



# ALVENTA PHARMA LIMITED

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

## Quality Control Department

### CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

|              |                                    |                    |              |
|--------------|------------------------------------|--------------------|--------------|
| Product Name | Gabatop-NT                         | A.R. No.           | FG/G/24A1235 |
| Generic Name | Gabapentin & Nortriptyline Tablets | Sample Quantity    | 60 Tablets   |
| Batch No.:   | AGT407117                          | Sample Received on | 02/09/2024   |
| Batch Size:  | 1.0 Lac                            | Analysis Date      | 02/09/2024   |
| Mfg. Date.   | 07/2024                            | Release Date       | NA           |
| Exp. Date    | 06/2026                            | Page No.:          | Page 1 of 1  |

| Sr. No. | Test Parameter                                         | Acceptance Criteria                                                                                                                                                              | Result                                                                                                      |            |         |
|---------|--------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|------------|---------|
| 1.      | Description                                            | White colour, elongated shaped, biconvex, scored line on one side and other side plain, film coated tablet.                                                                      | White colour, elongated shaped, biconvex, scored line on one side and other side plain, film coated tablet. |            |         |
| 2.      | Identification                                         | In the assay, the principal peak in the chromatogram obtained with the test solution should be corresponds to the peak in the chromatogram obtained with the reference solution. | Complies                                                                                                    |            |         |
| 3.      | Average weight                                         | 509.00 mg ± 3%                                                                                                                                                                   | 503.657 mg                                                                                                  |            |         |
| 4.      | Uniformity of weight                                   | ± 5% of its average weight.                                                                                                                                                      | Min: 495.58 mg ; Max: 507.91 mg<br>- 1.60% ; +0.84%                                                         |            |         |
| 5.      | Disintegration                                         | Not more than 30 minutes.                                                                                                                                                        | 05 minutes 05 seconds.                                                                                      |            |         |
| 6.      | Hardness                                               | NLT 4.0 Kg/cm <sup>2</sup>                                                                                                                                                       | 7.33 Kg/cm <sup>2</sup>                                                                                     |            |         |
| 7.      | Uniformity of content<br>(For Nortriptyline HCl)       | The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)                                                                     | 2.65                                                                                                        |            |         |
| 8.      | Assay:                                                 |                                                                                                                                                                                  |                                                                                                             |            |         |
|         | Each film coated tablet contains:                      | Claim                                                                                                                                                                            | Limit                                                                                                       | mg         | %       |
|         | Gabapentin IP                                          | 400 mg                                                                                                                                                                           | Between 90.0 % to 110.0 % of labeled amount.<br>(Between 360.0 mg to 440.0 mg)                              | 402.462 mg | 100.62% |
|         | Nortriptyline Hydrochloride IP<br>Eq. to Nortriptyline | 10 mg                                                                                                                                                                            | Between 90.0 % to 110.0 % of labeled amount.<br>(Between 9.0 mg to 11.0 mg)                                 | 10.041 mg  | 100.41% |
| 9.      | Microbial Limit Tests:                                 |                                                                                                                                                                                  |                                                                                                             |            |         |
| i.      | Total aerobic microbial count                          | NMT 1000 cfu/g                                                                                                                                                                   |                                                                                                             | Under test |         |
| ii.     | Total yeast and mould count                            | NMT 100 cfu/g                                                                                                                                                                    |                                                                                                             | Under test |         |
| iii.    | Pathogens: Escherichja coli                            | Should be absent/g                                                                                                                                                               |                                                                                                             | Under test |         |

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        | Baveen Kumar | Tanvej        | Ranjan Singh |
| Designation | Executive    | Sr. Executive | Head- QA     |
| Signature   |              |               |              |
| Date        | 05/09/2024   | 05/09/2024    | 05/09/2024   |