The production of the estetrol-containing granules in this process may suitably be carried out, for instance, in a high shear granulator, a low shear granulator or a fluidized bed granulator.

In another aspect, the disclosure relates to the use of an estetrol component for the manufacture of a medicament in the form of a solid dosage unit as described herein, for medical treatment or for female hormone replacement therapy, wherein said solid dosage unit is to be administered sublingually, buccally or sublabially.

In another aspect, the present disclosure relates to a method of female contraception, said method comprising sublingual, buccal or sublabial administration of a dosage unit as described herein.

BRIEF DESCRIPTION OF THE FIGURE

Figure 1 illustrates the manufacturing process flow chart used in Example 4.

DETAILED DESCRIPTION OF THE INVENTION

A first aspect of the invention relates to 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 80 wt.% of an estetrol component selected from estetrol, estetrol esters and combinations thereof; 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 solid dosage unit can be obtained by a process comprising:

- providing estetrol particles containing at least 80 wt.% of the estetrol component and having a volume median diameter of 2 µm to 50 µm;
- mixing the estetrol particles with one or more granulation excipients to produce a granulation mixture;
- mixing the granulation mixture with a granulation liquid to produce estetrol-containing granules, said granulation liquid containing at least 60 wt.% of liquid solvent;
- removing liquid solvent from the estetrol-containing granules to produce dry estetrol-containing granules;

- optionally mixing the dry granules with one or more tabletting excipients; and
- forming the dry granules or the mixture of the dry granules and the one or more tabletting excipients into a solid dosage unit.

The term ‘estetrol’ as used herein refers to 1,3,5 (10)-estratrien-3,15α,16α,17β-tetrol or 15α-hydroxyestriol as well as hydrates of estetrol, e.g. estetrol monohydrate.

The term ‘orodispersible dosage unit’ as used herein refers to a dosage unit that is designed to rapidly disintegrate in the oral cavity when it comes into contact with saliva and to disperse the