Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-EF31325A-341D-4005-BD93-D8D43B04CBF3_3_en-US
DOI: https://doi.org/10.31003/USPNF_M26090_03_01
DOI Ref: v1zt1

Dihydroergotamine Mesylate Injection

DEFINITION

Dihydroergotamine Mesylate Injection is a sterile solution of Dihydroergotamine Mesylate in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of dihydroergotamine mesylate ($C_{33}H_{37}N_5O_5 \cdot CH_4O_3S$).

IDENTIFICATION

- **A.**

Sample solution: 2 mL of Injection in 25 mL water

Acceptance criteria: The UV absorption spectrum of the *Sample solution* exhibits maxima and minima at the same wavelengths as those of a similar solution of USP Dihydroergotamine Mesylate RS.

ASSAY

- **Procedure**

Diluent: 10 mg/mL of tartaric acid in water

Solution A: Dissolve 250 mg of *p*-dimethylaminobenzaldehyde in a cooled mixture of 130 mL of sulfuric acid and 70 mL of water, and add 0.40 mL of ferric chloride solution (1 in 20).

Standard solution: 50 µg/mL of USP Dihydroergotamine Mesylate RS in *Diluent*

Sample solution: Nominally 50 µg/mL of dihydroergotamine mesylate from a suitable volume of Injection containing NLT 5 mg of dihydroergotamine mesylate in *Diluent*

Blank: *Diluent*

Instrumental conditions

Mode: Vis

Analytical wavelength: 585 nm

Cell: 1 cm

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Transfer 5.0 mL each of the *Standard solution*, the *Sample solution*, and the *Blank* to separate 50-mL conical flasks. Add 10.0 mL of *Solution A* to each flask, shake, and allow to stand for 30 min. Measure the absorbance of the resulting *Standard solution* and *Sample solution* against the *Blank*.

Calculate the percentage of the labeled amount of dihydroergotamine mesylate ($C_{33}H_{37}N_5O_5 \cdot CH_4O_3S$) in the portion of Injection 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 Dihydroergotamine Mesylate RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of dihydroergotamine mesylate in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **Bacterial Endotoxins Test ⟨85⟩:** NMT 175.0 USP Endotoxin Units/mg of dihydroergotamine mesylate
- **pH ⟨791⟩:** 3.4–4.9
- **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose containers, preferably of Type I glass, and protect from light.
- **USP Reference Standards** ⟨11⟩
  USP Dihydroergotamine Mesylate RS

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

Topic/Question	Contact	Expert Committee
DIHYDROERGOTAMINE MESYLATE INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-EF31325A-341D-4005-BD93-D8D43B04CBF3_3_en-US
Previous DocID: GUID-EF31325A-341D-4005-BD93-D8D43B04CBF3_1_en-US
DOI: https://doi.org/10.31003/USPNF_M26090_03_01
DOI ref: v1zt1