wherein the polymer is hypromellose acetate succinate (HPMCAS) or Copovidone (PVP VA 64).

Another aspect of the disclosure is a pharmaceutical preparation containing the solid dispersion as defined herein, together with additional pharmaceutically acceptable adjuvants.

Another aspect of the disclosure is the solid dispersion as defined herein for use as a medicament for the treatment of cancer, in particular AML or prostate cancer.

An embodiment of the disclosure is a pharmaceutical composition comprising the complexes of the disclosure wherein Compound A is present in a therapeutically effective amount.

Another embodiment of the disclosure is that the complex of the amorphous drug substance with the polymer is stable at high drug load.

Another embodiment of the disclosure is a process for making the complexes of the disclosure that contains pharmaceutically active compounds in stabilized amorphous form.

The key features of the disclosure are:

a) Preparation of stabilized solid amorphous dispersion of Compound A,

b) Drug loading of 10-70% in the final product.

2. The solid dispersion according to claim 1 wherein the ratio of the amount by weight of the compound of formula (A) within the solid dispersion to the amount by weight of the stabilizing polymer therein is between 5:95 to 70:30.

3. The solid dispersion of claim 1 wherein the ratio of the amount by weight of the compound of formula (A) within the solid dispersion to the amount by weight of the stabilizing polymer therein is 30:70 to 50:50.

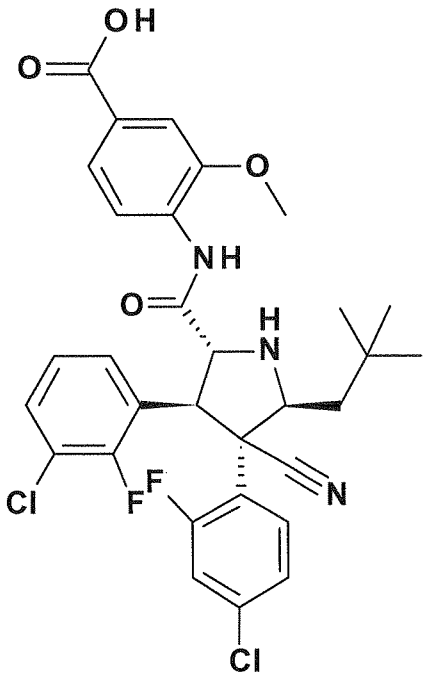
4. The solid dispersion of claim 3, wherein the solid dispersion is obtained by spray drying of a solution comprising the compound of formula (A) and the Copovidone (PVP VA 64).

5. The solid dispersion of claim 3, wherein the solid dispersion is obtained by microprecipitation of a solution comprising the compound of formula (A) and the hypromellose acetate succinate (HPMCAS).

6. A unit dose solid formulation comprising the solid dispersion according to any one of claims 1 to 5, together with pharmaceutical ingredients selected from the group consisting of disintegrants, diluents, lubricants, glidants together with a film coat.

7. The unit dose solid formulation according to claim 6, comprising approximately 80% of the solid dispersion according to any one of claims 1 to 4 as an amorphous solid dispersion, together with about 7% croscarmellose sodium, about 6.8% mannitol, about 4% crospovidone, about 1.5% colloidal silicon dioxide and about 0.7% of magnesium stearate which is then encapsulated or compressed and coated as tablet.

8. A method for preparing a solid dispersion of a compound having an aqueous solubility of less than 1 μg/ml and an ionic polymer which comprises forming a solution of the compound and the polymer in dimethyl-acetamide, or any other suitable solvent and co-precipitating the drug with the polymer using anti-solvent, wherein the compound is 4-{[(2R, 3S, 4R, 5S)-4-(4-Chloro-2-Fluoro-Phenyl)-3-(3-Chloro-2-Fluoro-Phenyl)-4-Cyano-5-(2,2-Dimethyl-Propyl)-Pyrrolidine-2-Carbonyl]-Amino}-3- Methoxy -Benzoic Acid, of the formula (A)



(A), and

wherein the polymer is hypromellose acetate succinate (HPMCAS) or Copovidone (PVP VA 64).

9. A pharmaceutical preparation containing the solid dispersion according to any one of claims 1 to 5, together with additional pharmaceutically acceptable adjuvants.

10. The solid dispersion according to any one of claims 1 to 5 for use as a medicament for the treatment of cancer, in particular AML or prostate cancer.

***