CLAIMS

1. An orodispersible solid pharmaceutical dosage unit having a weight between 30 and 1,000 mg, said dosage unit consisting of:
   - 0.1-25 wt.% of estetrol particles containing at least 90 wt.% of an estetrol component selected from estetrol, estetrol esters and combinations thereof and having a volume median diameter of 2 μm to 50 μm; and
   - 75-99.9 wt.% of one or more pharmaceutically acceptable ingredients;

   the solid dosage unit comprising at least 100 μg of the estetrol component;
   wherein the dosage form contains 0.1-2 wt.% of lubricant; and
   wherein the solid dosage unit can be obtained by a process comprising:
   - providing estetrol particles containing at least 90 wt.% of an estetrol component selected from estetrol, estetrol esters and combinations thereof, said estetrol particles having a volume median diameter in the range of 2 μm to 50 μm;
   - preparing a dry blend by mixing the estetrol particles with one or more pharmaceutically acceptable excipients; and
   - compressing the dry blend into a solid dosage unit.

2. Dosage unit according to claim 1, wherein the dosage unit has a weight between 40 and 500 mg.

3. Dosage unit according to claim 1 or 2, wherein the dosage unit contains 0.5-25 wt.% of the estetrol component.

4. Dosage unit according to any one of the preceding claims, wherein the dosage unit contains 0.3-100 mg of the estetrol component.

5. Dosage unit according to any one of the preceding claims, wherein the estetrol component is estetrol.

6. Dosage unit according to any one of the preceding claims, wherein the estetrol particles have a volume median diameter of 3-35 μm.

7. Dosage unit according to any one of the preceding claims, wherein the dosage unit contains 50-99.5 wt.% of filler selected from maltose, fructose, sucrose, lactose, glucose, galactose, trehalose, xylitol, sorbitol, erythritol, maltitol, mannitol, isomalt, microcrystalline cellulose, calcium salts and combinations thereof.

8. Dosage unit according to claim 7, wherein the dosage unit contains 50-99.5 wt.% of filler selected from lactose, xylitol, sorbitol, erythritol, mannitol, microcrystalline cellulose and combinations thereof.

9. Dosage unit according to claim 7 or 8, wherein the dosage unit contains at least 20 wt.% of sugar alcohol selected from mannitol, xylitol and combinations thereof.

10. Dosage unit according to any one of the preceding claims, wherein the dosage unit contains 0.1-20 wt.% of a disintegrating agent selected from starch, sodium salt of carboxymethyl starch, crosslinked polyvinyl pyrrolidone, crosslinked carmellose and combinations thereof.

11. Dosage unit according to any one of the preceding claims, wherein the dosage unit contains 0-60 wt.% of microcrystalline cellulose.

12. Dosage unit according to any one of the preceding claims, wherein the lubricant is selected from sodium stearyl fumarate, magnesium stearate, stearic acid, sodium lauryl sulfate, talc, polyethylene glycol, calcium stearate and mixtures thereof.

13. The dosage unit according to any one of the preceding claims, for use in medical treatment.

14. Use of an estetrol component for the manufacture of a medicament in the form of a solid dosage unit according to any one of claims 1-12 for female hormone replacement therapy, wherein said solid dosage unit is to be administered sublingually, buccally or sublabially.

15. The use according to claim 14, wherein said solid dosage unit is to be administered once daily during a period of at least 1 week.

16. Use of an estetrol component for the manufacture of a medicament in the form of a solid dosage unit according to any one of claims 1 to 12 for female contraception, wherein said solid dosage unit is to be administered sublingually, buccally or sublabially.

17. The use according to claim 16, wherein said solid dosage unit is to be administered once daily during a period of at least 1 week.

18. A process of preparing a solid dosage unit according to any one of claims 1-12, said process comprising the steps of:

- providing estetrol particles containing at least 90 wt.% of an estetrol component selected from estetrol, estetrol esters and combinations thereof, said estetrol particles having a volume median diameter in the range of 2 µm to 50 µm;
- preparing a dry blend by mixing 1 part by weight of the estetrol particles with 2-1,000 parts by weight of one or more pharmaceutically acceptable excipients; and
- compressing the dry blend into a solid dosage unit.

19. Process according to claim 18, wherein the process does not comprise addition of liquid solvent during or after the combining of the estetrol particles and the one or more pharmaceutically acceptable excipients.

20. Process according to claim 19 or 19, wherein the estetrol particles have a volume median diameter of 3-35 µm.

21. Process according to any one of claims 18-20, wherein the dry blend contains 50-99.5 wt.% of a filler selected from maltose, fructose, sucrose, lactose, glucose, galactose, trehalose, xylitol, sorbitol, erythritol, maltitol, mannitol, isomalt, microcrystalline cellulose, calcium salts and combinations thereof.

22. Process according to claim 21, wherein the dosage unit contains 50-99.5 wt.% of filler selected from lactose, xylitol, sorbitol, erythritol, mannitol, microcrystalline cellulose and combinations thereof.

23. Process according to claim 21 or 22, wherein the dry blend contains at least 20 wt.% of sugar alcohol selected from mannitol, xylitol and combinations thereof.

24. Process according to any one of claims 18-23, wherein the dry blend contains 0.1-20 wt.% of a disintegrating agent selected from starch, sodium salt of carboxymethyl starch, crosslinked polyvinylpyrrolidone, crosslinked carmellose and combinations thereof.

25. Process according to any one of claims 18-24, wherein the dosage unit contains 0-60 wt.% of microcrystalline cellulose.

26. Process according to any one of claims 18-25, wherein the dry blend contains 0.1-2 wt.% of lubricant selected from sodium stearyl fumarate, magnesium stearate, stearic acid, sodium lauryl sulfate, talc, polyethylene glycol, calcium stearate and mixtures thereof.

27. Process according to any one of claims 18-26, wherein the solid dosage unit is formed by direct compression.