CLAIMS

1. A solid oral unit dosage form of abiraterone acetate containing 125 mg of abiraterone acetate having a [D50] greater than 100 nm and less than 1200 nm, the unit dosage form further comprising lactose monohydrate, sodium lauryl sulfate, microcrystalline cellulose, croscarmellose sodium, sodium stearyl fumarate, butylated hydroxyanisole, and butylated hydroxytoluene,

   wherein a 500 mg dose of the unit dosage form is bioequivalent to a 1000 mg dose of Zytiga® Tablets (250 mg; National Drug Code Number 57894-150; NDA 202379) in healthy male subjects in the fasted state;

   wherein the dissolution rate of the abiraterone acetate in the unit dosage form is such that when the unit dosage form is tested in 900 ml of pH 4.5 phosphate buffer with 0.12% sodium lauryl sulfate using USP Apparatus II at 75 rpm, at least 70% of the abiraterone acetate dissolves in between 5 and 15 minutes; and

   wherein a 500 mg dose, upon oral administration to a population of healthy male subjects in the fasted state, provides a mean blood plasma C_{max} of 50-120 ng/ml and a mean blood plasma $AUC_{(0-\infty)}$ of 240-650 h×ng/ml.

2. The unit dosage form of abiraterone acetate of claim 1, wherein the ratio of the log of the geometric mean of the $AUC_{(0-\infty)}$ for a 500 mg dose administered to healthy male subjects in the fasted state compared to a 1000 mg dose of Zytiga® Tablets (250 mg; National Drug Code Number 57894-150; NDA 202379) administered to healthy male subjects in the fasted state is selected from: 0.6 to 1.4, 0.7 to 1.3, 0.8 to 1.2 and 0.9 to 1.1.

3. The unit dosage form of abiraterone acetate of claim 1, wherein the ratio of the log of the geometric mean of the C_{max} for a 500 mg dose administered to healthy male subjects in the fasted state compared to a 1000 mg dose of Zytiga® Tablets (250 mg; National Drug Code Number 57894-150; NDA 202379) administered to healthy male subjects in the fasted state is selected from: 0.6 to 1.4, 0.7 to 1.3, 0.8 to 1.2 and 0.9 to 1.1.

4. The unit dosage form of abiraterone acetate of claim 1, wherein:

the [D50] of the abiraterone acetate is greater than 100 nm and less than one of: 1000 nm, 800 nm, 500 nm, 400 nm, and 300 nm; and

the [D90] of the abiraterone acetate is greater than 300 nm and less than one of: 3000 nm, 2000 nm, 900 nm, 800 nm, and 700 nm.

5. The unit dosage form of abiraterone acetate of claim 1, wherein the [D4,3] of the abiraterone acetate is greater than 300 nm and less than one of: 1100 nm, 900 nm, and 800 nm.

6. The unit dosage form of abiraterone acetate of claim 1, wherein the dissolution rate of the abiraterone acetate in the unit dosage form is such that when the unit dosage form is tested in 900 ml of pH 4.5 phosphate buffer with 0.12% sodium lauryl sulfate using USP Apparatus II at 75 rpm, at least 70% of the abiraterone acetate dissolves in between 5 and 10 min.

7. The unit dosage form of abiraterone acetate of claim 1, wherein a 500 mg dose, upon oral administration to a population of healthy male subjects in the fasted state, provides a median blood plasma t_{max} of 1 to 2.5 hrs.

8. The unit dosage form of abiraterone acetate of claim 1, wherein the 90% confidence interval of the mean blood plasma C_{max} is a value between 50 and 120 ng/ml when a 500 mg dose is administered to healthy male subjects in the fasted state.

9. The unit dosage form of abiraterone acetate of claim 1, wherein the 90% confidence interval of the mean blood plasma AUC(0-∞) is a value between 240 and 650 h×ng/ml when a 500 mg dose is administered to healthy male subjects in the fasted state.

10. The unit dosage form of abiraterone acetate of claim 1, comprising abiraterone acetate at 5-50 wt. %, lactose monohydrate at 5-80 wt. %, sodium lauryl sulfate at 0.1-10 wt. %, microcrystalline cellulose at 5-80 wt. %, croscarmellose sodium at 1-15 wt. %, sodium stearyl fumarate at 0.01-10 wt. %, butylated hydroxyanisole at 0.001-1 wt. %, and butylated hydroxytoluene at 0.001-1 wt. %.

