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Estazolam Tablets

DEFINITION

Estazolam Tablets contain an amount of Estazolam equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of estazolam ($C_{16}H_{11}ClN_4$).

IDENTIFICATION

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**

Buffer: 2.8 g/L of potassium phosphate, monobasic in water. Adjust to a pH of 6.5 with 1 N NaOH.

Mobile phase: Acetonitrile, methanol, and *Buffer* (10:35:55)

Standard solution: 0.02 mg/mL of USP Estazolam RS in *Mobile phase*

Sample solution: 0.02 mg/mL of Estazolam in *Mobile phase*, from NLT 20 finely powdered Tablets. [Note—Sonicate for 5 min. Pass a portion through a suitable filter with no glass prefilter.]

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 15-cm; 3-µm packing L11

Flow rate: 1 mL/min

Injection size: 25 µL

Run time: 2.7 times the retention time of the estazolam peak

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{16}H_{11}ClN_4$ in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Estazolam RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of estazolam in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL, deaerated

Apparatus 2: 50 rpm

Time: 30 min

Buffer and **Mobile phase:** Proceed as directed in the *Assay*.

Standard stock solution: 0.1 mg/mL of USP Estazolam RS in methanol

Standard solution: Dilute the *Standard stock solution* with *Medium* to obtain a final concentration of about (L/1000) mg/mL, where L is the Tablet label claim in mg.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size, discarding the first few mL.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Proceed as directed in the *Assay*, except for the injection size and run time.

Injection size: 100 µL

Run time: 1.6 times the retention time of estazolam

System suitability: Proceed as directed in the *Assay*.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of estazolam dissolved:

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

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

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

C_S = concentration of USP Estazolam RS in the *Standard solution* (mg/mL)

L = Tablet label claim (mg)

V = volume of *Medium* (mL), 900

Tolerances: NLT 80% (Q) of the labeled amount of estazolam is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

Organic Impurities

• **Procedure**

Buffer, Mobile phase, Standard solution, and **Sample solution:** Proceed as directed in the *Assay*.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Proceed as directed in the *Assay*, except for the injection size and run time.

Injection size: 25 µL for the *Standard solution* and 50 µL for the *Sample solution*

Run time: 4 times the retention time of estazolam

System suitability: Proceed as directed in the *Assay*.

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Tablets taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of each individual impurity from the *Sample solution*

r_T = sum of the responses of all peaks from the *Sample solution*

Acceptance criteria

Any individual unspecified degradation product: NMT 0.5%

Total impurities: NMT 1.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers. Store at controlled room temperature.

• **USP Reference Standards ⟨11⟩**

USP Estazolam RS

4*H*-[1,2,4]Triazolo[4,3-*a*][1,4]benzodiazepine, 8-chloro-6-phenyl-.
8-Chloro-6-phenyl-4*H*-*s*-triazolo[4,3-*a*][1,4]benzodiazepine.

$C_{16}H_{11}ClN_4$	294.74

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ESTAZOLAM TABLETS	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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