingredients processed by hot melt extrusion (HME) or melt extrusion.

3. The use according to claim 1 or claim 2, characterized in that the applied spray-dried sorbitol reduces the glass transition temperature T_g and the melting temperature T_m of polymer containing compositions in hot melt extrusion (HME) or melt extrusion processes.

4. The use according to one or more of the claims 1 to 3, characterized in that the applied spray-dried sorbitol reduces the melting viscosity of the polymer containing thermoplastic composition.

5. The use according to one or more of the claims 1 to 4, characterized in that the applied spray-dried sorbitol stabilizes thermal instable active pharmaceutical ingredients (APIs) and reduces their thermal degradation.

6. The use according to one or more of the claims 1 to 5, characterized in that the sorbitol acts as solubilization-enhancer for the applied poorly water-soluble API during hot melt extrusion (HME) or melt extrusion and as stabilizer for the produced amorphous solid dispersion of the API in the polymer matrix.

7. The use according to one or more of the claims 1 to 6, characterized in that the spray-dried sorbitol is applied in a polymer containing composition wherein
a) the spray-dried sorbitol is contained in a weight percentage amount

in the range of 15 – 50 %,

b) the polymer is contained in a weight percentage amount in the range of 50 – 85 %

and

c) the API is contained in a weight percentage amount in the range of 0,01 – 40 %,

with the proviso that the sum of all ingredients of the composition add up to 100%.

8. A powdery composition, comprising polyvinyl alcohol, and a spray-dried sorbitol as plasticizer, at least one active pharmaceutical ingredient and optionally one or more additives, selected from the group consisting of a surface active material, an anti-oxidant, stabilizing agent, solubility-enhancing agents, pH control agents and flow regulators,

which is obtained by the steps of

a. physical blending or granulating of the ingredients into a homogeneous mixture,

b. hot melt extrusion or melt extrusion

and

c. subsequent confectioning into a powder.

9. The powdery composition according to claim 8, which is a long-term stable amorphous solid dispersion of at least one active pharmaceutical ingredient in a carrier matrix of a thermoplastic polymer and of at least one spray-dried sorbitol.

10. Process for the production of a powdery composition according to one or more of the claims 8 and 9, characterized in that

a) at least one thermoplastic polymer, a spray-dried sorbitol, at least one active pharmaceutical ingredient and optionally one or more additives, selected from the group consisting of a surface active material,

an anti-oxidant, stabilizing agent, solubility-enhancing agents, pH control agents and flow regulators, are processed into a homogeneous mixture by physical blending or granulating,

which is

b) processed by hot melt extrusion or melt extrusion,
whereby an amorphous solid dispersion of the API in the carrier matrix of a thermoplastic polymer and of at least one spray-dried sorbitol is built
and
c) subsequently confectioned into a powder.

11. The process according to claim 10, characterized in that polyvinyl alcohol, spray-dried sorbitol and at least one active pharmaceutical ingredient and optionally one or more additives, selected from the group consisting of a surface active material, an anti-oxidant, stabilizing agent, solubility-enhancing agents, pH control agents and flow regulators, are processed into a homogeneous mixture by physical blending or granulating, which is then processed by hot melt extrusion or melt extrusion at a temperature ≤ 160 °C and confectioned into a powder.