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Ethionamide Tablets

DEFINITION

Ethionamide Tablets contain NLT 95.0% and NMT 110.0% of the labeled amount of ethionamide ($C_8H_{10}N_2S$).

IDENTIFICATION

• A.

Sample solution: The solution of Tablets employed for measurement of absorbance in the Assay

Acceptance criteria:

The *Sample solution* exhibits an absorbance maximum at 290 ± 2 nm.

• B.

Sample solution: Nominally 20 mg/mL of ethionamide from digested powdered Tablets in methanol

Analysis: Filter the *Sample solution* through a sintered-glass funnel of medium pore size. Evaporate the filtrate on a steam bath to dryness.

Acceptance criteria: The residue so obtained melts at $155^{\circ}\text{--}164^{\circ}$.

ASSAY

• PROCEDURE

Standard solution: 10 μ g/mL of [USP Ethionamide RS](#) in methanol

Sample stock solution: Nominally 0.4 mg/mL of ethionamide prepared as follows. Transfer nominally 100 mg of ethionamide from powdered Tablets (NLT 20), to a sintered-glass funnel of medium pore size that is fitted into a 250-mL suction flask. Extract the sample by stirring it with successive 10-mL portions of methanol, using a total of about 100 mL of solvent, and drawing off each portion of liquid with gentle suction before adding the next portion. Transfer the combined methanol extracts to a 250-mL volumetric flask, and dilute with methanol to volume.

Sample solution: Nominally 10 μ g/mL of ethionamide in methanol from the *Sample stock solution*

Blank: Methanol

Instrumental conditions

Mode: UV

Analytical wavelength: 290 nm

Cell: 1 cm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ethionamide ($C_8H_{10}N_2S$) in the portion of Tablets taken:

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

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of [USP Ethionamide RS](#) in the *Standard solution* (μ g/mL)

C_U = nominal concentration of ethionamide in the *Sample solution* (μ g/mL)

Acceptance criteria: 95.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 1: 100 rpm

Time: 45 min

Detector: UV 274 nm

Standard solution: [USP Ethionamide RS](#) in *Medium*

Sample solution: Dilute with *Medium* to a concentration that is similar to that of the *Standard solution*.

Tolerances: NLT 75% (Q) of the labeled amount of ethionamide ($C_8H_{10}N_2S$) is dissolved.

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.

- [USP REFERENCE STANDARDS \(11\)](#)

[USP Ethionamide RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ETHIONAMIDE TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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