Carprofen 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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Further follow-up action as required.	

Carprofen Tablets

Carprofen Tablets contain not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of carprofen, $C_{15}H_{12}ClNO_2$.

Usual strength. 25 mg.

Identification

Disperse a quantity of the powdered tablets containing 0.1 g of Carprofen with 30 ml of *water* and 3 drops of *hydrochloric acid*. Add 30 ml of *dichloromethane* and shake. Allow to separate and filter the lower layer through absorbent cotton covered with *anhydrous sodium sulphate*. Filter and evaporate the filtrate to dry the residue at 60° for 30 minutes. On the residue, determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *carprofen IPRS* or with the reference spectrum of carprofen.

Tests

Dissolution (2.5.2).
Apparatus No. 2 (Paddle),
Medium. 900 ml of *0.05M phosphate buffer solution pH 7.5*,
Speed and time. 50 rpm and 45 minutes.

Withdraw a suitable volume of the medium, filter. Measure the absorbance of the filtrate, suitably diluted with the medium, if necessary at the maximum at about 300 nm (2.4.7). Calculate the content of $C_{15}H_{12}ClNO_2$ in the medium from the absorbance obtained from a solution of known concentration of *carprofen IPRS* prepared by dissolving 20 mg of *carprofen IPRS* in 10 ml of *methanol* and dilute to 100.0 ml with the dissolution medium. Dilute 5.0 ml of the solution to 50.0 ml with the dissolution medium.

Q. Not less than 75 per cent of the stated amount of $C_{15}H_{12}ClNO_2$ ~~in the medium~~.

Related substances. Determine by liquid chromatography (2.4.14).

Test solution. Disperse a quantity of the powdered tablets containing 50 mg of Carprofen in 75 ml of the mobile phase, with the aid of ultrasound and dilute to 100.0 ml with the mobile phase and filter.

Reference solution (a). a solution containing 0.005 per cent w/v *carprofen IPRS* in the mobile phase. Dilute 1.0 ml of the solution to 10.0 ml with the mobile phase.

Reference solution (b). a solution containing 0.025 per cent w/v *carprofen for system suitability IPRS* in the mobile phase.

Reference solution (c). Dilute 1.0 ml of reference solution (a) to 10.0 ml with the mobile phase.

Chromatographic system
- a stainless steel column 25 cm x 4.6 mm, packed with endcapped polar– embedded octadecylsilane bonded to amorphous organosilica polymer (5 µm), (Such as Water C18 XTerra RP),
- mobile phase: a mixture of 30 volumes of *0.01M potassium dihydrogen orthophosphate*, adjusted to pH 3.0 with *orthophosphoric acid* and 70 volumes of *methanol*.
- flow rate: 1.3 ml per minute,
- spectrophotometer set at 235 nm,
- injection volume: 20 µl.

The relative retention time with reference to carprofen for carprofen impurity C form is about 0.8.

Inject reference solution (b). The test is not valid unless the resolution between the peaks due to carprofen impurity C and carprofen is not less than 3.5.

Inject reference solution (a), ~~–~~(c) and the test solution. the area of any other secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (1.0 per cent) and the sum of areas of all the secondary peaks is not more than twice the area of the principal peak in the chromatogram obtained with reference solution (a) (2.0 per

cent). Ignore any peak with an area less than 3 times the area of the principal peak in the chromatogram obtained with reference solution (c) (0.3 per cent).

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Weigh and powder 20 tablets. Disperse a quantity of the powdered tablets containing 25 mg of Carprofen in 30 ml of the mobile phase, with the aid of ultrasound and dilute to 50.0 ml with the mobile phase and filter. Dilute 1.0 ml of the solution to 100.0 ml with the mobile phase.

Reference solution (a). a solution containing 0.0005 per cent w/v *carprofen IPRS* in the mobile phase.

Reference solution (b). a solution containing 0.025 per cent w/v *carprofen for system suitability IPRS* in the mobile phase.

Use chromatographic system as described under Related substances.

Inject reference solution (b). The test is not valid unless the resolution between the peaks due to carprofen impurity C and carprofen is not less than 3.5.

Inject reference solution (a). The relative standard deviation for the replicate injections is not more than 2.0 per cent.

Inject the reference solution (a) and the test solution.

Calculate the content of $C_{15}H_{12}ClNO_2$ in the tablets.

Storage. Store protected from light and moisture, at a temperature not exceeding 30°.