



Factory : Plot No. 19 & 20/2 MIDC Area, Village Dhalav, Roha, Dist. Raigad, Pin Code 402 116, State : Maharashtra, INDIA
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Certificate of Analysis



Product	MICONAZOLE EP		
Batch No.	023L018	Batch Size	110 Kg.
Pack Size	1 X 5 Kg	Packing lot size	5 Kg.
Mfg. Date	12.2023	Exp. Date	11.2028
Sampled Qty.	NA	Sampled by & on	NA
Inspection lot no.	40000248412		
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:	85.2°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 _c .
5.	Optical rotation	+0.0007°	- 0.10° to +0.10°
6.	Related substances	Complies	
	Un identified impurities	BDL	NMT 0.10 % of each.
	Total impurities	NIL	NMT 0.3 %
7.	Loss on drying	0.15%	NMT 0.5%
8.	Sulfated ash	0.04%	NMT 0.1%
9.	Assay by titration	100.1%	99.0 % – 101.0 % (on dried basis)
*10.	Residual solvents by GC	Complies	
	Petroleum ether (60-80°C)	130.41 ppm	NMT 500 ppm
	Toluene	67 ppm	NMT 500 ppm
	Benzene (from Toluene)	ND	NMT 2 ppm

* 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 10.7 /FPS:4000001958/R2

DATE OF RELEASE	DATE OF ISSUE	Mr.A.M.Shigvan PREPARED BY	Mr.P.K.Palav CHECKED BY Manager QC	Mr.P.D.Patil APPROVED BY QA Dy. Manager QA
12.03.2024	13.03.2024			

SOP:RS-Q-314:F1/E