Clarithromycin for oral suspension

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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.	

Clarithromycin Oral Suspension

Clarithromycin Oral Suspension is a dry mixture of clarithromycin, dispersing agents, diluents, preservatives and flavouring agent.

Clarithromycin Oral Suspension contains not less than 90.0 per cent and not more than 115.0 per cent of the stated amount of clarithromycin, $C_{38}H_{69}NO_{13}$.

Usual strength. 125 mg per ml, 125 mg per 5 ml, 250 mg per ml.

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). 4.0 to 5.4, determined on constituted suspension as directed in the labelling.

Loss on drying (2.4.19). Not more than 2.0 per cent, determined on 1 g by drying under vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours.

Other tests. Comply with the tests stated under Oral Liquids.

Assay. Determine by liquid chromatography (2.4.14).

Solution A. 0.067 M *dipotassium hydrogen orthophosphate*.

Test solution. Transfer a quantity of the oral suspension containing 0.5 g of Clarithromycin, with the aid of 165 ml of solution A to a 500-ml volumetric flask containing 50 ml of solution A. Shake by mechanical means for 30 minutes and dilute to volume with *methanol*. Sonicate for 30 minutes and allow to cool. Dilute to volume with *methanol*, add a magnetic stirring bar, and stir for 60 minutes. Allow to settle, and use the clear supernatant. Dilute 20.0 ml of the clear supernatant to 50.0 ml with the mobile phase, filter.

Reference solution. A 0.2 per cent w/v solution of *clarithromycin IPRS* in *methanol*. Dilute 5.0 ml of the solution to 25.0 ml with the mobile phase.

- a stainless steel column 15 cm x 4.6 mm, packed with octadecyl silane bonded to porous silica (5 µm),
- column temperature: 50°,
- mobile phase: a mixture of 60 volumes of *methanol* and 40 volumes of 0.067 M *potassium dihydrogen orthophosphate*, adjusted to pH 3.5 with *orthophosphoric acid*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 210 nm,
- injection volume: 50 µl.

Inject the reference solution. The test is not valid unless the tailing factor is in between 1.0 to 1.7 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Determine the weight per ml of the suspension (2.4.29) and calculate the content of $C_{38}H_{69}NO_{13}$.

Storage. Store at a temperature not exceeding 30°.