Dihydroergotamine Injection

Published on: 08.10.2024 **Last date for comments:** 22.11.2024

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

Document History and Schedule for the Adoption Process

Description	Details
Document version	2.0
Category	New Inclusion
Monograph proposed for inclusion	IP 2026
Tentative effective date of monograph	July, 2026
First draft published on IPC website for public comments	18.01.2024
Draft revision published on IPC website for public comments	08.10.2024
Further follow-up action as required.	

Dihydroergotamine Injection

Dihydroergotamine Mesylate Injection

Dihydroergotamine ~~Mesylate~~ Injection is a sterile solution of Dihydroergotamine Mesylate in water for injections.

Dihydroergotamine Injection contains not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of dihydroergotamine mesylate, $C_{33}H_{37}N_5O_5.CH_40_3S$.

Usual strength. 1 mg per ml.

Identification

When examined in the range 200 nm to 400 nm (2.4.7), a 0.08~~4.0~~ per cent w/v solution in *water* shows absorption maxima and minima at the same wavelength as that of *dihydroergotamine mesylate IPRS* prepared in the same manner.

Tests

pH (2.4.24). 3.4 to 4.9.

Bacterial endotoxins (2.2.3). Not more than 175.0 Endotoxin units per mg of dihydroergotamine mesylate.

Other tests. Comply with the test stated under Parenteral Preparations (Injections).

Assay

Solvent mixture. 1 per cent w/v solution of *tartaric acid* in *water*.

Solution A. Dissolve 0.25 g of *p-dimethylaminobenzaldehyde* in a cooled mixture of 130 ml of *sulphuric acid* and 70 ml of *water* and add 0.4 ml of *ferric chloride test solution.*

Test solution. Dilute a suitable volume of the injection with the solvent mixture to obtain a solution containing 0.005 per cent w/v of Dihydroergotamine Mesylate.

Reference solution. A 0.005 per cent w/v solution of *dihydroergotamine mesylate IPRS* in the solvent mixture.

Blank solution. Use solvent mixture as blank.

Transfer 5.0 ml, each of, the reference solution, the test solution and the blank to separate 50-ml volumetric flasks, add 10 ml of solution A to each volumetric flask, shake and allow to stand for 30 minutes. Measure the absorbance of the resulting reference solution and test solution at the maximum at about 585 nm (2.4.7) against blank solution.

Calculate the content of dihydroergotamine mesylate, $C_{33}H_{37}N_5O_5.CH_40_3S$ in the injection.

Storage. Store protected from light. Preserve in single dose containers, preferably of type 1 glass.