

METAPHARMACEUTICAL

N DE LOTE:

GUANGZHOU HANPU PHARMACEUTICAL CO.LTD

0240325

CERTIFICATE OF ANALYSIS

Address: No.9 Jufeng North Road, Aotou Town, Conghua City, Guangzhou, China

PRODUCT: Miconazole Nitrate Micronized		RD-QF-7019-03	
BATCH NO: H20241102		STANDARD: EP11.2	
PACKING: 25 kg/Drum		MANUFACTURE DATE: 2024.11.05	
BATCH SIZE: 1000 kg		EXPIRATION DATE: 2028.11.04	
TEST ITEM	ACCEPTANCE CRITERIA		RESULTS
Appearance	White or almost white powder.		White powder
Solubility	Very slightly soluble in water,sparingly soluble in methanol,slightly soluble in ethanol(96%)		Complies
Identification	A. Infrared adsorption spectropotometry (2.2.24)		A. Complies
	B. Melting point(2.2.14): Result A:178℃ to 184℃ Result B: the absolute difference between the melting point of the mixture and the value obtained in determination A is not greater than 2 ℃.		B. Result A: 182 ℃-183 ℃ Result B: 1.5 ℃
	C. It gives the reaction of nitrates.		C. Complies
	Solution S is clear and not more intensely coloured than reference solution Y ₇		Complies
Opticalrotation	-0.10°~ +0.10°		0°
Related substances	Impurity C: ≤ 0.2%		Not detected
	Sum of impurities F and G: ≤ 0.2%		0.09%
	Unspecified impurities: ≤ 0.10%		0.05%
	Total impurities ≤ 0.5%		0.14%
Loss on drying	≤ 0.5%		0.18%
Sulfated ash	≤ 0.1%		0.05%
Assay	99.0%-101.0% (dried substance)		99.85%
Residual Solvents	Benzene:≤2ppm		No detected
	Methylbenzene≤890ppm		25ppm
Microorganism	Total aerobic bacteria: ≤ 1000 cfu/g		< 10cfu/g
	Total yeasts and molds: ≤ 100 cfu/g		< 10cfu/g
	E. coli, S. aureus, P. aeruginosa & C. albicans: absent per g.		Absent
PARTICLE SIZE: 90% PASS 10 MICRON			
CONCLUSION: Test results comply with EP11.2			
Quality Authorizer	Report Date :		2024.11.14