

METAPHARMACEUTICAL

N DE LOTE:

0070423

FDC Limited

CIN : L24239MH1940PLC003176

F&A PHARMA



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

Product	MICONAZOLE EP		
Batch No.	022K038	Batch Size	100 Kg.
Pack Size	1 X 5 Kg	Packing lot size	5 Kg.
Mfg. Date	11.2022	Exp. Date	10.2027
Sampled Qty.	NA	Sampled by & on	NA
Inspection lot no.	40000208885		
COA Version	Copy 00		

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:	84.3°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	-0.0061°	- 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	0.12%	NMT 0.5%
8.	Sulfated ash	0.03%	NMT 0.1%
9.	Assay by titration	99.9%	99.0 % – 101.0 % (on dried basis)
*10.	Residual solvents by GC	Complies	
	Petroleum ether (60-80°C)	163 ppm	NMT 500 ppm
	Toluene	83 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.T. Phadatare PREPARED BY	Mr. P.K. Palav CHECKED BY Manager QC	Mr. P.D. Patil APPROVED BY QA Asst. Manager QA
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