

## Dihydroergotamine Mesylate Injection

<b>Type of Posting</b>	Notice of Intent to Revise
<b>Posting Date</b>	24–Apr–2020
<b>Official Date</b>	To Be Determined, Revision Bulletin
<b>Expert Committee</b>	Chemical Medicines Monographs 4

In accordance with section 7.04 (c) of the 2015–2020 Rules and Procedures of the Council of Experts and the [Pending Monograph Guideline](#), this is to provide notice that the Chemical Medicines Monographs 4 Expert Committee intends to revise the Dihydroergotamine Mesylate Injection monograph.

The purpose for the revision is to revise the pH limit in the monograph from 3.4–4.9 to 3.4–5.4 to accommodate the specifications of a recently approved drug product.

The proposed revision is contingent on FDA approval of a product that meets the proposed monograph specifications. The proposed revision will be published as a Revision Bulletin and an official date will be assigned to coincide as closely as possible with the FDA approval of the associated product.

See below for additional information about the proposed text.<sup>1</sup>

Should you have any questions, please contact Heather Joyce, Senior Scientific Liaison to the Chemical Medicines Monographs 4 Expert Committee (301-998-6792 or [hri@usp.org](mailto:hri@usp.org)).

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<sup>1</sup> This text is not the official version of a *USP–NF* monograph and may not reflect the full and accurate contents of the currently official monograph. Please refer to the current edition of the *USP–NF* for official text.

USP provides this text to indicate changes that we anticipate will be made official once the product subject to this proposed revision under the Pending Monograph Program receives FDA approval. Once FDA approval is granted for the associated revision request, a Revision Bulletin will be posted that will include the changes indicated herein, as well as any changes indicated in the product's final approval, combined with the text of the monograph as effective on the date of approval. Any revisions made to a monograph under the Pending Monograph Program that are posted without prior publication for comment in the *Pharmaceutical Forum* must also meet the requirements outlined in the [USP Guideline on Use of Accelerated Processes for Revisions to the USP–NF](#).

## 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

### Change to read:

- **PH** <791>: 3.4–▲5.4▲ (TBD)
- **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