Clindamycin 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.	

Clindamycin Tablets

Clindamycin Hydrochloride Tablets

Clindamycin Tablets contains clindamycin hydrochloride equivalent to not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of clindamycin, $C_{18}H_{33}ClN_2O_5S$.

Usual strengths. 150 mg; 300 mg.

Identification

A. Shake a quantity of the powdered tablets containing the equivalent to 30 mg of clindamycin with 50 ml of *dichloromethane*, filter and evaporate the filtrate to dryness. On the residue, determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *clindamycin hydrochloride IPRS* or with the reference spectrum of clindamycin 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

Dissolution (2.5.2).

Apparatus No. 1 (Basket),

Medium. 900 ml of *phosphate buffer pH 6.8*,

Speed and time. 100 rpm and 30 minutes.

Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography (2.4.14).

Test solution. Use the filtrate, dilute with the dissolution medium, if necessary to obtain a solution containing 0.0028 per cent w/v of clindamycin.

Reference solution. A 0.003 per cent w/v solution of *clindamycin hydrochloride IPRS* in the dissolution medium.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (such as Hypersil BDS),
- mobile phase: a mixture of 55 volumes of 0.68 per cent w/v solution of *potassium dihydrogen orthophosphate*, adjusted to pH 7.5 with a 25 per cent w/v solution of *potassium hydroxide* and 45 volumes of *acetonitrile*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 210 nm,
- injection volume: 20 µl.

Inject the reference solution and the test solution.

Calculate the content of $C_{18}H_{33}ClN_2O_5S$ in the medium.

Q. Not less than 80 per cent of the stated amount of $C_{18}H_{33}ClN_2O_5S$.

Related substances. Determine by liquid chromatography (2.4.14).

Test solution. Disperse a quantity of the powdered tablets containing the equivalent to 0.1 g of clindamycin in the mobile phase with the aid of ultrasound for 15 minutes and dilute to 100.0 ml with the mobile phase and filter.

Reference solution (a). A 0.11 per cent w/v solution of *clindamycin hydrochloride IPRS* in the mobile phase.

Reference solution (b). Dilute 1.0 ml of reference solution (a) to 50.0 ml with the mobile phase.

Reference solution (c). Dilute 1.0 ml of reference solution (b) to 20.0 ml with the mobile phase.

Use the chromatographic system as described under Dissolution.

Name	Relative retention time
Clindamycin Impurity B[1]	0.7
Clindamycin Impurity C[2]	0.8
Clindamycin (Retention time: about 10 minutes)	1.0

[1]methyl 7-chloro-6,7,8-trideoxy-6-[[[(2S,4R)-4-ethyl-1-methylpyrrolidin-2-yl]carbonyl]amino]-1-thio-L-threo-α-D-galactooctopyranoside,
[2]methyl 7-chloro-6,7,8-trideoxy-6-[[[(2S,4R)-1-methyl-4-propylpyrrolidin-2-yl]carbonyl]amino]-1-thio-D-erythro-α-Dgalacto-octopyranoside.

Inject reference solution (a). The test is not valid unless the resolution between the peaks due to clindamycin impurity B and clindamycin impurity C is not less than 3.0 and between the peaks due to clindamycin impurity C and clindamycin is not less than 2.0.

Inject reference solution (b) and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to clindamycin impurity B is not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (2.0 per cent), the area of any peak corresponding to clindamycin impurity C is not more than twice the area of the principal peak in the chromatogram obtained with reference solution (b) (4.0 per cent), the area of any other secondary peak is not more than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (1.0 per cent) and the sum of the areas of all the secondary peaks is not more than 3 times the area of the principal peak in the chromatogram obtained with reference solution (b) (6.0 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).

Uniformity of dosage units (2.5.4). Comply with the tests stated under Tablets.

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 powder containing the equivalent 0.2 g of clindamycin in the mobile phase with the aid of ultrasound for 15 minutes and dilute to 200.0 ml with the mobile phase, filter.

Reference solution. A 0.11 per cent w/v solution *clindamycin hydrochloride IPRS* in the mobile phase.

Use the chromatographic system as described under Dissolution.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, 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 clindamycin, $C_{18}H_{33}ClN_2O_5S$ in the tablets.

1 mg of clindamycin hydrochloride, $C_{18}H_{33}ClN_2O_5S.HCl$ is equivalent to 0.9209 mg of clindamycin $C_{18}H_{33}ClN_2O_5S$.

Storage. Store protected from moisture, at a temperature not exceeding 30º.

Labelling. The quantity of active ingredient is stated in terms of the equivalent amount of clindamycin.