

## Norgestimate and Ethinyl Estradiol Tablets

### Chromatographic purity—

*Mobile phase*—Proceed as directed in the Assay.

*Standard solution*—Use the *Standard preparation*, prepared as directed in the Assay.

*Test solution*—Use the *Assay preparation*, prepared as directed in the Assay.

*Chromatographic system* (see *Chromatography* ( 621 ))—The liquid chromatograph is equipped with a detector capable of detecting at ~~230 nm and~~ 254 nm, simultaneously, and a 4.6-mm × 10-cm column that contains 5-μm packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Standard solution*, and record the peak areas as directed for *Procedure*: the relative retention times are about 0.5 for ethinyl estradiol, 1.0 for (*Z*)-norgestimate, and 1.2 for (*E*)-norgestimate; the resolution, *R*, between (*Z*)-norgestimate and (*E*)-norgestimate is not less than 1.5; and the relative standard deviation for replicate injections of the ethinyl estradiol and norgestimate peaks is not more than 2.0%.

*Procedure*—Inject a volume (about 50 μL) of the *Test solution* into the chromatograph, record the chromatograms, and measure the areas for the major peaks. ~~Calculate the percentage of the impurity having a relative retention time of about 0.6, relative to the (*Z*)-norgestimate peak, and detected at 230 nm in the portion of Tablets taken by the formula:~~

$$100(1.31)(r_i / r_s)$$

~~in which 1.31 is the relative response factor of this impurity;  $r_i$  is the peak response for the impurity; and  $r_s$  is the sum of the peak responses for (*E*)-norgestimate and (*Z*)-norgestimate: not more than 7.5% is found.~~ Calculate the percentage of any impurity having a relative retention time of about 0.2 or 0.4, relative to the (*Z*)-norgestimate peak, and detected at 254 nm in the portion of Tablets taken by the formula:

$$100(1.54)(C_Z / C_E)(r_i / r_Z)$$

in which 1.54 is the relative response factor of the impurity peaks;  $C_Z$  and  $C_E$  are the quantities, in mg, of (*Z*)-norgestimate and ethinyl estradiol, respectively, as determined in the Assay;  $r_i$  is the peak response for each impurity; and  $r_Z$  is the peak response for (*Z*)-norgestimate: the sum of the impurities having relative retention times of about 0.2 and 0.4 is not more than 4.0%.