

# CHEMICAL STORE INC.

1059 Main Avenue, Clifton, NJ 07011

## CERTIFICATE OF ANALYSIS

### Miconazole Nitrate Micronized

Lot: Q3C989 (BATCH Number: H20240801)	Standard: USP43
Packaging: 25kg/Drum	Manufacturing Date: 2024.08.12
Quantity: 1000 kg	Expiration Date: 2027.08.11
Manufacturer: GUANGZHOU HANUP PHARMACEUTICAL CO. LTD.	Product of China.

TEST ITEM	SPECIFICATION	RESULTS
Characteristics	White either type white crystal powders	A white crystal powders
Identification	A. Infrared Absorption B. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay	A. Positive B. Positive
Residue on ignition	Not more than 0.2%	0.05%
Optical rotation	-0.10° to +0.10°	0°
Loss on drying	Less than 0.5%	0.15%
Organic impurities	Miconazole related compound C $\leq$ 0.25%	No detected
	Miconazole related compound I $\leq$ 0.25%	No detected
	Miconazole related compound F $\leq$ 0.25%	No detected
	Econazole nitrate $\leq$ 0.25%	No detected
	Deschlorobenzyl econazole $\leq$ 0.25%	No detected
	Miconazole quarternary salt $\leq$ 0.25%	No detected
	Miconazole benzyl analog $\leq$ 0.25%	No detected
	Miconazole 2,6-isomer $\leq$ 0.25%	No detected
	Miconazole 2,5-isomer $\leq$ 0.25%	0.12%
	Any individual unspecified impurity $\leq$ 0.10%	0.06%
Total impurities $\leq$ 0.5%	0.18%	
Residual Solvents	Benzene $\leq$ 2ppm	No detected
	Methylbenzene $\leq$ 890ppm	28ppm
Assay	98.0%-102.0% ( Calculated on dried basis)	99.85%
Microorganism	TPC < 1000 cfu/g	<10cfu/g
	Y and M < 100 cfu/g	<10cfu/g
	E-coli – Not detected	No detected
	Staphylococcus Aureus- No detected	No detected
	Pseudomonas Aeruginosa- No detected	No detected
	Albicans Saccharomyces- No detected	No detected
Remark:	PARTICLE SIZE: 90% PASS 10 MICRON	
CONCLUSION: Conforms with USP43		

**Disclaimer:** This Certificate of Analysis is provided for informational purposes only and is based on testing of a representative sample. Results may not reflect the characteristics of the entire batch. Some data may be derived from third-party or supplier-provided reports. The user is solely responsible for verifying the suitability, quality, and fitness of the product for their intended use. No warranties, express or implied, are made regarding accuracy, completeness, or performance, and the supplier assumes no liability for errors, omissions, or variations.

Quality Control Manager