

ALIVIRA ANIMAL HEALTH LIMITED
CERTIFICATE OF ANALYSIS

FENBENDAZOLE USP

Batch No.	ASA003437B	Quantity	225.00 Kg
Manufacturing Date	September-2022	Retest / Expiry Date	August-2027
A.R.NO.	ALIV-FP-220298	Lot No.	40000063127
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 or almost white powder.	Almost white powder
2	Solubility	Practically insoluble in water, sparingly soluble in Dimethyl formamide and very slightly soluble in methanol.	Complies
3	Identification	The infrared absorption spectrum of test sample should be concordant with the spectrum obtained with Fenbendazole working standard.	Complies
4	Related Substances by HPLC Fenbendazole impurity A Fenbendazole impurity B Other impurity Total impurities	Not more than 0.50% Not more than 0.50% Not more than 0.20% Not more than 1.00%	BDL(LOD:0.005%) 0.04% 0.05% 0.33%
5	Heavy Metals	Not more than 10 ppm	Less than 10 ppm
6	Loss on drying	Not more than 1.00% w/w	0.56% w/w
7	Sulphated Ash	Not more than 0.30% w/w	0.17% w/w
8	Assay	98.0 to 101.0% w/w (By Titrimetry, ODB)	100.1% w/w
9	Residual solvents by GC Methanol Acetone Toluene	Not more than 3000 ppm Not more than 5000 ppm Not more than 890 ppm	722 ppm BDL (LOD:150 ppm) 342 ppm

Remarks : The above batch complies as per USP Specifications

	PREPARED BY	REVIEWED BY	APPROVED BY
DESIGNATION	Sr.Analyst-L-1-QC	Head-QC/Designee	Head-QA/Designee
SIGNATURE	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
DATE	23/09/2022	23.9.2022	23/09/2022

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Alivira Animal Health Ltd.

Corporate Office: 301, Dosti Pinnacle, Plot No.22, Wagle Indl. Area, Thane (W)-400 604, India. T +912241114777

Factory Address: Plot No.104 to 109, Part of 112 & 113, Ramky Pharma City India Limited -SEZ, JNPC, Parawada Mandal, Visakhapatnam - 531 019, Andhra Pradesh, India. Email: info@alivira.co Web: www.alivira.co

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