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Certificate of Analysis


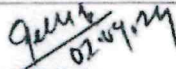
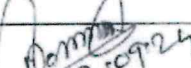


Product	MICONAZOLE EP		
Batch No.	024H046	Batch Size	110 Kg.
Pack Size	1 X 5 Kg	Packing lot size	5 Kg.
Mfg. Date	08.2024	Exp. Date	07.2029
Sampled Qty.	NA	Sampled by & on	NA
Inspection lot no.	40000265002		
COA Version	Copy 00		
CAS NO.	22916-47-8		

SR.NO	TEST APPLIED	RESULTS	LIMITS
1.	Appearance	Almost white powder.	A white or almost white powder.
2.	Solubility	Complies	Very slightly soluble in water, Freely soluble in methanol, soluble in ethanol (96 per cent) and alcohol.
3	Identification	Complies	
	A. IR	IR spectrum of sample is concordant with that of Miconazole working standard	IR spectrum of sample should be concordant with that of Miconazole working standard
	B. Melting Point:	84.2°C	83°C to 87 °C.
	C. Test for Chlorides	NA	To be positive.
4.	Appearance of Solution	Complies	Solution S is clear and is not more intensely coloured than reference solution Y ₆ .
5.	Optical rotation	-0.0005°	- 0.10° to +0.10°
6.	Related substances	Complies	
	Un identified impurities	0.06%	NMT 0.10 % of each.
	Total impurities	0.06%	NMT 0.3 %
7.	Loss on drying	0.21%	NMT 0.5%
8.	Sulfated ash	0.03%	NMT 0.1%
9.	Assay by titration	99.2%	99.0 % – 101.0 % (on dried basis)
*10.	Residual solvents by GC	Complies	
	Petroleum ether (60-80°C)	45.47 ppm	NMT 500 ppm
	Toluene	85 ppm	NMT 500 ppm
	Benzene (from Toluene)	ND	NMT 2 ppm
*11	Particle size (Microscopic method)	90 % < 25 Microns	90 % < 25 Microns

* Implies Additional In-House Test / NA Implies Not Applicable / BDL Implies Below detection Limit.

Result : The sample complies with the standards of quality prescribed in EP /FPS:4000001958/R3

DATE OF RELEASE	DATE OF ISSUE	 Mr. A.M. Shigvan PREPARED BY	 Mr. P.K. Palav CHECKED BY Manager QC	 Mr. V.A. Sawant APPROVED BY QA AGM QA
30.08.2024	02.09.2024			

SOP:RS-Q-314-F1/E

