

MICONAZOLUM 5 g

Lot No.: 24E15-AP24129

Autorisation :	1890IR06176	Date Of Analysis :	15/05/2024
Analytical Reference :	Ph. Eur. [04/2022:0935]	Production Number :	050624-0080424
CNK :	4732-863	Expiry Date :	11/2028

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 CRS	Complies
Identification B	Melting point	
Result A	83°C – 87°C	86°C
Result B	< 2°C	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and not more intensely coloured than reference solution Y6	Complies
Optical rotation	-0.10° - + 0.10°	+0.10°
Related substances		
Unspecified impurities	≤ 0.10%	0.06%
Total of impurities	≤ 0.30%	0.06%
Loss on drying	≤ 0.50%	0.2%
Sulfated ash	≤ 0.10%	< 0.1%
ASSAY	SPECIFICATION	RESULT
Assay	99.0 – 101.0%	99.5%

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: