

FDC Limited

CIN : L24239MH1940PLC003176



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

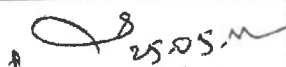
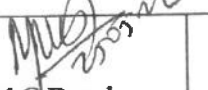
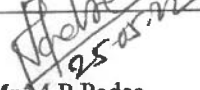
Product	MICONAZOLE NITRATE BP/EP		
Batch No.	022E015	Batch Size	135 Kg.
Pack Size	2 x 12.5 Kg	Packing lot Size	25.5 Kg.
Mfg. Date	05.2022	Exp. Date	04.2027
Sample Qty.	70 g	Sampled by & on	SDM/ 23.05.2022
Inspection Lot. No.	40000180854		
COA Version	Copy 01		

SR.NO	TEST APPLIED	RESULTS	LIMITS
1.	Appearance	Almost White powder.	White or almost white powder.
2.	Solubility	Complies	Very slightly soluble in water, sparingly soluble in methanol, slightly soluble in ethanol (96 per cent)
3	Identification	Complies	
	A. Melting Point: (BP/EP)	Melting Point: 181.5°C	178°C to 184 °C.
	B. IR (BP/EP)	IR spectrum of sample is concordant with that of Miconazole Nitrate working standard	IR spectrum of sample should be concordant with that of Miconazole Nitrate working standard
	C. By TLC (BP)	NA	To comply.
	C. Melting Point: (EP)	181.7°C	178°C to 184 °C.
	D. Test for Nitrates(BP/EP)	NA	To be positive.
4	Appearance of Solution	Complies	Solution S is clear and is not more intensely coloured than reference solution Y ₇ .
5.	Optical rotation	+0.0075°	- 0.10° to +0.10 °
6.	Related substances (BP)	Complies	
	Impurity A	ND	NMT 0.15 %
	Impurity B	ND	NMT 0.15 %.
	Impurity D	ND	NMT 0.15 %
	Impurity F	0.05%	NMT 0.15 %.
	Impurity G	ND	NMT 0.15 %
	Any Unspecified impurities	BDL	NMT 0.10 % of each
	Total impurities	0.05%	NMT 0.5 %
7	Related substances by HPLC (EP)	Complies	
	Any Unspecified impurities	0.05%	NMT 0.10 % of each
	Total impurities	0.05%	NMT 0.3 %
8.	Loss on drying	0.2%	Maximum 0.5%
9.	Sulfated ash	0.05%	Maximum 0.1%
10.	Assay by potentiometric titration	100.3 %	99.0 % – 101.0 % (on dried basis)
*11	Residual solvents.	Complies	
	Ethanol	16 ppm	NMT 200 ppm
	Toluene	12 ppm	NMT 500 ppm
*12	Boron	Less than 50 ppm	Maximum 50 ppm
**13.	Particle size (Malvern method)	100 % < 13.48 Microns	100 % < 20 Microns

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

/** customer requested test

Result : The sample complies with the standards of quality prescribed in BP 2022/ EP10.7

DATE OF RELEASE	DATE OF ISSUE	 Mr.A.T.Phadatare PREPARED BY	 Mr.M.G.Dapake CHECKED BY Sr.Executive QC	 Mr.M.P.Padse APPROVED BY QA Sr.Manager QA
25.05.2022	25.05.2022			

SOP:RS-Q-314:F1/D

Regd. Office : B-8, MIDC Industrial Area, Waluj - 431 136, Dist - Aurangabad, State Maharashtra INDIA.