Oxytocin Concentrated Solution

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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

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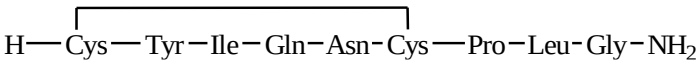
Further follow-up action as required.	

Oxytocin Concentrated Solution



$C_{43}H_{66}N_{12}O_{12}S_2$ Mol. Wt.1007

Oxytocin concentrated is L-Cysteinyl-L-tyrosyl-L-isoleucyl-L-glutamyl-L-asparaginyl-L-cysteinyl-L-prolyl-L-leucylglycinamide cyclic (1→6)-disulphide.

Solution of oxytocin, a synthetic cyclic nonapeptide having the structure of the hormone produced by the posterior lobe of the pituitary gland that stimulates contraction of the uterus and milk ejection in receptive mammals. It is available as a solution with a stated concentration of not less than 150 oxytocin units (IU) per ml, in a solvent that may contain an appropriate antimicrobial preservative.

Oxytocin Concentrated Solution contains not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of the oxytocin units (IU) per ml.

Category. Uterine stimulant.

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.

Related substances. Determine by liquid chromatography (2.4.14).

Test solution. Use the oxytocin concentrated solution under examination, dilute with *water*, if necessary.

Reference solution. Dissolve the contents of a vial of *oxytocin/desmopressin validation mixture IPRS* in 1.0 ml of mobile phase A.

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 1.56 per cent w/v solution of *sodium dihydrogen phosphate*,
  B. a mixture of equal volumes of *acetonitrile* and *water*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 220 nm,
- injection volume: 50 µl.

Time (in min)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	70	30
30	40	60
30.1	70	30
45	70	30

The relative retention time with reference to oxytocin for desmopressin is about 1.3.

Inject the reference solution. The test is not valid unless the resolution between the peaks due to oxytocin and desmopressin is not less than 5.0.

Inject the test solution. The area of any secondary peak is not more than 1.5 per cent and the sum of the areas of all the secondary peaks is not more than 5.0 per cent, calculated by area normalization. Ignore any peak with an area less than 0.1 per cent.

Assay. Determine by liquid chromatography (2.4.14), as described under Related substances with the following modifications.

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

– injection volume: 25 µl.

Inject the reference solution and the test solution.

Calculate the content of oxytocin units (IU) per ml.

Oxytocin concentrated solution intended for use in the manufacture of parenteral preparations without a further procedure for the removal of bacterial endotoxins complies with the following additional requirement.

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

Oxytocin concentrated solution intended for use in the manufacture of parenteral preparations without a further sterilisation procedure complies with the following additional requirement.

Sterility (2.2.11). Complies with the test for sterility.

Storage. Store protected from light, at a temperature between 2° to 8°. If the substance is sterile, store in sterile airtight, tamper-proof container.

Labelling. The label states (1) the oxytocic activity in terms of number of oxytocin units (IU) per ml; (2) whether or not the contents are intended for use in the manufacture of parenteral preparations.