# Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

## 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 Phosphate Gel contains clindamycin phosphate equivalent to not less than 90.0 per cent and not more than 110.0 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 reference solution (a).

## Tests

**pH** (2.4.24). 4.5 to 6.5,

**Other tests**. Comply with the tests stated under Gels.

**Assay**. Determine by liquid chromatography (2.4.14).

*Test solution.* Shake a quantity of the gel containing 20 mg of clindamycin in the mobile phase by mechanical means for 30 minutes and dilute to 100.0 ml with the mobile phase. Centrifuge a portion of the solution and if necessary, filter a portion of the supernatant. Use the clear filtrate.

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

*Reference solution (b)*. A solution containing 0.06 per cent w/v, each of, *clindamycin phosphate IPRS* and *clindamycin hydrochloride IPRS* in the mobile phase.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with octylsilane bonded to porous silica (5 µm) (Such as Zorbax C8),
- mobile phase: a mixture of 77.5 volumes of a buffer solution prepared by dissolving 13.6 g of *sodium dihydrogen orthophosphate* in 1000 ml of *water*, adjusted to pH 2.5 with *orthophosphoric acid* and 22.5 volumes of *acetonitrile*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 210 nm,
- injection volume: 20 µl.

The relative retention time with reference to clindamycin phosphate, for clindamycin is about 1.5.

Inject reference solution (a) and (b). The test is not valid unless the resolution between the peaks due to clindamycin phosphate and clindamycin is not less than 6.0 in the chromatogram obtained with reference solution (b), the column efficiency is not less than 1700 theoretical plates, the tailing factor is not more than 1.3 and the relative standard deviation for replicate injections is not more than 2.5 per cent in the chromatogram obtained with reference solution (a).

Inject reference solution (a) and the test solution.

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

**Storage**. Store in well-closed containers.

**Labelling**. The label states the quantity of clindamycin phosphate in terms of the equivalent amount of clindamycin.