WHAT IS CLAIMED IS

1. A solid dosage form for oral administration comprising a stable, amorphous matrix comprising: (a) abiraterone acetate; (b) one or more water soluble polymers, and (c) one or more antioxidants, wherein said solid oral dosage form preferably further comprises a disintegrant and one or more pharmaceutically acceptable excipients, and wherein said solid dosage form for oral administration is capable of rapid reconstitution or disintegration in the oral cavity or an aliquot of liquid, prior to ingestion.

2. The solid dosage form for oral administration according to claim 1, wherein said stable, amorphous matrix exhibits one or more of the following: (i), X-ray amorphous character in the solid form; (ii), a glass transition when assessed via differential scanning calorimetry (DSC), and (iii), is stable for at least 3 months at 40°C, as demonstrated by a lack of significant decomposition and/or oxidation and/or crystallization of abiraterone acetate.

3. The solid dosage form for oral administration according to claim 1 or claim 2, wherein said stable, amorphous matrix comprises one or more water-soluble polymers selected from: polyvinylcaprolactam-polyvinyl acetate-polyethylene-glycol graft copolymers, poloxamers; polyvinylpyrrolidone, poly(acrylic acid), polyvinyl alcohol, ethylene glycol and vinyl alcohol graft copolymer, hydroxypropyl methylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, hypromellose acetate succinate, polyethylene oxide, polyethylene-glycol, poly(2-Ethyl-2-oxazoline), poly(methyl vinyl ether/maleic anhydride), poly(maleic acid-co-methyl vinyl ether, polyoxylglycerides, D - α-tocopherol polyethylene glycol 1000 succinate, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polylactic acid, poly(lactic-co-glycolic acid) and copolymers of vinylpyrrolidone and vinyl-acetate and poly(maleic acid-co-methyl-vinyl-ether), preferably polyvinylpyrrolidone, such as K12 or Kollidon 17PF, Kollidon 25, Kollidon 30 or Kollidon 90, most preferably a K12 grade.

4. The solid dosage form for oral administration according to any of claims 1 to 3, wherein said stable, amorphous matrix comprises one or more antioxidants selected from: ascorbic acid, ascorbyl palmitate, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHA), hypophosphorous acid, monothioglycerol, potassium metabisulfite, propyl gallate, sodium bisulfite, sodium formaldehyde sulfoxylate, sodium

metabisulfite, sodium sulfite, sodium thiosulfate and tocopherols, preferably BHA and/or BHT.

5. The solid dosage form for oral administration according to claim 1, wherein said one or more pharmaceutically excipients are selected from group consisting of: diluents or fillers, binders, disintegrants and dispersing agents, lubricants, glidants, antiadherents, surfactants, sweeteners and flavourings.

6. The solid dosage form for oral administration according to claim 5, wherein said diluents or fillers are selected from: pullulan, lactose (anhydrous), lactose monohydrate, mannitol, sucrose, glucose, plant cellulose, calcium carbonate, magnesium carbonate, magnesium oxide, microcrystalline cellulose, silicified microcrystalline cellulose, sorbitol, starch, pregelatinized starch, isomalt, anhydrous dibasic calcium phosphate, dibasic calcium phosphate dihydrate, calcium silicate, magnesium aluminium silicate, maltodextrin, dextrates.

7. The solid dosage form for oral administration according to claim 5, wherein said binders are selected from: pullulan, cellulose, methyl cellulose, microcrystalline cellulose, cellulose ethers such as hydroxypropyl cellulose, polyvinylpyrrolidone, polyethylene glycol, lactose, sucrose, mannitol, sorbitol and xylitol and their co-processed versions such as alpha-Lactose-monohydrate and cellulose or starch, urea crystals, sodium sulfate and calcium sulfate dihydrate.

8. The solid dosage form for oral administration according to claim 5, wherein said disintegrants and dispersing agents are selected from: polyvinylpyrrolidone, crosslinked polyvinylpyrrolidone (crospovidone), polyvinylcaprolactam-polyvinyl acetate-polyethylene-glycol graft copolymers, carboxymethyl cellulose, crosslinked cellulose and its sodium salt (crosscarmellose), crosslinked sodium carboxymethyl cellulose, modified starch, sodium starch glycolate, crosslinked starch, crosslinked alginic acid and sodium starch glycolate, colloidal silicon dioxide, soy polysaccharides and sodium deoxycholate.

9. The solid dosage form for oral administration according to claim 5, wherein said lubricants are selected from: polyethylene glycol, calcium stearate, silica, talc, stearic acid, sodium stearyl fumarate, sodium lauryl sulfate, sodium benzoate, stearic acid and magnesium stearate.

10. The solid dosage form for oral administration according to claim 5, wherein said glidants are selected from: silica gel, colloidal silicon dioxide, fumed silica, talc and magnesium carbonate.

11. The solid dosage form for oral administration according to claim 5, wherein said antiadherents are selected from: magnesium stearate, talc and starch.

12. The solid dosage form for oral administration according to claim 5, wherein said surfactants are selected from: polysorbates such as Tweens, polysorbates, Sodium dodecyl sulfate (sodium lauryl sulfate), lauryl dimethyl amine oxide, docusate sodium, cetyl trimethyl ammonium bromide (CTAB), polyethoxylated alcohols, polyoxyethylene sorbitan, octoxynol, N,N–dimethyldodecylamine–N–oxide, hexadecyltrimethylammonium bromide, polyoxyl 10 lauryl ether, Brij, bile salts (sodium deoxycholate, sodium cholate), polyoxyl castor oil, nonylphenol ethoxylate cyclodextrins, lecithin, methylbenzethonium chloride, petroleum sulphonates, alkylbenzenesulphonates, sulphated alkanolamides, polyoxyethylene surfactants, carboxylic esters, polyethylene glycol esters, glycol esters of fatty acids, carboxylic amides, quaternary ammonium salts, preferably docusate sodium and/or sodium lauryl sulfate.

13. The solid dosage form for oral administration according to claim 5, wherein said sweeteners are selected from: sodium saccharine, sucrose, saccharine, aspartame, acesulfame-K, sodium cyclamate and sorbitol.

14. The solid dosage form for oral administration according to any preceding claim, wherein said abiraterone acetate is present in said stable, amorphous matrix at an amount ranging from about 1.0 % by weight to about 95.0 % by weight, based on the total weight of the stable, amorphous matrix.

15. The solid dosage form for oral administration according to any preceding claim, wherein said stable, amorphous matrix is present at an amount ranging from about 1.0 % by weight to about 95.0 % by weight, based on the total weight of the solid dosage form, preferably wherein said stable, amorphous matrix is present in particulate form, preferably as a particulate or milled extrudate.

16. The solid dosage form for oral administration according to any preceding claim, wherein said solid dosage form is selected from: a tablet, coated tablet, effervescent tablet, tablet for oral suspension, fast melt tablet, lyophilized tablet, lyophilized wafer, disintegrating tablet, dispersible tablet, orodispersible tablet, mini-tablet, multilayer tablet, bi-layered tablet, tablet-in-tablet, pill, micro-pellet, small tablet unit, powder, powder for reconstitution, powder for oral suspension, pellets, beads, MUPS (multiple unit pellet system), granules, dry granules, roller compacted granules, effervescent granules, granules for oral suspension, slugs, microspheres, multiparticulates, sprinkles, preferably granules for oral suspension, wherein said solid dosage form is preferably packaged as a blister, bottle, capsule, stick or sachet.

17. The solid dosage form for oral administration according to claim 16, wherein said micro-pellet, small tablet unit, powder, powder for reconstitution, powder for oral suspension, pellets, beads, MUPS (multiple unit pellet system), granules, dry granules, roller compacted granules, effervescent granules, granules for oral suspension, slugs, microspheres, multiparticulates and sprinkles preferably have a D50 of greater than 300 micron and where less than about 10 % by weight of the total mass of the solid dosage form is less than 63 microns, preferably wherein less than about 10% by weight of the total mass of the solid dosage form is less than 50 microns, as measured by laser diffraction or preferably sieve fractionation.

18. The solid dosage form for oral administration according to any preceding claim, wherein said solid dosage form is presented as one of the following: controlled release formulation, immediate release formulation, fast melt formulation, lyophilized formulations, delayed release formulation, extended release formulation, pulsatile release formulation, or mixed immediate release and controlled release formulation.

19. The solid dosage form for oral administration according to any preceding claim, which comprises a therapeutically effective amount of abiraterone acetate, ranging from about 10 mg to 2000 mg per dosage form, or about 50 mg to 1000 mg per dosage form, preferably about 62.5 mg to about 250 mg per dosage form.

20. The solid dosage form for oral administration according to any preceding claim, wherein said solid dosage form disintegrates and/or releases abiraterone acetate into an aliquot of liquid suitable for human consumption.

21. The solid dosage form for oral administration according to claim 20, wherein said aliquot of liquid suitable for human use is selected from: water, fruit juice such as orange juice, apple juice, pineapple juice or cranberry juice, coconut water, coconut milk, almond milk, oat milk, soya milk, rice milk, and dairy-derived milks such as cow's milk.

22. The solid dosage form for oral administration according to any of claim 20 or claim 21, wherein said solid dosage form disintegrates and/or releases at least 85 % or more of said abiraterone acetate into said aliquot of liquid in less than about 10 minutes, preferably less than about 5 minutes, more preferably less than about 3 minutes, or less than about 1 minute or less, wherein said aliquot is 250 ml or less, such as about 50 or 60 ml.

23. The solid dosage form for oral administration according to any preceding claim, wherein said abiraterone acetate is present in said solid dosage form at about 1.0 % by weight to about 20.0 % by weight, or about 1.0% to about 10.0 % by weight, preferably about 1.0 % to about 5.0 % by weight, based on the total weight of the solid dosage form.

24. A solid dosage form for oral administration comprising: (a) abiraterone acetate; (b) one or more water soluble polymers, and (c) one or more antioxidants, wherein said solid oral dosage form preferably further comprises a disintegrant and one or more pharmaceutically acceptable excipients, and wherein said solid dosage form for oral administration is capable of rapid reconstitution or disintegration in the oral cavity or an aliquot of liquid prior to ingestion, comprising:

(a) 1-20 % abiraterone acetate,
(b) 5-60 % water soluble polymer,
(c) 35-90 % fillers and/or diluents,
(d) 5-20 % binders,
(e) 5-45 % disintegrants,
(f) 0.1-5 % lubricants,
(g) 0.1-5 % antiadherents,
(h) 0.1- 5 % glidants,
(i) 0.01-2 % antioxidants, and
(j) 0.05-5 % flavouring agents and/or sweeteners.

25. The solid dosage form for oral administration according to any of claims 1 to 24, for use in the treatment of prostate cancer.

26. Use of a solid dosage form for oral administration according to any of claims 1 to 24, in the manufacture of a medicament for the treatment of prostate cancer.

27. A method of producing a solid dosage form for oral administration comprising abiraterone acetate, wherein said solid dosage form for oral administration is capable of rapid reconstitution or disintegration in the oral cavity or an aliquot of liquid prior to ingestion, wherein said method comprising the steps of:

(a) providing abiraterone acetate;

(b) providing one or more water-soluble polymers, preferably polyvinylpyrrolidone, such as K12 or Kollidon 17PF, Kollidon 25, Kollidon 30 or Kollidon 90, most preferably a K12.grade;

(c) providing one or more antioxidants;

(d) processing (a), (b) and (c) by blending to produce powder blend comprising (a) to (c);

(e) processing the product of step (d) by an extrusion process to produce an extruded composition;

(f) processing the extruded composition of step (e) by size reduction such as milling, to produce a particulate or milled extrudate;

(g) blending the particulate or milled extruded composition of step (f) with one or more pharmaceutically acceptable excipients such as fillers, diluents, binders, disintegrants, lubricants, antiadherents, glidants, flavoring agents and sweeteners to produce a composition blend; and

(h) compressing the composition blend of step (g) into a solid dosage form such as via direct compression to form a tablet, or, preparing granules from the composition blend of step (g), via slugging and/or milling and/or roller compaction to produce such granules.

28. The method of producing a solid dosage form for oral administration according to claim 27, wherein said extrusion process of step (e) comprises a hot melt extrusion (HME) process.

29. A method of treatment of prostate cancer comprising administering a therapeutically effective amount of a solid dosage form for oral administration according to any of claims 1 to 24, to a human patient in need thereof.

30. A solid dosage form for oral administration substantially as herein described with reference to the examples.

31. A method of treating, reducing, inhibiting or controlling prostate cancer in a human patient in need thereof, comprising administering a therapeutically effective amount of a solid dosage form for oral administration comprising a stable, amorphous matrix comprising: (a) abiraterone acetate; (b) one or more water soluble polymers, and (c) one or more antioxidants, wherein said solid oral dosage form preferably further comprises a disintegrant and one or more pharmaceutically acceptable excipients, and wherein said solid dosage form for oral administration is capable of rapid reconstitution or disintegration in the oral cavity or an aliquot of liquid prior to ingestion by said human patient.

32. The method according to claim 31, wherein said solid dosage form for oral administration is selected from: a tablet, coated tablet, effervescent tablet, tablet for oral suspension, fast melt tablet, lyophilized tablet, lyophilized wafer, disintegrating tablet, dispersible tablet, orodispersible tablet, mini-tablet, multilayer tablet, bilayered tablet, tablet-in-tablet, pill, micro-pellet, small tablet unit, powder, powder for reconstitution, powder for oral suspension, pellets, beads, MUPS (multiple unit pellet system), granules, dry granules, roller compacted granules, effervescent granules, granules for oral suspension, slugs, microspheres, multiparticulates, sprinkles, preferably granules for oral suspension, wherein said solid dosage form is preferably packaged as a blister, bottle, capsule, stick or sachet.

33. The method according to claim 31 or claim 32, wherein said solid dosage form for oral administration is presented as one of the following: controlled release formulation, immediate release formulation, fast melt formulation, lyophilized formulation, delayed release formulation, extended release formulation, pulsatile release formulation, or mixed immediate release and controlled release formulation.

34. The method according to any of claims 31 to 33, wherein said administration results in one or more of the following features:
(a)a peak abiraterone plasma concentration which is about 248 ng/ml to 662 ng/ml and a more uniform abiraterone plasma concentration than the abiraterone plasma concentration provided by the same dosage of a conventional abiraterone acetate tablet formulation;
(b)an abiraterone exposure (AUC) which is about 500 h*ng/ml to 1350 h*ng/ml and a more uniform abiraterone exposure (AUC) than the abiraterone exposure (AUC) provided by the same dosage of a conventional abiraterone acetate tablet formulation;
(c) exhibits no positive food effect, such as where the fed/fasted ratio is under 1.25;
(d) allows significant dose reduction or dose sparing when compared to Zytiga;
(e) abandonment of the requirement for taking the drug on an empty stomach;
(f) the variability of exposure is significantly reduced when compared to Zytiga.

35. The method according to any of claims 31 to 34, wherein the therapeutically effective amount of abiraterone acetate administered is from about 62.5 mg/day to about 1000 mg/day, preferably from about 62.5 mg/day to about 725 mg/day and more preferably from about 62.5 mg/day to about 500 mg/day, most preferably as a divided dose.

36. The method according to any of claims 31 to claim 35, wherein the therapeutically effective amount of abiraterone acetate is administered as a total daily dose of between about 62.5 mg and 1000 mg or between about 125 and 750 mg or between about 250 mg and 500 mg abiraterone acetate, administered in a single or divided dose, such as administered once a day, two times a day (BID), three times a day (TID), or four times a day (QID), optionally wherein said total daily dose comprises administration of between one to four 62.5 mg sachets suitably comprising granules for oral suspension, adminstered once, twice, three or four time a day.

37. The method according to any of claims 31 to claim 36, further comprising simultaneously, separately or sequentially administering a therapeutically-effective amount of a steroid, wherein said steroid is selected from: hydrocortisone, hydrocortisone acetate, cortisone acetate, tixocortol pivalate, prednisolone, methylprednisolone, prednisone, or dexamethasone, preferably prednisone.

38. The method according to any of claims 31 to claim 37, wherein said prostate cancer in a human patient is selected from: high-risk Castrate Sensitive Prostate Cancer (CSPC), metastatic Castrate Sensitive Prostate Cancer (mCSPC) and metastatic Castrate Resistant Prostate Cancer (mCRPC).

39. The method according to any of claims 31 to claim 38, wherein said therapeutically effective amount of a solid dosage form for oral administration is first introduced into an aliquot of liquid suitable for human consumption, prior to ingestion by said human patient, preferably wherein said aliquot is 250 ml or less, such as about 50 or about 60 ml.

40. The method according to claim 39, wherein said aliquot of liquid suitable for human use is selected from: water, fruit juice such as orange juice, apple juice, pineapple juice or cranberry juice, coconut water, coconut milk, almond milk, oat milk, soya milk, rice milk, and dairy-derived milks such as cow's milk.