



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/24A0042
Generic Name	Clindamycin Injection IP 150 mg/ml	Sample Quantity	65 Ampoules
Batch No.:	AA40508	Sample Received on	29/05/2024
Batch Size:	25,500 Amp.	Analysis Date	29/05/2024
Mfg. Date.	05/2024	Release Date	12/06/2024
Exp. Date	04/2027	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	6.54		
4.	Extractable volume	Not less than 2.0 ml	2.05 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)	148.20 mg	98.80%
	Benzyl Alcohol (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)	0.9114%w/v	101.27%

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	DURGESH KUMAR	Gaurtan Singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	12/06/2024	12/06/2024	12/06/2024