Clindamycin Gel

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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 Gel

Clindamycin Phosphate Gel

Clindamycin Gel 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/w.

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

Related substances. Determine by liquid chromatography (2.4.14).

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

Buffer solution. Dissolve 13.6 g of *potassium dihydrogen orthophosphate* in 1000 ml of *water*, adjusted to pH 6.0 with 45 per cent w/v solution of *potassium hydroxide*.

Test solution. Disperse a quantity of the gel containing the equivalent of 12.5 mg of clindamycin in mobile phase A and dilute to 5.0 ml with mobile phase A. Centrifuge the solution and filter.

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

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

Reference solution (c). A 0.3 per cent w/v solution of *clindamycin phosphate for system suitability IPRS* (containing clindamycin impurities B, E, F, G, I, J, K and L) in mobile phase A.

Chromatographic system
- a stainless steel column 15 cm × 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 the buffer solution and 21 volumes of *acetonitrile*;
  B. a mixture of 40 volumes of the buffer solution and 60 volumes of *acetonitrile*,
- flow rate: 1.1 ml per minute,
- a gradient programme using the conditions given below,
- 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
40	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]methyl 6,8-dideoxy-6-[[[(2S,4*R*)-1-methyl-4-propylpyrrolidin-2-yl]carbonyl]amino]-2-O-phosphono-1-thio-D-*erythro*-α-D-*galacto*-octopyranoside (lincomycin 2-phosphate).
[2]methyl 6,8-dideoxy-2,4-O-(hydroxyphosphoryl)-6-[[[(2S,4*R*)-1-methyl-4-propylpyrrolidin-2-yl]carbonyl]amino]-1-thio-D-*erythro*-α-D-*galacto*-octopyranoside (2,4-phosphatidyl lincomycin).
[3]methyl 7-chloro-6,7,8-trideoxy-6-[[[(2S,4*R*)-1-methyl-4-propylpyrrolidin-2-yl]carbonyl]amino]-2,4-di-O-phosphono-1-thio-L-*threo*-α-D-*galacto*-octopyranoside (clindamycin 2,4-bisphosphate).
[4]methyl 7-chloro-6,7,8-trideoxy-6-[[[(2S,4*R*)-4-ethyl-1-methylpyrrolidin-2-yl]carbonyl]amino]-2-O-phosphono-1-thio-L-*threo*-α-D-*galacto*-octopyranoside (clindamycin B 2-phosphate).
[5]methyl 7-chloro-6,7,8-trideoxy-6-[[[(2S,4*R*)-1-methyl-4-propylpyrrolidin-2-yl]carbonyl]amino]-2-O-phosphono-1-thio-D-*erythro*-α-D-*galacto*-octopyranoside (7-epiclindamycin 2-phosphate).
[6]methyl 7-chloro-6,7,8-trideoxy-6-[[[(2S)-1-methyl-4-propylidenepyrrolidin-2-yl]carbonyl]amino]-2-O-phosphono-1-thio-L-*threo*-α-D-*galacto*-octopyranoside (propylidene analog of clindamycin 2-phosphate).
[7]methyl 7-chloro-6,7,8-trideoxy-6-[[[(2S,4*R*)-1-methyl-4-propylpyrrolidin-2-yl]carbonyl]amino]-1-thio-L-*threo*-α-D-*galacto*-octopyranoside (clindamycin).
[8]2,2′-oxybis(hydroxyphosphoryl)bis[methyl 7-chloro-6,7,8-trideoxy-6-[[[(2S,4*R*)-1-methyl-4-propylpyrrolidin-2-yl]carbonyl]amino]-1-thio-L-*threo*-α-D-*galacto*-octopyranoside] (diclindamycin pyrophosphate).

Inject reference solution (c) to identify the peaks due to clindamycin impurity B, E, F, G, I, J, K and L.

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 is not more than 1.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (1.5 per cent), the area of any peak corresponding to clindamycin impurity F and clindamycin 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 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.2 per cent) and the sum of the 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 per cent).

Other tests. Comply with the tests stated under Gels.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Disperse a quantity of the gel containing the equivalent of 25 mg of clindamycin in 20 ml of the mobile phase, shake for 1 hour and dilute to 100.0 ml with the mobile phase. Centrifuge the solution and filter.

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

Chromatographic system
- a stainless steel column 15 cm × 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 mixture of 79 volumes of 1.36 per cent solution of *potassium dihydrogen orthophosphate*, adjusted to pH 6.0 with 45 per cent w/v solution of *potassium hydroxide* and 21 volumes of *acetonitrile*;
- flow rate: 1.1 ml per minute,
- spectrophotometer set at 210 nm,
- injection volume: 20 µl.

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 $C_{18}H_{33}ClN_2O_5S$.

1 mg of clindamycin phosphate, $C_{18}H_{34}ClN_2O_8PS$ is equivalent to 0.8416 mg of clindamycin, $C_{18}H_{33}ClN_2O_5S$.

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.
