

CERTIFICATE OF ANALYSIS

Product Name	:	FENBENDAZOLE Ph. Eur.(Micronised)		
Batch No	:	LASA/L2/013B/01/21	Dispatch Qty.	: 20.0 Kg
Mfg. Date	:	JAN-2021	Exp. Date	: DEC-2025
Pack size	:	20 Kg X 01	Date of Issue	: 08/02/21
Customer Name	:	META PHARMACEUTICALS		
Sr No	Test	Specification	Result	
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 by IR	IR spectrum of the sample is concordant with the Working standard spectrum.	Complies	
4	Related Substances (By HPLC)	Fenbendazole impurity A : Not more than 0.50% Fenbendazole impurity B : Not more than 0.50% Unspecified impurity : Not more than 0.20% Total impurities : Not more than 1.00%	0.01% 0.11% 0.02% 0.14%	
5	Heavy Metals	Not more than 10 ppm.	Complies	
6	Loss on drying	Not more than 1.0% w/w	0.31%	
7	Sulphated Ash	Not more than 0.3% w/w	0.12%	
8	Assay	98.0 to 101.00 w/w (By Titrimetry, ODB)	99.24%	
9*	Particle size	98% < 20 microns	Complies	
10*	Residual solvent by GC			
	Methanol	Not more than 3000 ppm	Complies	
	Acetone	Not more than 5000 ppm	Complies	
	Toluene	Not more than 890 ppm	Complies	

*** Additional test**

Remark: The above batch complies as Ph. Eur. specification.

Prepared by : D.S.Phadtare Designation : QC Officer Date : 08/02/21	Checked by : A.R.Utkar Designation : QC Executive Date : 08/02/21	Approved by : P.D.Lote Designation : QC Head Date : 08/02/21
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