CLAIMS

1. A solid pharmaceutical composition comprising Compound A which is 5-(5-chloro-2-{[(3*S*)-3-(morpholin-4-ylmethyl)-3,4-dihydroisoquinolin-2(1*H*)-yl]carbonyl} phenyl)-*N*-(5-cyano-1,2-dimethyl-1*H*-pyrrol-3-yl)-*N*-(4-hydroxyphenyl)-1,2-dimethyl-1*H*-pyrrole-3-carboxamide, or a pharmaceutically acceptable salt thereof, and a hydroxypropyl- β-cyclodextrin (HP- β-cyclodextrin), wherein the molar ratio between the HP- β-cyclodextrin and Compound A is at least 5 : 1.

2. A solid pharmaceutical composition according to claim 1, wherein Compound A is in the form of the hydrochloride salt or a hydrogen sulfate salt.

3. A solid pharmaceutical composition according to any of claim 1 or 2, wherein the molar ratio between the HP- β-cyclodextrin and Compound A is 5 : 1.

4. A solid pharmaceutical composition according to any of claims 1 to 3, wherein the HP- β-cyclodextrin is a HP- β-cyclodextrin having a degree of substitution of 4.1-5.1 and an approximate molecular weight of 1410 g/mol or is HP-β-cyclodextrin having a molar substitution range of 0.58-0.68 and an approximate molecular weight of 1387 g/mol.

5. A solid pharmaceutical composition according to any of claims 1 to 4, further comprising one or more pharmaceutically acceptable excipients.

6. A solid pharmaceutical composition according to claim 5, comprising at least one pharmaceutically acceptable excipient selected from glucose, mannitol, sucrose, trehalose and sorbitol.

7. A solid pharmaceutical composition according to any of claims 1 to 6, which is a lyophilisate.

8. A pharmaceutical composition comprising Compound A which is 5-(5-chloro-2-{[(3*S*)-3-(morpholin-4-ylmethyl)-3,4-dihydroisoquinolin-2(1H)-yl]carbonyl}phenyl)-*N*-(5-cyano-1,2-dimethyl-1*H*-pyrrol-3-yl)-*N*-(4-hydroxyphenyl)-1,2-dimethyl-1*H*-pyrrole-3-carboxamide, or a pharmaceutically acceptable salt thereof, a hydroxypropyl- β-cyclodextrin (HP- β-cyclodextrin), and one or more solvents, wherein the molar ratio between the HP- β-cyclodextrin and Compound A is at least 5 : 1.

9. The pharmaceutical composition according to claim 8 wherein the solvent is an aqueous buffer or water, and more particularly water.

10. The pharmaceutical composition according to claim 8 or 9, wherein Compound A is in the form of the hydrochloride salt or a hydrogen sulfate salt.

11. The pharmaceutical composition according to claim 10, having a pH value comprised between 2.5 and 4.3, more particularly the pH value is comprised between 2.5 and 3.5.

12. The pharmaceutical composition according to any of claims 8 to 11, wherein the HP- β-cyclodextrin is a HP- β-cyclodextrin having a degree of substitution of 4.1-5.1 and an approximate molecular weight of 1410 g/mol or is HP-β-cyclodextrin having a molar substitution range of 0.58-0.68 and an approximate molecular weight of 1387 g/mol.

13. The pharmaceutical composition according to any of claims 8 to 12, wherein the molar ratio between the HP- β-cyclodextrin and Compound A is 5 : 1.

14. The pharmaceutical composition according to any of claims 8 to 13 having a concentration of 200 mg/mL of HP- β-cyclodextrin.

15. The pharmaceutical composition according to any of claims 8 to 13 having a concentration of 20 mg/mL of Compound A, free base.

16. The pharmaceutical composition according to any of claims 8 to 15, further comprising a tonicity adjusting agent.

17. The pharmaceutical composition according to claim 16, wherein the tonicity adjusting agent is selected from glucose, mannitol, sucrose, trehalose and sorbitol.

18. The pharmaceutical composition according to claim 8 comprising 'Compound A, H_2SO_4', a HP- β-cyclodextrin having a degree of substitution of 4.1-5.1 and an approximate molecular weight of 1410 g/mol, and having a pH value comprised between 2.5 and 4.3, more particularly the pH value is comprised between 2.5 and 3.5.

19. The pharmaceutical composition according to claim 8 comprising 'Compound A, H_2SO_4', a HP- β-cyclodextrin having a degree of substitution of 4.1-5.1 and an approximate molecular weight of 1410 g/mol, water and glucose, and having a pH value comprised between 2.5 and 4.4, more particularly the pH value is comprised between 3.3 and 4.4.

20. The pharmaceutical composition according to any of claims 8 to 19, for parenteral administration.

21. The pharmaceutical composition according to claim 20, for infusion or intravenous injection.

22. A process for preparing a pharmaceutical composition according to claim 8 suitable for parenteral administration comprising the dissolution of a solid pharmaceutical composition as defined in claims 1 to 7 in water.

23. A process according to claim 22 comprising an additional step of dilution with a solution of 5% Glucose.

24. A process according to claim 22 or 23, wherein the dissolution takes place immediately prior to administration to the patient.

25. Use of the composition according to any of claims 8 to 21 for preparation of a medicament to modulate Bcl-2 receptor activity in a subject, comprising administering to the subject a therapeutically effective amount of the composition.

26. Use of the composition according to any of claims 8 to 21 for the preparation of a medicament to treat cancer comprising administering to a subject a therapeutically effective amount of the composition, wherein the cancer is selected from cancers of the bladder, brain, breast and uterus, chronic lymphoid leukaemias, colorectal cancer, cancers of the œsophagus and liver, lymphoblastic leukaemias, acute myeloid leukaemia, lymphomas, melanomas, malignant haemopathies, myelomas, ovarian cancer, non-small-cell lung cancer, prostate cancer, pancreatic cancer and small-cell lung cancer.

27. Use according to claim 26, wherein the cancer is selected from non-Hodgkin's B-cell lymphoma, diffuse large B-cell lymphoma, multiple myeloma, myelodysplastic syndrome, chronic lymphoid leukaemias and acute myeloid leukaemia.

28. Use according to any of claims 25 to 27, wherein the composition according to any of claims 8 to 21, is administered once weekly.

29. Use of solid pharmaceutical composition according to any of claims 1 to 7, for the preparation of a medicament to treat cancer, wherein the cancer is selected from cancers of the bladder, brain, breast and uterus, chronic lymphoid leukaemias, colorectal cancer, cancers of the œsophagus and liver, lymphoblastic leukaemias, acute myeloid leukaemia, lymphomas, for example non-Hodgkin's B-cell lymphoma and diffuse large B-cell lymphoma, melanomas, malignant haemopathies, for example myelodysplastic syndrome, myelomas, for example multiple myeloma, ovarian cancer, non-small-cell lung cancer, prostate cancer, pancreatic cancer and small-cell lung cancer, in particular non-Hodgkin's B-cell lymphoma, diffuse large B-cell lymphoma, multiple myeloma, myelodysplastic syndrome, chronic lymphoid leukaemias and acute myeloid leukaemia.

30. A combination comprising:

- a pharmaceutical composition according to any of claims 8 to 21, and
- one or more therapeutically active agents, for simultaneous, sequential or separate use.