

Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

Oxytocin Injection

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This draft revision contains revised monograph text for inclusion in the Indian Pharmacopoeia (IP). The content of this draft document is not final, and the text may be subject to further revisions prior to publication in the IP. This draft does not necessarily represent the decisions or the stated policy of the IP or Indian Pharmacopoeia Commission (IPC).

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 revised 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	1.0
Monograph proposed for inclusion	IP 2026
Tentative effective date of monograph	January, 2026
First draft published on IPC website for public comments	01.08.2024
Draft revision published on IPC website for public comments	
Further follow-up action as required.	

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Change to: Oxytocin Injection

Oxytocin Injection is a sterile solution of Oxytocin in a suitable vehicle.

Oxytocin Injection contains not less than 90.0 per cent and not more than 110.0 per cent of the stated number of Units (IU) of oxytocic activity.

Usual strengths. 5 Units per ml; 10 Units per ml.

Description. A clear colourless liquid.

Identification

In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

Tests

pH (2.4.24). 3.0 to 5.0.

Bacterial endotoxins (2.2.3). Not more than 0.5 Endotoxin Unit per Unit of oxytocin.

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

Assay. Determine by liquid chromatography (2.4.14).

Solvent mixture. Dissolve 5.0 g of *chlorobutanol* in 5.0 ml of *glacial acetic acid*, add 6.3 ml of *ethanol (95 per cent)*, 1.1 g of *sodium acetate*, and 1000 ml of *water*, and mix.

Test solution. Use undiluted injection.

Reference solution. Dissolve the contents of one vial of *oxytocin IPRS* in the solvent mixture to obtain a solution having similar concentration as that of the test solution.

Chromatographic system

- a stainless steel column 12.5 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: A. a buffer solution of 0.1 M *sodium dihydrogen phosphate*,
B. a mixture of 50 volumes of *acetonitrile* and 50 volumes of *water*,
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 220 nm,
- injection volume: 100 µl.

Equilibrate the column using 70 per cent v/v of mobile phase A and 30 per cent v/v of mobile phase B.

After each injection, the composition of the mobile phase is changed linearly over the next 25 minutes so that it consists of a mixture of 50 per cent v/v of mobile phase A and 50 per cent v/v of mobile phase B.

Note: Adjust the flow rate or the composition of the mobile phase such that the retention time is approximately 10 minutes for *oxytocin* and between 15 and 17 minutes for *chlorobutanol*.

Inject the reference solution. The test is not valid unless the resolution between oxytocin and the nearest adjacent peak is not less than 1.5, and the relative standard deviation for replicate injections is not more than 2.0 per cent for oxytocin.

Inject the reference solution and the test solution.

Calculate the content of oxytocin Units (IU) per ml in the injection.

Storage. Store protected from light and unless otherwise indicated on the label, at a temperature between 2° to 8°.

Labelling. The label states the oxytocic activity in terms of number of oxytocin units (IU) per ml.