



ALIVIRA

**ALIVIRA ANIMAL HEALTH LIMITED**  
**CERTIFICATE OF ANALYSIS**

**FENBENDAZOLE USP**



|                           |   |                      |                |
|---------------------------|---|----------------------|----------------|
| Batch No.                 | ASA04761SA  | Quantity             | 700.00 Kg      |
| Manufacturing Date        | October-2024  | Retest / Expiry Date | September-2029 |
| A.R.NO.                   | ALIV-FP1-240064   | Lot No.              | 40000080159    |
| Storage Condition         | Preserve in well closed containers, Store at 25°C, (Excursions permitted between 15°C to 30°C). |                      |                |
| Customer Name/Vendor Name | SUAN FARMA INC.   |                      |                |

| S.No. | TEST PARAMETERS   | SPECIFICATIONS  | RESULTS  |
|-------|---|---|--|
| 1     | Description   | White to off-white powder.  | Almost white powder                            |
| 2     | Solubility  | Sparingly soluble in Dimethyl formamide and very slightly soluble in methanol and Practically insoluble in water.                   | Complies                                       |
| 3     | Identification  | The infrared absorption spectrum of test sample should be concordant with the spectrum obtained with Fenbendazole working standard. | Complies                                       |
| 4     | Organic impurities by HPLC<br>Fenbendazole Related compound-A<br>Fenbendazole Related compound-B<br>Any individual impurity<br>Total impurities | Not more than 0.50%<br>Not more than 0.50%<br>Not more than 0.50%<br>Not more than 1.00%  | Not detected<br>0.02%<br>Not detected<br>0.02% |
| 5     | Loss on drying  | Not more than 1.00% w/w   | 0.16% w/w                                      |
| 6     | Residue on ignition   | Not more than 0.30% w/w   | 0.08% w/w                                      |
| 7     | Assay (on dry basis)  | 98.0%w/w - 101.0% w/w.  | 99.9% w/w                                      |
| 8     | Residual solvents by GC<br>Methanol<br>Acetone<br>Toluene   | Not more than 3000 ppm<br>Not more than 5000 ppm<br>Not more than 890 ppm   | 602 ppm<br>BDL(LOD:150 ppm)<br>106 ppm         |

**Remarks : The above batch complies as per USP/IH Specifications.**

|             |                 |                  |                  |
|-------------|-----------------|------------------|------------------|
|             | PREPARED BY     | REVIEWED BY      | APPROVED BY      |
| DESIGNATION | Asst.Manager-QC | Head-QC/Designee | Head-QA/Designee |
| SIGNATURE   | <i>Ravi</i>     | <i>HL</i>        | <i>HL</i>        |
| DATE        | 22/11/2024      | 22/11/2024       |                  |

Format No.: QC/116/FMT-001/R1



**Alivira Animal Health Limited**

Regd.Off: 301, 3<sup>rd</sup> Floor, Dosti Pinnacle, Plot No. E7, Road No. 22, Wagle Industrial Estate, Thane (W), Mumbai - 400604 India Tel No.: +91-22-4111-4777  
Factory: Plot No: 104 to 109, Part of 112 & 113, Ramky Pharma City India Limited-SEZ, JNPC, Parawada Mandal, Anakapalli (District)-531019, A.P., India. Tel.: +9108924-660888 CIN: U74120MH2013PLC248708  
Website: <http://www.alivira.co> Email Id: [info@alivira.in](mailto:info@alivira.in)