

## Ethinodiol Diacetate and Ethinyl Estradiol Tablets

Ethinodiol Diacetate and Ethinyl Estradiol Tablets contain not less than 93.0 per cent and not more than 107.0 per cent of the stated amount of ethynodiol diacetate,  $C_{24}H_{32}O_4$  and not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of ethinyl estradiol,  $C_{20}H_{24}O_2$ .

**Usual strength.** Ethynodiol Diacetate 1mg and Ethinyl Estradiol 0.05 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 the reference solution.

### Tests

**Disintegration** (2.5.1). Not more than 15 minutes, perform the test without discs.

**Uniformity of content** (2.5.4). 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 10 ml of the mobile phase, with the aid of ultrasound and dilute to 25.0 ml with the mobile phase.

Inject the reference solution and the test solution.

Calculate the contents of  $C_{24}H_{32}O_4$  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).

*Test solution.* Disperse 10 intact tablets in 200 ml of the mobile phase, with the aid of ultrasound and dilute to 250.0 ml with the mobile phase.

*Reference solution.* A solution containing 0.004 per cent w/v of ethynodiol diacetate IPRS and 0.0002 per cent w/v of ethinyl estradiol IPRS in the mobile phase.

#### Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with nitrile groups bonded to porous silica (5  $\mu$ m) (Such as Zorbax CN),
- mobile phase: a mixture of 15 volumes of *methanol*, 35 volumes of *acetonitrile* and 50 volumes of *water*,
- flow rate: 2 ml per minute,
- spectrophotometer set at 210 nm,
- injection volume: 50  $\mu$ l.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 3000 theoretical plates, the tailing factor is not more than 1.5 for ethynodiol diacetate peak and the relative standard deviation for replicate injections is not more than 2.0 per cent for both the peaks.

Inject the reference solution and the test solution.

Calculate the contents of  $C_{24}H_{32}O_4$  and  $C_{20}H_{24}O_2$  in the tablets.

**Storage.** Store protected from moisture.