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26/08/2025

CERTIFICATE OF ANALYSIS

Product	: FENBENDAZOLE EP		
Batch No.	: FBZ/05/004/2025	A.R. No.	: FP/0208/2025
Mfg. Date	: May - 2025	Expiry Date	: April - 2028
Batch Quantity	: 509.15 Kg	Date of Sampling	: 19/05/2025
Quantity sampled	: 120 gm	Date of Release	: 20/05/2025
Storage condition	: Kept in well closed light resistant containers and stored at a temperature not exceeding 30°C		

Sr. No.	Test	Specification	Result
1	Description	A white or almost white powder.	Almost white powder.
2	Solubility	Practically insoluble in water, Sparingly soluble in Dimethylformamide, very slightly soluble in methanol.	Practically insoluble in water, Sparingly soluble in Dimethylformamide, very slightly soluble in methanol.
3	Identification by IR	Spectra of sample and Fenbendazole CRS are concordant.	Complies
4	Heavy metals	Not more than 20 ppm	Less than 20 ppm
5	Loss on drying	Not more than 1.0 % w/w	0.27%
6	Sulfated ash	Not more than 0.3 % w/w	0.06%
7	Related substances by HPLC		
	i) Impurity A	Not more than 0.5%	Below detection limit
	ii) Impurity B	Not more than 0.5%	0.01%
	iii) Unspecified impurity	Not more than 0.5%	0.01%
	iv) Total impurities	Not more than 1.0%	0.03%
8	Assay by Potentiometry	98.0% to 101.0% on dried substance.	100.21%
*9	Residual solvent	i) Toluene : Not more than 890 ppm ii) Methanol : Not more than 3000 ppm iii) Acetone : Not more than 5000 ppm	175.49 ppm 550.59 ppm 4.28 ppm
*10	Particle size	90% < 10 µm	Complies

*Additional test

Remarks: The above batch material complies as SPEC/QC/FP/063/01 specification.

Prepared By: Jr. Executive QC	Checked By: Sr. Manager QC	Approved By: AGM QA
 23/07/2025 Shakuntala Karande	 23/07/2025 Sanjay Mitra	 23/07/2025 Ganesh Hosmakki

