Clindamycin Lotion

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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 Lotion

Clindamycin Phosphate Lotion

Clindamycin Lotion contains Clindamycin Phosphate in a suitable vehicle.

Clindamycin Lotion contains clindamycin phosphate 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 strength. 1 per cent w/v.

Identification

A. Determine by thin-layer chromatography (2.4.17), coating the plate with *silica gel GF60*.

Solvent mixture. 77.5 volumes of *1M potassium dihydrogen orthophosphate*, adjusted to pH 2.5 with *orthophosphoric acid*, and 22.5 volumes of *acetonitrile*.

Mobile phase. A mixture of 20 volumes of *water*, 20 volumes of *glacial acetic acid* and 60 volumes of *butan-1-ol*.

Test solution. Shake a quantity of the lotion containing 5 mg of Clindamycin in the solvent mixture and dilute to 5.0 ml with the solvent mixture, filter.

Reference solution. A solution of *clindamycin phosphate IPRS* containing 0.10 per cent w/v of clindamycin in the solvent mixture.

Apply to the plate 10 µl of each solution. Allow the mobile phase to rise 15 cm. Dry the plate at 100° for about 30 minutes, allow to cool and spray with a 0.1 per cent w/v solution of *potassium permanganate* and examine under day light. The principal spot in the chromatogram obtained with the test solution corresponds to the spot in the chromatograms obtained with the reference solution.

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

Related substances. Determine by liquid chromatography (2.4.14).

NOTE- Prepare the solutions immediately before use and protect from light.

Solvent mixture. 85 volumes of *water*, adjusted to pH 2.0 with *orthophosphoric acid*, and 15 volumes of *acetonitrile.*

Test solution. Disperse a quantity of the lotion containing the equivalent of 25 mg of Clindamycin in 10 ml of the solvent mixture and filter. Wash 5.0 ml of the filtrate with three 5 ml quantities of *diethyl ether*. Use the aqueous layer.

Reference solution (a). A solution of *clindamycin phosphate IPRS* containing 0.0025 per cent w/v of clindamycin in the solvent mixture.

Reference solution (b). Dilute 1.0 ml of reference solution (a) to 10.0 ml with the solvent mixture.

Reference solution (c). A 0.3 per cent w/v solution of *clindamycin phosphate for system suitability IPRS* in the solvent mixture.

Chromatographic system
- a stainless steel column 15 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (Such as Symmetry C18),
- column temperature: 30°,
- sample temperature: 4°,
- mobile phase: A. a mixture of 79 volumes of *1M potassium dihydrogen phosphate*, adjusted to pH 6.0 with 45 per cent w/v solution of *potassium hydroxide* and 21 volumes of *acetonitrile*,

B. a mixture of 40 volumes of *1M potassium dihydrogen phosphate*, adjusted to pH 6.0 with 45 per cent w/v solution of *potassium hydroxide* and 60 volumes of *acetonitrile*,

– a gradient programme using the conditions given below,
– flow rate: 1.1 ml per minute,
– spectrophotometer set at 210 nm,
– injection volume: 20 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	100	0
13	100	0
18	50	50
39	50	50
45	100	0
50	100	0

Name	Relative retention time
Clindamycin impurity F[1]	0.15
Clindamycin impurity G[2]	0.2
Clindamycin impurity I[3]	0.35
Clindamycin impurity B[4]	0.45
Clindamycin impurity L[5]	0.65
Clindamycin (Retention time: about 12 minutes)	1.0
Clindamycin impurity J[6]	1.2
Clindamycin impurity E[7]	1.75
Clindamycin impurity K[8]	1.9

