Clarithromycin 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 mixture of Clarithromycin with buffering agents and other excipients. It contains a suitable flavouring agent. It is filled in a sealed container.

The suspension is constituted by dispersing the contents of the sealed container in the specified volume of Water just before use.

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, $C_{38}H_{69}NO_{13}$.

When stored at the temperature and for the period stated on the label during which the constituted suspension may be expected to be satisfactory for use, it contains not less than 80.0 per cent of the stated amount of clarithromycin, $C_{38}H_{69}NO_{13}$.

Storage. Store at a temperature not exceeding 30°.

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

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

The constituted suspension complies with the tests stated under Oral liquids and with the following 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.

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 25 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 $C_{38}H_{69}NO_{13}$ weight in volume.

Repeat the procedure using a portion of the constituted suspension that has been stored at the temperature and for the period stated on the label.

Labelling. The label states (1) the quantity of active ingredient in terms of the equivalent amount of clarithromycin; (2) the temperature of storage and the period during which the constituted suspension may be expected to be satisfactory for use.