

MICONAZOLI NITRAS 10 g

Lot No.: 22H24-APR22261

Authorisation:	1890R05429	Date Of Analysis:	14/07/2022
Analytical Reference:	Ph. Eur. 10.7 [04/2022:0513]	Production Number:	080922-GS22097
CNK:	3490-612	Expiry Date:	04/2027

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	The spectrum complies with the spectrum obtained with Miconazole nitrate CRS	Complies
Identification B	Result A: 178 °C to 184 °C.	Complies
	Result B: the absolute difference between the melting point of the mixture and the value obtained in determination A is not greater than 2 °C.	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and not more intensely coloured than reference solution Y ₇	Complies
Optical rotation	- 0.10° to + 0.10°	-0.01°
Related substances		
Unspecified impurities	≤ 0.10%	< 0.05%
Total	≤ 0.3%	< 0.05%
Loss on drying	≤ 0.5%	0.2%
Sulfated ash	≤ 0.1%	0.03%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	99.0% to 101.0% (dried substance)	99.5%

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: