Claims

1. Use of low molecular weight amino polyol 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 processes.

2. Use according to claim 1, characterized in that the amino polyol is an amino sugar, selected from the group D-glucosamine, D-galactosamnine, mannosamine, D-fucosamine, N-acetyl-D-fucosamine, N-acetyl-D-glucosamine, N-acetyllactosamine, N-acetylmannosamine, meglumine (D-(-)-N-methylglucamine) and sialic acid.

3. Use according to claims 1 or 2 characterized in that the applied amino polyol is meglumine (D-(-)-N-methylglucamine).

4. Use according to one or more of the claims 1 to 3, characterized in that the applied amino polyol 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.

5. Use according to one or more of the claims 1 to 4, characterized in that the applied amino polyol reduces the melting viscosity of the polymer containing thermoplastic composition.

6. Use according to one or more of the claims 1 to 5, characterized in that the applied amino polyol stabilizes thermal instable active pharmaceutical ingredients (APIs) and reduces their thermal degradation.

7. Use according to one or more of the claims 1 to 6, characterized in that the amino polyol acts as solubilisation-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.

8. Use according to one or more of the claims 1 to 7, characterized in that the applied amino polyol acts as solubilisation-enhancer for the acidic APIs.

9. Use according to one or more of the claims 1 or 4 to 8, characterized in that the applied amino polyol is meglumine.

10. Use according to one or more of the claims 1 to 9, characterized in that the amino polyol is applied in a polymer containing composition wherein
    a) the amino polyol is contained in a weight percentage amount in the range of 15 – 30%,
    b) the polymer is contained in a weight percentage amount in the range of 50 – 70%
    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%.

11. A powdery composition produced by hot melt extrusion, comprising at least polyvinyl alcohol as thermoplastic polymer, and at least one amino sugar, selected from the group D-glucosamine, D-galactosamine, mannosamine, D-fucosamine, N-acetyl-D-fucosamine, N-acetyl-D-glucosamine, N-acetyllactosamine, N-acetylmannosamine, meglumine (D-(-)-N-methylglucamine) and sialic acid as plasticizer, at least one active pharmaceutical ingredient and optionally one or more additives, selected from the group surface active material, 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.

12. A powdery composition according to claim 11, comprising polyvinyl alcohol as thermoplastic polymer in combination with meglumine as plasticizer and at least one active pharmaceutical ingredient.

13. A powdery composition according to claim 10 or claim 12, 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 amino sugar.

14. Process for the production of a powdery composition according to one or more of the claims 11, 12 or 13, characterized in that
    a) at least one thermoplastic polymer, at least one amino sugar, at least one active pharmaceutical ingredient and optionally one or more additives, selected from the group surface active material, 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 amino sugar is built
    and
    c) subsequently confectioning into a powder.

15. Process according to claim 14, characterized in that polyvinyl alcohol, meglumine and at least one active pharmaceutical ingredient and optionally one or more additives, selected from the group surface active material, 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 ≤ 150 °C and confectioned into a powder.