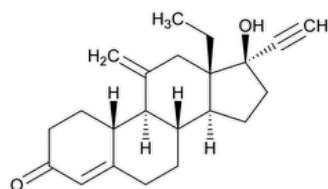


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Add the following:

^Etonogestrel



$C_{22}H_{28}O_2$ 324.46

18,19-Dinor-17 α -pregn-4-en-20-yn-3-one, 13-ethyl-17-hydroxy-11-methylene-

13-Ethyl-17-hydroxy-11-methylene-18,19-dinor-17 α -pregn-4-en-20-yn-3-one CAS RN®: 54048-10-1; UNII: 304GTH6RNH.

DEFINITION

Etonogestrel contains NLT 97.5% and NMT 101.5% of etonogestrel ($C_{22}H_{28}O_2$), calculated on the dried basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197A or 197K
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Mobile phase: [Methanol](#) and [water](#) (67.5: 32.5)

System suitability solution: 2 μ g/mL each of [USP Etonogestrel RS](#) and [USP Etonogestrel Related Compound A RS](#) in [methanol](#)

Standard solution: 200 μ g/mL of [USP Etonogestrel RS](#) in [methanol](#)

Sample solution: 200 μ g/mL of Etonogestrel in [methanol](#)

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 244 nm

Column: 4-mm $\times$ 25-cm; 5- μ m packing [L1](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 10 μ L

Run time: NLT 3 times the retention time of etonogestrel

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—See [Table 1](#) for the relative retention times for etonogestrel related compound A and etonogestrel. These relative retention times are provided as information that could aid in peak assignment.]

Suitability requirements

Resolution: NLT 1.5 between etonogestrel related compound A and etonogestrel, *System suitability solution*

Tailing factor: 0.9–2.0 for etonogestrel, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of etonogestrel ($C_{22}H_{28}O_2$) in the portion of Etonogestrel taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of etonogestrel from the *Sample solution*

r_S = peak response of etonogestrel from the *Standard solution*

C_S = concentration of [USP Etonogestrel RS](#) in the *Standard solution* (µg/mL)

C_U = concentration of Etonogestrel in the *Sample solution* (µg/mL)

Acceptance criteria: 97.5%–101.5% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• ORGANIC IMPURITIES

Mobile phase, System suitability solution, and Sample solution: Prepare as directed in the Assay.

Standard solution 1: 2 µg/mL of [USP Etonogestrel RS](#) in [methanol](#)

Standard solution A: 2 µg/mL of [USP Etonogestrel Related Compound A RS](#) in [methanol](#)

Standard solution B: 2 µg/mL of [USP Etonogestrel Related Compound B RS](#) in [methanol](#)

Standard solution C: 2 µg/mL of [USP Etonogestrel Related Compound C RS](#) in [methanol](#)

Standard solution D: 2 µg/mL of [USP Etonogestrel Related Compound D RS](#) in [methanol](#)

Standard solution E: 4 µg/mL of [USP Etonogestrel Related Compound E RS](#) in [methanol](#)

Sensitivity solution: 0.1 µg/mL of [USP Etonogestrel RS](#) and 0.2 µg/mL of [USP Etonogestrel Related Compound E RS](#) in [methanol](#)

Blank solution: [Methanol](#)

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 244 nm. For etonogestrel related compound E, use UV 205 nm.

Column: 4.0-mm × 25-cm; 5-µm packing [L1](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 10 µL

Run time: NLT 3 times the retention time of etonogestrel

System suitability

Samples: *System suitability solution*, *Standard solution 1*, and *Sensitivity solution*. [NOTE—The relative retention times in [Table 1](#) are provided as information that could aid in peak assignment.]

Table 1

Name	Relative Retention Time
Etonogestrel related compound B	0.36
Etonogestrel related compound C	0.49
Etonogestrel related compound D	0.72
Etonogestrel related compound A	0.92
Etonogestrel	1.0
Etonogestrel related compound E	1.29

Suitability requirements

Resolution: NLT 1.5 between etonogestrel related compound A and etonogestrel, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution 1*

Signal-to-noise ratio: NLT 10 for etonogestrel; NLT 3 for etonogestrel related compound E, *Sensitivity solution*

Analysis