Dicyclomine 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.	

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Change **to: Dicyclomine Injection**

Dicyclomine Hydrochloride Injection; Dicycloverine Hydrochloride Injection

Dicyclomine Injection is a sterile, isotonic solution of Dicyclomine Hydrochloride in Water for Injections.

Dicyclomine Injection contains not less than 93.0 per cent and not more than 107.0 per cent of the stated amount of dicyclomine hydrochloride, $C_{19}H_{35}NO_2$,HCl.

Usual strength. 10 mg per ml.

Identification

A. To a volume containing 0.1 g of Dicyclomine Hydrochloride, add 10 ml of *water* and 1 ml of *hydrochloric acid,* shake with 30 ml of *ether* and allow to separate. Extract the aqueous layer with 30 ml of *chloroform,* wash the extract with two quantities, each of 20 ml, of *water* and 1 ml of 10 per cent w/v *sodium hydroxide*. Filter the chloroform solution through *anhydrous sodium sulphate.* Add 3 ml of a freshly prepared 5 per cent w/v solution of *acetyl chloride* in *anhydrous methanol* (prepared by adding *acetyl chloride* dropwise to *anhydrous methanol* with stirring). Evaporate under reduced pressure at room temperature until the residue has been thoroughly dried.

On the residue, determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *dicyclomine hydrochloride IPRS* treated in the same manner or with the reference spectrum of dicyclomine hydrochloride.

B. 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

Limit of dicyclomine related compound A. Determine by liquid chromatography (2.4.14).

*Solvent mixture.*70 volumes of *acetonitrile* and 30 volumes of *water.*

Test solution. Prepare a composite sample of not less 5 ampoules or vials. Dilute a volume of the pooled sample containing about 20 mg of Dicyclomine Hydrochloride to 10.0 ml with the solvent mixture.

Reference solution (a). A 0.0004 per cent w/v solution of *dicyclomine hydrochloride related compound A ([1,1'-Bi (cyclohexane)]-1-carboxylic acid) IPRS* in the solvent mixture.

Reference solution (b). Dilute 5.0 ml of reference solution (a) to 10.0 ml with the solvent mixture.

Chromatographic system

- a stainless steel column 15 cm x 4.6 mm packed with octylsilane bonded to porous silica (3.5µm), (Such as X Bridge BEH C8),
- mobile phase: a mixture of 55 volumes of *acetonitrile* and 45 volumes of a buffer solution prepared by dissolving 2.72 g of *potassium dihydrogen orthophosphate* in 900 ml of *water*, adjusted to pH 3.5 with *orthophosphoric acid* and dilute to 1000 ml with *water*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 215 nm,
- injection volume: 100 µl.

Inject reference solution (a) and (b) The test is not valid unless the relative standard deviation for replicate injections is not more than 5.0 per cent in the chromatogram obtained with reference solution (a), and the signal-to-noise ratio is not less than 10 in the chromatogram obtained with reference solution (b).

Inject reference solution (a) and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to dicyclomine hydrochloride related compound A is not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (0.2 per cent).

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

Bacterial endotoxins (2.2.3). Not more than 17.2 Endotoxin Unit per mg of Dicyclomine Hydrochloride.

Assay. Determine by liquid chromatography (2.4.14).

*Solvent mixture.*70 volumes of *acetonitrile* and 30 volumes of *water.*

Test solution. Prepare a composite sample of not less 5 ampoules or vials. Transfer a volume containing about 20 mg of Dicyclomine Hydrochloride to a 50-ml volumetric flask and dilute to volume with the solvent mixture.

Reference solution. A 0.04 per cent w/v solution of *dicyclomine hydrochloride IPRS* in the solvent mixture.

Chromatographic system

- a stainless steel column 15 cm x 4.6 mm packed with octylsilane bonded to porous silica (3.5µm), (Such as X Terra RP-8),
- mobile phase: a mixture of 70 volumes of *acetonitrile* and 30 volumes of a buffer solution prepared by dissolving 2.72 g of *potassium dihydrogen orthophosphate* in 900 ml of *water*, adjusted to pH 7.5 with 10 per cent w/v of *sodium hydroxide solution* and dilute to 1000 ml with *water*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 215 nm,
- injection volume: 50 µl

Inject the reference solution. The test is not valid unless the tailing factor is not more than 2.0, and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{19}H_{35}NO_2$,HCl in the injection.

Storage. Store in single dose or multiple dose containers, at a temperature not exceeding 30°, protect from freezing.