11. The unit dosage form of abiraterone acetate of claim 1, comprising abiraterone acetate at 10-30 wt. %, lactose monohydrate at 20-40 wt. %, sodium lauryl sulfate at 1-5 wt. %, microcrystalline cellulose at 20-60 wt. %, croscarmellose sodium at 2-10 wt. %, sodium stearyl fumarate at 0.1-2 wt. %, butylated hydroxyanisole at 0.01-2 wt. %, and butylated hydroxytoluene at 0.01-2 wt. %.

12. A unit dosage form of abiraterone acetate containing 125 mg of abiraterone acetate having a [D50] greater than 100 nm and less than 1200 nm, the unit dosage form further comprising lactose monohydrate, sodium lauryl sulfate, microcrystalline cellulose, croscarmellose sodium, sodium stearyl fumarate, butylated hydroxyanisole, and butylated hydroxytoluene;

    wherein the dissolution rate of the abiraterone acetate in the unit dosage form is such that when the unit dosage form is tested in 900 ml of pH 4.5 phosphate buffer with 0.12% sodium lauryl sulfate using USP Apparatus II at 75 rpm, at least 70% of the abiraterone acetate dissolves in between 5 and 15 minutes; and

    wherein a 500 mg dose, upon oral administration to a population of healthy male subjects in the fasted state, provides a mean blood plasma C_{max} of 50-120 ng/ml and a mean blood plasma $AUC_{(0-\infty)}$ of 240-650 h×ng/ml.

13. The unit dosage form of abiraterone acetate of claim 12, wherein:

    the [D50] of the abiraterone acetate greater than 100 nm and is less than one of: 1000 nm, 800 nm, 500 nm, 400 nm, and 300 nm; and

    the [D90] of the abiraterone acetate is greater than 300 nm and less than one of: 3000 nm, 2000 nm, 900 nm, 800 nm, and 700 nm.

14. The unit dosage form of abiraterone acetate of claim 12, wherein the [D4,3] of the abiraterone acetate is greater than 300 nm and less than one of: 1100 nm, 900 nm, and 800 nm.

15. The unit dosage form of abiraterone acetate of claim 12, wherein the dissolution rate of the abiraterone acetate in the unit dosage form is such that when the unit dosage form is tested in 900 ml of pH 4.5 phosphate buffer with 0.12% sodium lauryl sulfate using USP Apparatus II at 75 rpm, at least 70% of the abiraterone acetate dissolves in between 5 and 10 min.

16. The unit dosage form of abiraterone acetate of claim 12, wherein a 500 mg dose, upon oral administration to a population of healthy male subjects in the fasted state, provides a median blood plasma t_{max} of 1 to 2.5 hrs.

17. The unit dosage form of abiraterone acetate of claim 12, wherein the 90% confidence interval of the mean blood plasma $AUC_{(0-\infty)}$ is a value between 240 and 650 h×ng/ml when a 500 mg dose is administered to healthy male subjects in the fasted state.

18. The unit dosage form of abiraterone acetate of claim 12, wherein the 90% confidence interval of the mean blood plasma C_{max} is a value between 50 and 120 ng/ml when a 500 mg dose is administered to healthy male subjects in the fasted state.

19. The unit dosage form of abiraterone acetate of claim 12, comprising abiraterone acetate at 5-50 wt. %, lactose monohydrate at 5-80 wt. %, sodium lauryl sulfate at 0.1-10 wt. %, microcrystalline cellulose at 5-80 wt. %, croscarmellose sodium at 1-15 wt. %, sodium stearyl fumarate at 0.01-10 wt. %, butylated hydroxyanisole at 0.001-1 wt. %, and butylated hydroxytoluene at 0.001-1 wt. %.

20. The unit dosage form of abiraterone acetate of claim 12, comprising abiraterone acetate at 10-30 wt. %, lactose monohydrate at 20-40 wt. %, sodium lauryl sulfate at 1-5 wt. %, microcrystalline cellulose at 20-60 wt. %, croscarmellose sodium at 2-10 wt. %, sodium stearyl fumarate at 0.1-2 wt. %, butylated hydroxyanisole at 0.01-2 wt. %, and butylated hydroxytoluene at 0.01-2 wt. %.