



ALIVIRA ANIMAL HEALTH LIMITED
CERTIFICATE OF ANALYSIS

FENBENDAZOLE USP

ALIVIRA

Batch No.	ASA001319A	Quantity	500.0 Kg
Manufacturing Date	July-2019	Retest / Expiry Date	June-2022
A.R.NO.	ALIV-FP-190335	Lot No.	40000027436
Storage Condition	Preserve in Well-closed,light resistant containers and store at room temperature.		
Purpose	SUAN FARMA INC.		

S.No	TEST PARAMETERS	SPECIFICATIONS	RESULTS
1	Description	A 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-0.00021%) 0.06% 0.07% 0.17%
5	Heavy Metals	Not more than 10 ppm	Complies
6	Loss on drying	Not more than 1.0% w/w	0.31% w/w
7	Sulphated Ash	Not more than 0.3% w/w	0.03% w/w
8	Assay	98.0 to 101.0% w/w (By Titrimetry, ODB)	100.8% 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	677 ppm BDL (BDL 150 ppm) 152 ppm

Remarks : The above batch complies as per the Specification No: FBZF/01F/FP/R2

	PREPARED BY	REVIEWED BY	APPROVED BY
DESIGNATION	Sr.Officer-QC	Head-QC	Head-QA
SIGNATURE	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
DATE	31/07/2019	31/07/2019	31/07/2019

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