



## American Remedies Healthcare Pvt. Ltd.

Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)

### QUALITY CONTROL DEPARTMENT

#### CERTIFICATE OF FINISHED PRODUCT ANALYSIS

<b>Product Name:</b>	<b>Clindacan Injection (Clindamycin Phosphate Injection IP 150mg/ml)</b>		
<b>Batch No.</b>	25AR025	<b>A.R. No.</b>	AFP250025
<b>Batch Size</b>	40200 Ampoules	<b>Sample Quantity</b>	60 Nos
<b>Mfg. Date</b>	09/2025	<b>Date of Testing</b>	21/09/2025
<b>Exp. Date</b>	08/2027	<b>Date of Release</b>	08/10/2025
<b>Reference Batch No</b>	25AR025	<b>MFG. Lic. No.</b>	HP-MB-LL-00235

Sr. No.	Test	Specification	Observation
1.	<b>Description</b>	An almost colorless solution	Clear and colorless solution
2.	<b>Identification</b> A. By TLC  B. By Assay	<p>The principal spot in the chromatogram obtained with the test solution corresponds to the principal spot in the chromatogram obtained with the reference solution.</p> <p>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).</p>	Complies
3.	<b>pH</b>	Between 5.5 to 7.0	6.69
4.	<b>Related Substance</b>	<p>Inject the reference solution. The test is not valid unless the resolution between the peaks due to lincomycin hydrochloride and clindamycin phosphate is not less than 7.7. Inject the test solution. The sum of the areas of all the secondary peaks is not more than 8.0 per cent, calculated by area normalization. Ignore any peak obtained due to benzyl alcohol.</p>	Complies



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<b>5.</b>	<b>Extractable Volume</b>	NLT 2.0 ml	2.0 ml
<b>6.</b>	<b>Bacterial Endotoxins</b>	NMT 6.0 Endotoxin unit per mg of Clindamycin Phosphate	Less than 6.0 Endotoxin unit per mg of Clindamycin Phosphate
<b>7.</b>	<b>Particulate Matter</b>	Injections that are solutions, when examined under suitable conditions of visibility, are clear and practically free from particles that can be observed on visual inspection by the unaided eye.	Complies
<b>8.</b>	<b>Sterility</b>	Should be complies	Sterile
<b>9.</b>	<b>Assay:</b> <b>Each ml contains:</b> <b>Clindamycin Phosphate</b> <b>IP Eq. to anhydrous</b> <b>Clindamycin 150 mg</b>	135.0 mg to 180.0 mg (90.0 % to 120.0 %)	152.32 mg 101.55 %

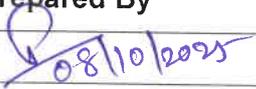
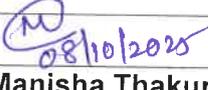
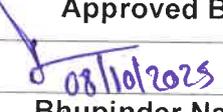


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Remark: The sample is complies as per IP /BP/ USP/IH specification.

	Prepared By	Checked By	Approved By
Sign/Date	 08/10/2025	 08/10/2025	 08/10/2025
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC

