

**MICONAZOLI NITRAS 25 g**

Lot No.: 22L22-APR23221

Autorisation :	1890R05429	Date Of Analysis :	27/10/2022
Analytical Reference :	Ph. Eur. 10.7 [04/2022 :0513]	Production Number :	120723-GS22152
CNK :	3490-620	Expiry Date :	07/2027

**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 <sub>7</sub>	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%	0.03%
Sulfated ash	≤ 0.1%	0.02%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	99.0% to 101.0% (dried substance)	100.3%
Manufacturer identification code: S/GS/057		

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: