



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 Fenbendazole Related compound-A Fenbendazole Related compound-B Any individual impurity Total impurities	Not more than 0.50% Not more than 0.50% Not more than 0.50% Not more than 1.00%	Not detected 0.02% Not detected 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 Methanol Acetone Toluene	Not more than 3000 ppm Not more than 5000 ppm Not more than 890 ppm	602 ppm BDL(LOD:150 ppm) 106 ppm
Remarks : The above batch complies as per USP/TH 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	

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