

MICONAZOLUM 5 g

Lot No.: 25C04-AP25005

Autorisation :	1890IR06176	Date Of Analysis :	04/03/2025
Analytical Reference :	Ph. Eur. [04/2022:0935]	Production Number :	040325-0131024
CNK :	4732-863	Expiry Date :	07/2029

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white powder	White powder
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	The spectrum complies with the spectrum obtained with miconazole CRS	Complies
Identification B	Melting point	
Result A	83°C – 87°C	84.6°C
Result B	< 2°C	1°C
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and not more intensely coloured than reference solution Y ₆	Complies
Optical rotation	-0.10° - + 0.10°	+0.0°
Related substances		
Unspecified impurities	≤ 0.10%	< 0.10%
Total of impurities	≤ 0.30%	< 0.3%
Loss on drying	≤ 0.5%	0.08%
Sulfated ash	≤ 0.1%	0.07%
ASSAY	SPECIFICATION	RESULT
Assay	99.0 – 101.0%	99.7%

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: