Desogestrel and Ethinyl Estradiol Tablets

Desogestrel and Ethinyl Estradiol Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of desogestrel, $C_{22}H_{30}O$ and ethinyl estradiol, $C_{20}H_{24}O_2$.

Usual strengths. Desogestrel, 0.025 mg and Ethinyl Estradiol, 0.04 mg; Desogestrel, 0.1 mg and Ethinyl Estradiol, 0.03 mg; Desogestrel, 0.125 mg and Ethinyl Estradiol, 0.03 mg.

Identification

In the Assay, the principal peaks in the chromatogram obtained with the test solution correspond to the principal peaks in the chromatogram obtained with reference solution (c).

Tests

Dissolution (2.5.2).
Apparatus No. 2 (Paddle),
Medium. 500 ml of 0.05 per cent w/v solution of *sodium lauryl sulphate*,
Speed and time. 50 rpm and 30 minutes.

Determine by liquid chromatography (2.4.14).

Test solution. Withdraw a suitable volume of the medium, and centrifuge it**,** use the clear supernatant liquid.

Reference solution (a). A 0.025 per cent w/v solution of *desogestrel IPRS* in *methanol*. Dilute 1.0 ml of the solution to 50.0 ml with the dissolution medium.

Reference solution (b). A 0.025 per cent w/v solution of *ethinyl estradiol IPRS* in *methanol.* Dilute 1.0 ml of the solution to 50.0 ml with the dissolution medium.

Reference solution (c). Dilute a suitable volume of reference solution (a) and reference solution (b) with dissolution medium to obtain a solution having similar concentration to the test solution.

Chromatographic system

- a stainless steel column 15 cm x 4.6 mm, packed with phenyl groups bonded to porous silica (5 µm),
- mobile phase: a mixture of 50 volumes of a buffer solution prepared by dissolving 2.72 g of *monobasic potassium phosphate* in 1000 ml of *water,* adjusted to pH 6.0 with *2M sodium hydroxide* and 50 volumes of *acetonitrile,*
- flow rate: 2 ml per minute,
- spectrophotometer, set at 210 nm for desogestrel and fluorescence detector excitation at 285 nm and emission at 310 nm for ethinyl estradiol,
- injection volume: 200 µl.

The relative retention time with reference to desogestrel for ethinyl estradiol is about 0.2.

Inject reference solution (c). The test is not valid unless the relative standard deviation for replicate injections is not more than 3.0 per cent for both the peaks.

Inject reference solution (c) and the test solution.

Calculate the contents of $C_{22}H_{30}O$ and $C_{20}H_{24}O_2$, in the medium.

Q. Not less than 80 per cent of the stated amounts of $C_{22}H_{30}O$ and $C_{20}H_{24}O_2$.

Uniformity of content. Complies with the test stated under Tablets.

Determine by liquid chromatography (2.4.14), as described under Assay with the following modifications.

Test solution. Disperse one intact tablet in the solvent mixture, with the aid of mechanical shaker for 30 minutes and dilute to 25.0 ml with the solvent mixture. Dilute a suitable volume of the solution to obtain a solution containing 0.00005 per cent w/v of Desogestrel.

Inject reference solution (c) and the test solution.

Calculate the content of $C_{22}H_{30}O$ and $C_{20}H_{24}O_2$ in the tablet.

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

Solvent mixture. Equal volumes of *acetonitrile* and *water*.

Test solution. Disperse 10 intact tablets in 60 ml of the solvent mixture, with the aid of mechanical shaker for 30 minutes, and dilute to 100.0 with the solvent mixture, centrifuge and dilute clear supernatant liquid with the solvent mixture to obtain a solution containing 0.00005 per cent w/v of desogestrel.

Reference solution (a). A 0.025 per cent w/v solution of *desogestrel IPRS* in *methanol*.

Reference solution (b). A 0.03 per cent w/v solution of *ethinyl estradiol IPRS* in *methanol*.

Reference solution (c). Dilute a suitable volume of reference solution (a) and reference solution (b) with the solvent mixture to obtain a solution having similar concentration to the test solution.

Use chromatographic system as described under Dissolution.

Inject reference solution (c). The test is not valid unless the tailing factor is not more than 2.0 per cent and relative standard deviation for replicate injections is not more than 2.0 per cent for both the peaks.

Inject reference solution (c) and the test solution.

Calculate the content of $C_{22}H_{30}O$ and $C_{20}H_{24}O_2$ in the tablets.

Storage. Store protected from moisture, at a temperature not exceeding 30°.