



ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Clindacan 300	A.R. No.	FG/G/24A0121
Generic Name	Clindamycin Injection IP 150 mg/ml	Sample Quantity	65 Ampoules
Batch No.:	AA40906	Sample Received on	10/10/2024
Batch Size:	0.25 Lac	Analysis Date	10/10/2024
Mfg. Date.	09/2024	Release Date	24/10/2024
Exp. Date	08/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	A clear and colourless liquid filled in 2 ml clear glass ampoule.	A clear and colourless liquid filled in 2 ml clear glass ampoule.		
2.	Identification :				
	A. By TLC	The principal spot in the chromatogram obtained with the test solution corresponds to the principal spot in the chromatogram obtained with the reference solution.	Complies		
	B. By HPLC	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).	Complies		
3.	pH	Between 5.5 to 7.0	6.48		
4.	Extractable volume	Not less than 2.0 ml	2.07 ml		
5.	Particulate Matter	The Solution should be clear, colourless and free from any visible particle.	The Solution is clear, colourless and free from any visible particle.		
6.	Sterility	Should be sterile.	Sterile		
7.	Bacterial Endotoxins Tests	Not more than 6.0 EU/ml of Clindamycin.	Less than 6.0 EU/ml of Clindamycin.		
8.	Assay:				
	Each ml contains:	Claim	Limit	mg	%
	Clindamycin Phosphate IP Eq. to Clindamycin	150 mg	Between 90.0 % to 120.0 % of stated amount of Clindamycin (Between 135.0 mg to 180.0 mg)	149.78 mg	99.85%
	Benzyl Alcohol IP (As Preservative)	0.9%w/v	Between 90.0% to 110.0% of Stated amount of Benzyl Alcohol. (Between 0.81 %w/v to 0.99 %w/v)	0.89540%w/v	99.49%

Remarks: The above test parameters are complies/ not-complies as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Kuljeet Kaur	Ravita Nandwani
Designation	Executive	Head QC	QA Manager
Signature			
Date	24/10/2024	24/10/2024	24/10/2024