



# ALVENTA PHARMA LIMITED

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

## Quality Control Department

### CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

|              |                                                      |                    |              |
|--------------|------------------------------------------------------|--------------------|--------------|
| Product Name | Diaraheal Plus                                       | A.R. No.           | FG/G/24A0233 |
| Generic Name | Ofloxacin, Ornidazole & Racecadotril Oral Suspension | Sample Quantity    | 14 Bottles   |
| Batch No.:   | AGL40623                                             | Sample Received on | 18/06/2024   |
| Batch Size:  | 15,000 Bottles                                       | Analysis Date      | 18/06/2024   |
| Mfg. Date.   | 06/2024                                              | Release Date       | 26/06/2024   |
| Exp. Date    | 05/2026                                              | Page No.:          | Page 1 of 1  |

| Sr. No. | Test Parameter                | Acceptance Criteria                                                                                                                                                    | Result                                                                                           |                     |         |
|---------|-------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|---------------------|---------|
| 1.      | Description                   | Orange colour Suspension filled in 30 ml amber colour PET bottle sealed with ROPP aluminium cap.                                                                       | Orange colour Suspension filled in 30 ml amber colour PET bottle sealed with ROPP aluminium cap. |                     |         |
| 2.      | Identification                | 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.      | Weight per ml                 | Between 0.800 gm/ml to 1.200 gm/ml                                                                                                                                     | 1.120 gm/ml                                                                                      |                     |         |
| 4.      | pH                            | Between 4.0 to 6.0                                                                                                                                                     | 5.49                                                                                             |                     |         |
| 5.      | Average fill Volume           | Not less than 30.0 ml                                                                                                                                                  | 30.06 ml                                                                                         |                     |         |
| 6.      | Uniformity of filled Volume   | Not less than 28.5 ml                                                                                                                                                  | Min:- 30.0 ml      Max:- 30.2 ml                                                                 |                     |         |
| 7.      | Assay:                        |                                                                                                                                                                        |                                                                                                  |                     |         |
|         | Each 5 ml contains:           | Claim                                                                                                                                                                  | Limit                                                                                            | mg                  | %       |
|         | Ofloxacin IP                  | 50 mg                                                                                                                                                                  | Between 90.0 % to 110.0 % of stated amount<br>(Between 45.0 mg to 55.0 mg)                       | 51.06 mg            | 102.12% |
|         | Ornidazole IP                 | 125 mg.                                                                                                                                                                | Between 90.0 % to 110.0 % of stated amount<br>(Between 112.5 mg to 137.5 mg)                     | 123.55 mg           | 98.84%  |
|         | Racecadotril IP               | 15 mg                                                                                                                                                                  | Between 90.0 % to 110.0 % of stated amount<br>(Between 13.5 mg to 16.5 mg)                       | 15.146 mg           | 100.98% |
| 8.      | Microbial Limit Tests:        |                                                                                                                                                                        |                                                                                                  |                     |         |
| a.      | Total aerobic microbial count | NMT 100 cfu/ml                                                                                                                                                         |                                                                                                  | 25 cfu/ml           |         |
| b.      | Total yeast and mould count   | NMT 10 cfu/ml                                                                                                                                                          |                                                                                                  | Less than 10 cfu/ml |         |
| c.      | Pathogens:                    |                                                                                                                                                                        |                                                                                                  |                     |         |
| i.      | Escherichia coli              |                                                                                                                                                                        | Should be absent/ml                                                                              | Absent/ml           |         |
| ii.     | Salmonella                    |                                                                                                                                                                        | Should be absent/ml                                                                              | Absent/ml           |         |

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 | Gautam Singh |
| Designation | Executive     | QC Head       | Head QA      |
| Signature   |               |               |              |
| Date        | 26/06/2024    | 26/06/2024    | 26/06/2024   |