



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 600	A.R. No.	FG/G/24A0046
Generic Name	Clindamycin Injection IP 150 mg/ml	Sample Quantity	65 Ampoules
Batch No.:	AA40509	Sample Received on	06/06/2024
Batch Size:	25500 Amp.	Analysis Date	06/06/2024
Mfg. Date.	05/2024	Release Date	20/06/2024
Exp. Date	04/2027	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	4 ml clear colourless liquid filled in 5 ml clear glass ampoule with blue dot.	4 ml clear colourless liquid filled in 5 ml clear glass ampoule with blue dot.		
2.	Identification :				
	a) 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 the reference solution.	Complies		
	b) By TLC	The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution (a).	Complies		
3.	pH	Between 5.5 to 7.0	6.63		
4.	Extractable volume	Not less than 4.0 ml	4.05 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)	148.25 mg	98.83%
	Benzyl Alcohol (As Preservative)	0.9%w/v	Between 90.0% to 110.0% Stated amount of Benzyl Alcohol. (Between 0.81 %w/v to 0.99 %w/v)	0.9121%w/v	101.34%

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	Praveen Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	20/06/2024	20/06/2024	20/06/2024