[1]methyl6,8-dideoxy-6-[[[(2S,4R)-1-methyl-4-propylpyrrolidin-2-yl]carbonyl]amino]-2-O-phosphono-l-thio-ᴅ-erythro-α-ᴅ-galacto-octopyranoside (lincomycin 2-phosphate),
[2]methyl6,8-dideoxy-2,4-O-(hydroxyphosphoryl)-6-[[[(2S,4R)-1-methyl-4-propylpyrrolidin-2-yl]carbonyl]amino]-1-thio-ᴅ-erythro-α-ᴅ-galacto-octopyranoside (2,4-phosphatidyl lincomycin),
[3]methyl7-chloro-6,7,8-trideoxy-6-[[[(2S,4R)-1-methyl-4-propylpyrrolidin-2-yl)carbonyl]amino]-2,4-di-O-phosphono-l-thio-ʟ-threo-α-ᴅ-galacto-octopyranoside (clindamycin 2,4-bisphosphate),
[4]methyl 7-chloro-6,7,8-trideoxy-6-[[[(2S,4R)-4-ethyl-l-methylpyrrolidin-2-yl]carbonyl]amino]-2-O-phosphono-l-thio-ʟ-threo-α-ᴅ-galacto-octopyranoside (c1indamycin B2-phosphate),
[5]methyl7-chloro-6,7,8-trideoxy-6-[[[(2S,4R)-1-methyl-4-propylpyrrolidin-2-yl]carbonyl]amino]-2-O-phosphono-l-thio-ᴅ-erythro-α-ᴅ-galacto-octopyranoside (7-epiclindamycin 2-phosphate).
[6]methyl7-chloro-6,7,8-trideoxy-6-[[[(2S)-1-methyl-4-propylidenepyrrolidin-2-yl]carbonyl]amino]-2-O-phosphono-l-thio-ʟ-threo-α-ᴅ-galacto-octopyranoside (propylidene analog of clindamycin 2-phosphate),
[7]methyl 7-chloro-6,7,8-trideoxy-6-[[[(2S,4R)-1-methyl-4-propylpyrrolidin-2-yl]carbonyl]amino]-l-thio-ʟ-threo-α-ᴅ-galacto-octopyranoside (clindamycin),
[8]2,2'-oxybis(hydroxyphosphoryl)bis[methyl 7-choro-6,7,8-trideoxy-6-[[[(2S,4R)-1-methyl-4-propylpyrrolidin-2-yl]carbonyl]amino]-1-thio-ʟ-threo-α-ᴅ-galacto-octopyranoside) (diclindamycin pyrophosphate).

Inject reference solution (c). The test is not valid unless the resolution between the peaks due to clindamycin impurity F and clindamycin impurity G is not less than 2.0.

Inject reference solution (a), (b) and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to clindamycin impurity E is not more than twice the area of the principal peak in the chromatogram obtained with reference solution (a) (2.0 per cent), the area of any peak corresponding to clindamycin impurity B, impurity F and impurity L, each of, is not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (1.0 per cent), the area of any other secondary peak is not more than twice the area of the principal peak in the chromatogram obtained with reference solution (b) (0.2 per cent) and the sum of areas of all the secondary peaks is not more than 4 times the area of the principal peak in the chromatogram obtained with reference solution (a) (4.0 per cent). Ignore any peak with an area less than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.1 percent).

Other tests. Comply with the tests stated under Lotion.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Disperse a quantity of the lotion containing 25 mg of Clindamycin in the solvent mixture, with the aid of ultrasound for 30 minutes and dilute to 100 ml with the solvent mixture, filter.

Reference solution. A solution of *clindamycin phosphate IPRS* containing 0.025 per cent w/v of

clindamycin in the solvent mixture.

Use the Chromatographic system as described under Related substances with the following modifications.

– mobile phase: a mixture of 79 volumes of *1M potassium dihydrogen phosphate*, adjusted to pH 6.0 with 45 per cent w/v solution of *potassium hydroxide* and 21 volumes of *acetonitrile*.

Inject the reference solution. The test is not valid unless the tailing factor is not less than 0.8 and not more than 3.0.

Inject the reference solution and the test solution.

Calculate the content of $C_{18}H_{38}ClN_2O_5S$ in the lotion.

1 mg of clindamycin phosphate, $C_{18}H_{34}ClN_2O_8PS$ is equivalent to 0.8416 mg of clindamycin, $C_{18}H_{38}ClN_2O_5S$.

Storage. Store at a temperature not exceeding 30°. It should not be allowed to freeze.

Labelling. The label states the strength in terms of the equivalent amount of clindamycin.
