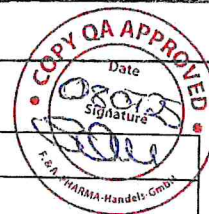




Factory : Plot No. 19 & 20/2 MIDC Area, Village Dhatav, Roha, Dist. Raigad, Pin Code 402 116, State : Maharashtra, INDIA
Phone : + 91 89561 87312/13, Email - roha@fdcindia.com

Certificate of Analysis



Product	MICONAZOLE EP		
Batch No.	025D076	Batch Size	110 Kg.
Pack Size	1 X 10 Kg	Packing lot size	10 Kg.
Mfg. Date	04.2025	Exp. Date	03.2030
Sampled Qty.	NA	Sampled by & on	NA
Inspection lot no.	40000294360		
COA Version	Copy 01(cep)		
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). It shows polymorphism.
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:	84.7°C	83°C to 87 °C.
	C. Test for Chlorides	NA	To be positive.
4.	Solution S	Complies	Solution S is clear
5.	Appearance of Solution	Complies	Solution S is clear and is not more intensely coloured than reference solution Y ₆ .
6.	Optical rotation	+0.0000°	- 0.10° to +0.10°
	Related substances	Complies	
7.	Unspecified impurities	BDL	NMT 0.10 % of each.
	Total impurities	NIL	NMT 0.3 %
8.	Loss on drying	0.22%	NMT 0.5%
9.	Sulfated ash	0.04%	NMT 0.1%
10	Assay by titration	100.2%	99.0 % – 101.0 % (on dried basis)
*11.	Residual solvents by GC	Complies	
	Petroleum ether (60-80°C)	218.06 ppm	NMT 500 ppm
	Toluene	46 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 11.0 /FPS:4000001958/R3
CEP 2022-233-Rev 01

DATE OF RELEASE 07.06.2025	DATE OF ISSUE 11.06.2025	Mr. A.M. Shigvan PREPARED BY	Mr. M.C. Dapake CHECKED BY Asst. Manager QC	Mr. V.A. Sawant APPROVED BY QA AGM QA
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SOP:RS-Q-314:F1/E