Minocycline for Injection

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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.	

Minocycline for Injection

Minocycline Hydrochloride for Injection

Minocycline for Injection is a sterile freeze-dried Minocycline Hydrochloride.

The injection is constituted by dissolving the contents of the sealed container in the requisite amount of sterile Water for Injections, immediately before use.

The constituted solution complies with the requirements for Clarity of solution and Particulate matter stated under Parenteral Preparations (Injections).

Storage. The constituted solution should be used immediately after preparation but, in any case, within the period recommended by the manufacturer.

Minocycline for Injection contains not less than 90.0 per cent and not more than 120.0 per cent of the stated amount of minocycline, $C_{23}H_{27}N_3O_7$.

Usual strength. 100 mg per vial.

Identification

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

Tests

pH (2.4.24). 2.0 to 3.5, determined in a 1.0 per cent w/v solution of minocycline.

Limit of Epiminocycline. Determine by liquid chromatography (2.4.14).

NOTE — Carry out the test protected from light. Store the solution at 2° to 8° and use within 3 hours of preparation.

Test solution. Reconstitute one vial with *water for injections*, corresponding to the volume of solvent specified in the labelling. Reconstitute 4 more vials. Pool the content of 5 vials to prepare a composite sample. Dilute a suitable volume of the pooled sample with *water* to obtain a solution containing 0.05 per cent w/v of minocycline.

Reference solution (a). A solution of *minocycline hydrochloride IPRS* containing 0.05 per cent w/v of minocycline in *water*.

Reference solution (b). Dissolve 10 mg of *minocycline hydrochloride IPRS* in 20 ml of *0.2 M ammonium oxalate* and heat at 60° in a water bath for 3 hours, cool and dilute to 25.0 ml with *water*.

Chromatographic system
- a stainless steel column 25 cm × 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm)
- column temperature: 40º,
- mobile phase: a mixture of 60 volumes of *0.2 M ammonium oxalate*, 18 volumes of *0.01 M edetate disodium*, 12 volumes of *dimethylformamide* and 8 volumes of *tetrahydrofuran*,
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 280 nm,
- injection volume: 20 µl.

The relative retention time with reference to minocycline for epiminocycline is about 0.7.

Inject reference solution (a) and (b). The test is not valid unless the resolution between the peaks due to epiminocycline and minocycline is not less than 1.5 in the chromatogram obtained with reference solution (b), the

capacity factor is not less than 5.0 and not more than 11.5, the tailing factor is not less than 0.9 and not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent in the chromatogram obtained with reference solution (a).

Inject the test solution. The area of any peak corresponding to epiminocycline is not more than 6.0 per cent, calculated by area normalization.

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

Bacterial endotoxins (2.2.3). Not more than 1.25 Endotoxin Unit per mg of minocycline.

Sterility (2.2.11). Complies with the test for sterility

Assay. Determine by liquid chromatography (2.4.14), as described under Limit of Epiminocycline with the following modifications.

Inject reference solution (a) and (b). The test is not valid unless the resolution between the peaks due to epiminocycline and minocycline is not less than 1.5 in the chromatogram obtained with reference solution (b), the capacity factor is not less than 5.0 and not more than 11.5, the tailing factor is not less than 0.9 and not more than 2.0 and relative standard deviation for replicate injections is not more than 2.0 per cent in the chromatogram obtained with reference solution (a).

Inject reference solution (a) and the test solution.

Calculate the content of $C_{23}H_{27}N_3O_7$ in the injection.

Storage. Store protected from light.

Labelling. The label states (1) the strength in terms of equivalent amount of minocycline; (2) the direction for the reconstitution and dilution.