



American Remedies Healthcare Pvt. Ltd.

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

CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	Clindacan 600 Injection (Clindamycin Phosphate Injection IP 150mg/ml)		
Batch No.	25AR051	A.R. No.	AFP250040
Batch Size	50500 Ampoules	Sample Quantity	60 Nos
Mfg. Date	10/2025	Date of Testing	16/10/2025
Exp. Date	09/2027	Date of Release	03/11/2025
Reference Batch No	25AR051	MFG. Lic. No.	HP-MB-LL-00235

Sr. No.	Test	Specification	Observation
1.	Description	An almost colorless solution	Clear and colorless solution
2.	Identification 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.	pH	Between 5.5 to 7.0	6.42
4.	Related Substance	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.	Complies



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5.	Extractable Volume	NLT 4.0 ml	4.0 ml
6.	Bacterial Endotoxins	NMT 6.0 Endotoxin unit per mg of Clindamycin Phosphate	Less than 6.0 Endotoxin unit per mg of Clindamycin Phosphate
7.	Particulate Matter	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
8.	Sterility	Should be complies	Sterile
9.	Assay: Each ml contains: Clindamycin Phosphate IP Eq. to anhydrous Clindamycin 150 mg	135.0 mg to 180.0 mg (90.0 % to 120.0 %)	153.5 mg 102.33 %

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



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	Prepared By	Checked By	Approved By
Sign/Date	 03/11/2025	 03/11/2025	 03/11/2025
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC

