Claims

1. Process for preparing a solid unit dosage form for oral administration containing abiraterone acetate as active ingredient, wherein the process comprises the steps:

    a) preparing a blend consisting of the active ingredient, a first surfactant and optionally a disintegrant and optionally a binder,
    b) subjecting the blend obtained in step (a) to wet-granulation, wherein the granulation liquid is a solvent containing optionally a binder and optionally a second surfactant to obtain granules consisting of the active ingredient, the binder, the surfactant and optionally the disintegrant, and
    c) optionally mixing the granules obtained in step (b) with a pharmaceutical excipient.

2. The process according to claim 1, wherein the process comprises the steps:

    d) subjecting the granules obtained in step (b) or the blend obtained in step (c) to compression to obtain a tablet, and
    e) optionally subjecting the tablet obtained in step (d) to film-coating.

3. The process according to claim 1 or 2, wherein the pharmaceutical excipient is selected from a diluent, a disintegrant, a surfactant, a glidant and a lubricant.

4. The process according to any one of the preceding claims, wherein the first surfactant and the second surfactant are selected from anionic and nonionic surfactants.

5. The process according to claim 4, wherein the first surfactant is an anionic surfactant.

6. The process according to claim 4 or 5, wherein the anionic surfactant is selected from sodium lauryl sulfate (SLS), sodium cholate and sodium deoxycholate.

7. The process according to any one of claims 4 to 6, wherein the nonionic surfactant is selected from a poloxamer, a polyoxyethylene alkyl ether, a polyoxyethylene castor oil and a polyoxyethylene sorbitan fatty acid ester (polysorbate).

8. The process according to any one of the preceding claims, wherein the disintegrant is selected from croscarmellose sodium, crospovidone and sodium starch glycolate.

9. The process according to any one of the preceding claims, wherein the granules obtained in step (b) consist of the active ingredient, the binder, the first surfactant and optionally the second surfactant and optionally the disintegrant.

10. A solid unit dosage form for oral administration containing abiraterone acetate as active ingredient prepared by the process according to any one of the preceding claims.

11. The solid unit dosage form according to claim 10, wherein the solid unit dosage form is a capsule that contains a capsule formulation prepared by a process comprising the steps:

    a) preparing a blend consisting of the active ingredient, a first surfactant and optionally a disintegrant and optionally a binder,

b) subjecting the blend obtained in step (a) to wet-granulation, wherein the granulation liquid is a solvent containing optionally a binder and optionally a second surfactant to obtain granules consisting of the active ingredient, the binder, the surfactant and optionally the disintegrant, and

c) optionally mixing the granules obtained in step (b) with a pharmaceutical excipient;

wherein the capsule formulation contains the active ingredient in an amount of at least 50% by weight.

12. The solid unit dosage form according to claim 10, wherein the solid unit dosage form is an optionally film-coated tablet prepared by a process comprising the steps:

a) preparing a blend consisting of the active ingredient, a first surfactant and optionally a disintegrant and optionally a binder,

b) subjecting the blend obtained in step (a) to wet-granulation, wherein the granulation liquid is a solvent containing optionally a binder and optionally a second surfactant to obtain granules consisting of the active ingredient, the binder, the surfactant and optionally the disintegrant,

c) optionally mixing the granules obtained in step (b) with a pharmaceutical excipient,

d) subjecting the granules obtained in step (b) or the blend obtained in step (c) to compression to obtain a tablet, and

e) optionally subjecting the tablet obtained in step (d) to film-coating wherein the optionally film-coated tablet contains the active ingredient in an amount of at least 50% by weight.

13. The solid unit dosage form according to claim 11 or 12, wherein the capsule formulation or the optionally film-coated tablet contains the active ingredient preferably in an amount of at least 55% by weight, and more preferred in an amount of at least 60% by weight.

14. The solid unit dosage form according to any one of claims 10 to 13, wherein the solid unit dosage form contains 250-1000 mg of the active ingredient, preferably 250 mg, 500 mg or 1000 mg.