amount of the drug of at least 50 % by weight, which provides excellent dissolution properties and chemical stability to the drug. This objective is attained by the subject matter as defined in the claims.

SUMMARY

In an aspect, the present disclosure refers to a 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.

In another aspect, the present disclosure refers to a solid unit dosage form for oral administration containing abiraterone acetate as active ingredient prepared by the process as disclosed herein.

The process of the present invention is a wet-granulation process in which granules consisting of abiraterone acetate, a binder and a surfactant are obtained. The granules are optionally mixed with a pharmaceutical excipient to obtain a blend that may be filled into a capsule. Alternatively, the blend may be compressed to obtain a tablet. It was found that the chemical stability of the drug is improved upon storage, if the wet-granulation process is performed only with the drug, a surfactant and a binder, and that the presence of the surfactant is necessary in order to obtain a solid unit dosage form exhibiting sufficiently high drug dissolution.

The present invention thus relates to a 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.

Preferably, the granules are converted into a tablet by:

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