Cefprozil Tablets

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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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Cefprozil Tablets

Cefprozil Tablets contain not less than 90.0 per cent and not more than 120.0 per cent of the stated amount of cefprozil, $C_{18}H_{19}N_3O_5S$.

Usual strengths. 250 mg; 500 mg.

Identification

A. Determine by thin-layer chromatography (2.4.17), coating the plate with *silica gel G.*

Mobile phase. A mixture of 60 volumes of *butyl alcohol*, 20 volumes of *glacial acetic acid* and 20 volumes of *water*.

Solvent mixture. 80 volumes of *acetone* and 20 volume of *0.1 M hydrochloric acid*.

Test solution. Shake a quantity of the powdered tablets containing 250 mg of *cefprozil* in the solvent mixture for 5 minutes and dilute to100.0 ml with the solvent mixture. Allow the mixture to settle and use the supernatant liquid.

Reference solution. A 0.5 per cent w/v solution of *cefprozil Z-Isomer IPRS* in the solvent mixture.

Apply to the plate 10 µl of each solution. Dry the spots and develop the chromatogram in an equilibrated chamber with the mobile phase. Allow the mobile phase to rise three-fourths of the length of the plate. Remove the plate and dry in air in a hood. Place the plate in a chamber containing iodine vapors. Examine the plate and locate the spots. The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution.

B. In the Assay, the principal peaks in the chromatogram obtained with the test solution correspond to the peaks in the chromatogram obtained with reference solution (a) and (c).

Tests

Dissolution (2.5.2).

Apparatus No. 1 (Basket),

Medium. 900 ml of *water*,

Speed and time. 100 rpm and 45 minutes.

Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography (2.4.14)

(Note- Use these solutions within 6 hour)

Test solution. Use the filtrate, dilute if necessary with the dissolution medium to obtain a solution having similar concentration to that of reference solution (a) and (c).

Reference solution (a). A 0.025 per cent w/v solution of *cefprozil (Z)-isomer IPRS* in *water.*

Reference solution (b). A 0.025 per cent w/v solution of *cefprozil (E)-isomer IPRS* in *water*.

Reference solution (c). Dilute 5.0 ml of reference solution (b) to 50.0 ml with *water*.

Reference solution (d). Dilute 5.0 ml of reference solution (a) to 10.0 ml with reference solution (b).

Chromatographic system

- a stainless steel column 25 cm x 3.9 mm, packed with octadecylsilane bonded to porous silica (5 µm) (Such as Econosphere C18),
- mobile phase: a mixture of 90 volumes of a buffer solution prepared by dissolving 11.5 g of *ammonium dihydrogen phosphate* in *water*, adjusted to pH 4.4 with *orthophosphoric acid* and 10 volumes of *acetonitrile,*
- flow rate: 1 ml per minute,
- spectrophotometer set at 280 nm,
- injection volume: 10 µl.

The relative retention time with reference to cefprozil (E)-isomer, for cefprozil (Z)-isomer is about 0.7.

Inject reference solution (a) and (d). The test is not valid unless the resolution between the peaks due to cefprozil (Z)-isomer and cefprozil (E)-isomer is not less than 2.5 in the chromatogram obtained with reference solution (d), the column efficiency is not less than 2500 theoretical plates, the tailing factor is between 0.9 to 1.1 (measured at 10 per cent height of the peak) 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 reference solution (a) (for Z-isomer), (c) (for E-isomer) and the test solution and calculate the contents of cefprozil (Z)-isomer and cefprozil (E)-isomer.

Calculate the content of Cefprozil, $C_{18}H_{19}N_3O_5S$ in the medium by adding the contents of cefprozil (Z) isomer and cefprozil (E) isomer.

Q. Not less than 75 per cent of the stated amount of $C_{18}H_{19}N_3O_5S$.

Other tests. Comply with the tests stated under Tablets.

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

(Note- Use these solutions within 6 hour)

Test solution. Weigh and powder 20 tablets. Disperse a quantity of powder containing 600 mg of cefprozil in *water*, with the aid of ultrasound with intermittent shaking and dilute to 100.0 ml with *water*. Dilute 5.0 ml of the solution to 100.0 ml with *water*.

Inject reference solution (a) and (d). The test is not valid unless the resolution between the peaks due to cefprozil (Z)-isomer and cefprozil (E)-isomer is not less than 2.5 in the chromatogram obtained with reference solution (d), the column efficiency is not less than 2500 theoretical plates, the tailing factor is 0.9 to 1.1 (measured at 10 per cent height of the peak) 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 reference solution (a) (for Z-isomer), (c) (for E-isomer) and the test solution and calculate the contents of cefprozil (Z)-isomer and cefprozil (E)-isomer.

Calculate the content of Cefprozil, $C_{18}H_{19}N_3O_5S$ by adding the contents of cefprozil (Z) isomer and cefprozil (E) isomer.

Storage. Store at a temperature not exceeding 30°.