

GUFIC GROUP OF TESTING LABORATORIES



CERTIFICATE OF ANALYSIS

Product	: Miconazole Nitrate USP	QC Ref. No.	: QC-FP-API-24- 0257
Batch No.	: AG240076E ✓	Quantity Received	: 301 Kg.
Date of Mfg.	: May.2024	Sampling Date	: 05/06/2024
Date of Exp.	: Apr.2029 ✓	Release Date	: 20/06/2024
Manufacturer	: Gufic Biosciences Limited.	Quantity Sampled	: 25 gm.
Testing Specification No	: SPC/FPR/BD/037	Specification	: USP
CAS No.	: 22832-87-7		

TESTS	RESULTS	LIMITS
Description	A white crystalline powder, having not more than slight odor.	White or practically white, crystalline powder, having not more than slight odor.
Solubility	Freely soluble in Dimethyl sulfoxide; soluble in Dimethyl formamide, sparingly soluble in methanol, slightly soluble in alcohol, in chloroform, and in propylene glycol; very slightly soluble in water and in isopropyl alcohol; insoluble in ether.	Freely soluble in Dimethyl sulfoxide; soluble in Dimethyl formamide, sparingly soluble in methanol, slightly soluble in alcohol, in chloroform, and in propylene glycol; very slightly soluble in water and in isopropyl alcohol; insoluble in ether.
Identification		
A: By Infrared Absorption Spectrophotometry	An IR spectrum of sample is concordant with the standard spectra of working standard of Miconazole Nitrate.	An IR spectrum of sample should be concordant with the standard spectra of working standard or reference standard of Miconazole Nitrate.
B: By HPLC	The retention time of the major peak of the sample solution is correspond to that of the standard solution, as obtained in the assay.	The retention time of the major peak of the sample solution should correspond to that of the standard solution, as obtained in the assay.
Melting Range	179.6° C to 180.3° C	Between: 178° to 183° C
Optical Rotation	+0.0023°	-0.10° to + 0.10°
Loss on drying	0.23%	Not more than 0.5 %
Residue on Ignition	0.06%	Not more than 0.2 %
Organic Impurities (By Liquid Chromatography By HPLC)	Deschlorobenzyl econazole ^a	0.00% Not more than 0.25%
	Miconazole quarternary salt ^b	0.00% Not more than 0.25%
	Miconazole benzyl analog ^c	0.00% Not more than 0.25%
	Miconazole Related Compound C	0.00% Not more than 0.25%
	Miconazole Related Compound I	0.00% Not more than 0.25%
	Econazole Nitrate	0.00% Not more than 0.25%
	Miconazole 2,6-isomer ^d	0.00% Not more than 0.25%
	Miconazole 2,5 isomer ^e	0.00% Not more than 0.25%
	Miconazole Related Compound F	0.00% Not more than 0.25%
	Any individual Unspecified Impurity	0.00% Not more than 0.10%
	Total Impurities	0.00% Not more than 0.5%
Assay By HPLC (On Dried Basis)	99.77%	Not less than 98.0% and not more than 102.0%
Residual solvent	Methanol 9 ppm	Not more than 3000 ppm
	Dichloromethane 0 ppm	Not more than 600 ppm
	Toluene 43 ppm	Not more than 890 ppm

REMARK: This is to certify that above product Complies/ Does not comply with prescribed standard quality of USP 44.

PREPARED BY

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