



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/25A1252 |
| Generic Name | Clindamycin Injection IP 150 mg/ml | Sample Quantity | 65 Ampoules |
| Batch No.: | AA50701 | Sample Received on | 05/08/2025 |
| Batch Size: | 21000 Amp, | Analysis Date | 05/08/2025 |
| Mfg. Date. | 07/2025 | Release Date | 20/08/2025 |
| Exp. Date | 06/2027 | 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 | 6.4 | | |
| 4. | Extractable volume | Not less than 4.0 ml | 4.03 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) | 152.34 mg | 101.56% |
| | 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) | 0.93%w/v | 102.98% |

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 | Pravesh Kumar | Kamlesh Kant | Subjeet Kaur |
| Designation | Executive | Executive | -/Lead QC |
| Signature | | | |
| Date | 20/08/2025 | 20/08/2025 | 20/08/2025 |