CLAIMS

1. The compound trans-clomiphene and pharmaceutically acceptable salts and solvates thereof, characterized in that the compound is in particulate form, said particles having a mean particle size of less than about 30 microns, at least about 90% of said particles have a size of less than about 50 microns.

2. The compound of claim 1 wherein said particles have a mean particle size of between about 5 and about 20 microns.

3. A compound of claim 1 which is a non-solvated crystalline form.

4. The compound of any of claims 1-3 wherein the compound is trans-clomiphene citrate.

5. A pharmaceutical formulation comprising or formulated using the compound of claim 1 and one or more pharmaceutically acceptable carriers, diluents or excipients.

6. The pharmaceutical formulation according to claim 5 wherein the compound is trans-clomiphene citrate.

7. The pharmaceutical formulation according to claim 5 or 6 wherein the formulation is a capsule.

8. The pharmaceutical formulation according to claim 7 comprising about 5 to about 100 mg trans-clomiphene citrate.

9. The pharamceutical formulation according to claim 8 comprising 12.5 mg, 25 mg or 50 mg trans-clomiphene citrate.

10. The pharmaceutical formulation according to any one of claims 5-9, further comprising microcrystalline cellulose and/or magnesium stearate.

11. The pharmaceutical formulation according to claim 10, each capsule comprising about 12.5 mg trans-clomiphene citrate, about 85.5 mg microcrystalline cellulose and about 2.0 mg magnesium stearate.

12. The pharmaceutical formulation according to any of claims 5-11, for use in treating secondary hypogonadism in a human male or for treating a disorder associated therewith.

13. The pharmaceutical formulation for use according to claim 12, wherein the disorder associated with secondary hypogonadism is selected from reduction of muscle mass, reduction of bone density, reduction of libido, oligospermia, and azoospermia.

14. The pharmaceutical formulation according to any of claims 5-11 for use in treating infertility in a human female.

15. The pharmaceutical formulation for use according to claim 14, wherein the formulation is administered to an anovulatory female as a daily dose for a period of five consecutive days.

16. The pharmaceutical formulation according to any of claims 5-11 for use in a method for treating and/or preventing type 2 diabetes in a human male.

17. The pharmaceutical formulation according to any of claims 5-11 for treating or preventing breast cancer in a human female

18. The pharmaceutical formulation according to any of claims 5-11 for treating endometrial, uterine or ovarian cancer in a human female.

WHAT WE CLAIM IS:

1. A pharmaceutical composition for oral administration comprising 12.5 mg or 25 mg of-trans-clomiphene citrate, wherein the trans-clomiphene citrate is in particulate form, said particles having a mean particle size of between 5 and 20 microns, at least about 90% of said particles have a size of less than about 50 microns; and one or more pharmaceutically acceptable carriers, diluents or excipients.

2. The pharmaceutical composition of claim 1, wherein the trans-clomiphene citrate is in a non-solvated crystalline form.

3. The pharmaceutical composition according to claim 1 wherein the composition is a capsule.

4. The pharmaceutical composition according to any one of claims 1 to 3, further comprising microcrystalline cellulose and/or magnesium stearate.

5. The pharmaceutical composition according to claim 4, wherein the composition is a capsule, and each capsule comprises 12.5 mg trans-clomiphene citrate, 85.5 mg microcrystalline cellulose and 2.0 mg magnesium stearate.

6. Use of trans-clomiphene citrate in the manufacture of a medicament for treating infertility in a human female, wherein the trans-clomiphene citrate is in particulate form, said particles having a mean particle size of between 5 and 20 microns, at least about 90% of said particles have a size of less than about 50 microns, and wherein the trans-clomiphene citrate is present in the medicament in an amount of 12.5 mg or 25 mg, and the medicament is in a form for oral administration.

7. Use according to claim 6, wherein the formulation is suitable to be administered to an anovulatory female as a daily dose for a period of five consecutive days.

8. Use of trans-clomiphene citrate in the manufacture of a medicament for treating or preventing breast cancer in a human female, wherein the trans-clomiphene citrate is in particulate form, said particles having a mean particle size of between 5 and 20 microns, at least about 90% of said particles have a size of less than about 50 microns, and wherein the trans-clomiphene citrate is present in the medicament in an amount of 12.5 mg or 25 mg, and the medicament is in a form for oral administration.

9. Use of trans-clomiphene citrate in the manufacture of a medicament for treating endometrial, uterine or ovarian cancer in a human female, wherein the trans-clomiphene citrate is in particulate form, said particles having a mean particle size of between 5 and 20 microns, at least about 90% of said particles have a size of less than about 50

microns, and wherein the trans-clomiphene citrate is present in the medicament in an amount of 12.5 mg or 25 mg, and the medicament is in a form for oral administration.

10. Use according to any one of claims 6 to 9, wherein the trans-clomiphene citrate is in a non-solvated crystalline form.

11. Use according to any one of claims 6 to 9, wherein the medicament is in capsule form.

12. Use according to any one of claims 6 to 11, wherein the medicament further comprises microcrystalline cellulose and/or magnesium stearate.

13. Use according to claim 12, wherein the medicament is in capsule form, and each capsule comprises 12.5 mg trans-clomiphene citrate, 85.5 mg microcrystalline cellulose and 2.0 mg magnesium stearate.

14. Use according to any one of claims 6 to 13, wherein the medicament further comprises one or more pharmaceutically acceptable carriers, diluents or excipients.