

ERREGIERRE

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CERTIFICATE OF ANALYSIS N°

199258

MICONAZOLE NITRATE USP - EP

CAS N. 22832-87-7

CODE 597

BATCH A220001

MAN. DATE 03/2022

RETEST DATE 03/2028

TEST FOR	SPECIFICATIONS	RESULTS
Description	white or almost white crystalline powder	Complies
Identification		
· IR	positive	Complies
· HPLC	positive	Complies
· Melting range	≥ 178 ≤ 183 °C (EP spec.: 178-184°C)	179.6 - 182.2
Loss on drying	≤ 0.5 %	0.06
Sulphated ash (Residue on ignition)	≤ 0.1 %	0.06
Appearance of solution	(USP spec.: NMT 0.2%) according to EP	Complies
Optical rotation	≥ -0.10 ≤ +0.10 °	0.00
Assay (volumetric, on dried basis)	≥ 99.0 ≤ 101.0 %	99.9
Assay (HPLC, on dried basis)	≥ 98.0 ≤ 102.0 %	100.3
Organic impurities (HPLC)		
· USP Desclorobenzyl econazole / EP Imp. A	≤ 0.10 % (USP spec.: NMT 0.25%)	<0.05 (LOQ)
· USP Miconazole quaternary salt / EP Imp. E	≤ 0.10 % (USP spec.: NMT 0.25%)	<0.05 (LOQ)
· USP Miconazole benzyl analog / EP Imp. H	≤ 0.10 % (USP spec.: NMT 0.25%)	<0.05 (LOQ)
· USP Imp. C / EP Imp. C	≤ 0.10 % (USP spec.: NMT 0.25%)	0.07
· USP Imp. I / EP Imp. I	≤ 0.10 % (USP spec.: NMT 0.25%)	<0.05 (LOQ)
· USP Econazole nitrate / EP Imp. B	≤ 0.10 % (USP spec.: NMT 0.25%)	<0.05 (LOQ)
· USP Miconazole 2,6-isomer / EP Imp. D	≤ 0.10 % (USP spec.: NMT 0.25%)	<0.05 (LOQ)
· USP Miconazole 2,5-isomer / EP Imp. G	≤ 0.10 % (USP spec.: NMT 0.25%)	<0.05 (LOQ)
· USP Imp. F / EP Imp. F	≤ 0.10 % (USP spec.: NMT 0.25%)	<0.05 (LOQ)
· any other impurity (highest)	≤ 0.10 %	<0.05 (LOQ)
· total	≤ 0.3 % (USP spec.: NMT 0.5%)	0.07
Additional specifications		
Residual solvents (GC)		
· acetone	≤ 2000 ppm	212
· tetrahydrofuran	≤ 720 ppm	143

OBSERVATIONS:

N° lote ACOFARMA:

224398

Firma y fecha:

[Signature]
12/08/21

Copies of this CoA are not valid

APPROVED

QUALITY CONTROL

Dr. R. Poli