



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

| | | | |
|--------------|----------------------------------|--------------------|--------------|
| Product Name | Naproheal D-500 | A.R. No. | FG/G/23A0827 |
| Generic Name | Naproxen and Domperidone Tablets | Sample Quantity | 60 Tablets |
| Batch No.: | AGT30997 | Sample Received on | 04/10/2023 |
| Batch Size: | 1.0 Lac | Analysis Date | 04/10/2023 |
| Mfg. Date. | 09/2023 | Release Date | 11/10/2023 |
| Exp. Date | 08/2025 | Page No.: | Page 1 of 1 |

| Sr. No. | Test Parameter | Acceptance Criteria | Result | | |
|---------|---|--|---|-----------|--------------------|
| 1. | Description | Yellow colour, elongated shaped, biconvex, break line on one side and other side plain, film coated tablet. | Yellow colour, elongated shaped, biconvex, break line on one side and other side plain, film coated tablet. | | |
| 2. | Identification (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 | | |
| 3. | Average weight | 663.0 mg \pm 3% | 667.57 mg | | |
| 4. | Uniformity of weight | \pm 5.0 % of its average weight. | Min: 641.98 mg ; Max: 681.55 mg -3.83% ; + 2.09% | | |
| 5. | Disintegration | Not more than 30 minutes. | 04 minutes 45 seconds. | | |
| 6. | Hardness | NLT 4.0 Kg/cm ² | 7.0 Kg/cm ² | | |
| 7. | Uniformity of content (Domperidone) | The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25) | 4.79 | | |
| 8. | Assay: | | | | |
| | Each film coated tablet contains: | Claim | Limit | mg | % |
| | Naproxen IP | 500 mg | Between 90.0 % to 110.0 % of stated amount (Between 450.0 mg to 550.0 mg) | 514.23 mg | 102.85% |
| | Domperidone Maleate IP eq. to Domperidone | 10 mg | Between 90.0 % to 110.0 % of stated amount (Between 9.0 mg to 11.0 mg) | 9.842 mg | 98.42% |
| 9. | Microbial Limit Tests: | | | | |
| i. | Total aerobic microbial count | NMT 1000 cfu/g | | | 30 cfu/g |
| ii. | Total yeast and mould count | NMT 100 cfu/g | | | Less than 10 cfu/g |
| iii. | Pathogens: Escherichia coli | Should be absent/g | | | Absent/g |

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 | Dipu Khatyar | Gaurav Singh |
| Designation | Executive | QC Head | Head- QA |
| Signature | | | |
| Date | 11/10/2023 | 11/10/2023 | 11/10/2023 |