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Add the following:

^Exemestane Tablets

DEFINITION
Exemestane Tablets contain Exemestane equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of exemestane (C₂₀H₂₄O₂).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The UV absorption spectra of the *Sample solution* and the *Standard solution* exhibit maxima and minima at the same wavelengths, as obtained in the Assay.

ASSAY

- **PROCEDURE**
Solution A: [Methanol](#) and [water](#) (5:95)
Solution B: [Methanol](#) and [water](#) (95:5)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	72.2	27.8
35	38.9	61.1
40	5.6	94.4
50	5.6	94.4
52	72.2	27.8
60	72.2	27.8

Diluent: [Acetonitrile](#) and [water](#) (50:50)
Standard solution: 0.1 mg/mL of [USP Exemestane RS](#) prepared as follows. Transfer a weighed amount of [USP Exemestane RS](#) into a suitable volumetric flask and add [acetonitrile](#) equivalent to 5% of the final volume. Sonicate to dissolve and dilute with *Diluent* to volume.
Sample stock solution: Nominally equivalent to 1.0 mg/mL of exemestane prepared as follows. Place 10 Tablets in a 250-mL volumetric flask. Add 100 mL of *Diluent*, sonicate for 15 min, and then shake mechanically for 15 min. Dilute with *Diluent* to volume.
Sample solution: Nominally equivalent to 0.1 mg/mL of exemestane in *Diluent* from *Sample stock solution*. Pass this solution through a suitable filter of 0.45-µm pore size and discard the first few milliliters.

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

Mode: LC
Detector: UV 247 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.
Column: 4.6-mm × 15-cm; 3-µm packing [L1](#)
Column temperature: 40°–50°
Flow rate: 1.0 mL/min
Injection volume: 10 µL

System suitability**Sample:** *Standard solution***Suitability requirements****Tailing factor:** NMT 1.5**Relative standard deviation:** NMT 2.0%**Analysis****Samples:** *Standard solution and Sample solution*Calculate the percentage of the labeled amount of exemestane ($C_{20}H_{24}O_2$) in the portion of Tablets taken:

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

 r_U = peak response of exemestane from the *Sample solution* r_S = peak response of exemestane from the *Standard solution* C_S = concentration of [USP Exemestane RS](#) in the *Standard solution* (mg/mL) C_U = nominal concentration of exemestane in the *Sample solution* (mg/mL)**Acceptance criteria:** 90.0%–110.0%**PERFORMANCE TESTS**• **[DISSOLUTION \(711\)](#)****Medium:** 5 g/L [sodium dodecyl sulfate](#) in [water](#), do not degas; 900 mL**Apparatus 1:** 100 rpm**Time:** 30 min**Standard solution:** 0.03 mg/mL of [USP Exemestane RS](#) prepared as follows. Transfer a weighed amount of [USP Exemestane RS](#) into a suitable volumetric flask and add [methanol](#) equivalent to 2% of the final volume. Sonicate to dissolve and dilute with *Medium* to volume.**Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.2- μ m pore size. Discard NLT 2 mL and use the filtrate for analysis.**Instrumental conditions****Mode:** UV**Analytical wavelength:** 250 nm**Cell length:** 0.5 cm**Analysis****Samples:** *Standard solution and Sample solution*Calculate the percentage of the labeled amount of exemestane ($C_{20}H_{24}O_2$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times (V/L) \times 100$$

 A_U = absorbance of the *Sample solution* A_S = absorbance of the *Standard solution* C_S = concentration of the *Standard solution* (mg/mL) V = volume of *Medium*, 900 mL L = label claim (mg/Tablet)**Tolerances:** NLT 80% (Q) of the labeled amount of exemestane ($C_{20}H_{24}O_2$) is dissolved.• **[UNIFORMITY OF DOSAGE UNITS \(905\)](#):** Meet the requirements**IMPURITIES**• **ORGANIC IMPURITIES****Mobile phase, Diluent, Sample solution, and Chromatographic system:** Proceed as directed in the Assay.**Standard stock solution:** Use *Standard solution* in the Assay.**Standard solution:** 0.3 μ g/mL of [USP Exemestane RS](#) in *Diluent* from *Standard stock solution***Sensitivity solution:** 0.05 μ g/mL of [USP Exemestane RS](#) in *Diluent* from *Standard solution***System suitability**