

**MICONAZOLI NITRAS 5 g**

Lot No.: 24K26-F250027

Authorisation:	1890R05429	Date Of Analysis:	05/09/2024
Analytical Reference:	Ph.Eur. [07/2023:0513]	Production Number:	220125-G240164
CNK:	3490-638	Expiry Date:	05/2029

**ANALYTICAL TESTS**

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	178°C to 184°C	Complies
Identification B	The spectrum complies with the spectrum obtained with Miconazole nitrate CRS	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		
Impurity C	≤ 0.2%	< 0.05%
sum of impurities F and G	≤ 0.2%	< 0.05%
Unspecified impurities	≤ 0.10%	< 0.05%
Total	≤ 0.5%	< 0.05%
Loss on drying	≤ 0.5%	< 0.1%
Sulfated ash	≤ 0.1%	< 0.1%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	99.0% to 101.0% (dried substance)	100.2%
Manufacturer identification code: S/GS/057		

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: