

ISONIAZIDUM 100 g

Lot No.: 23C08-AP23143

Autorisation :	1890IR06233	Date Of Analysis :	08/03/2023
Analytical Reference :	Ph.Eur. 11.0	Production Number :	120723-0070123
CNK :	4691-648	Expiry Date :	07/2027

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder or colourless crystals	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	Melting point: 170 – 174 °C	173 °C
Identification B	The spectrum complies with the spectrum obtained with isoniazid CRS	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY7	Complies
pH	6.0 – 8.0	7.3
Impurity E	≤ 15 ppm	1.0 ppm
Related substances		
Impurity A	≤ 0.15 %	Not Detected
Impurity B	≤ 0.15 %	Not Detected
Unspecified impurities	≤ 0.10 %	< 0.05 %
Total impurities	≤ 0.5 %	< 0.05 %
Loss of drying	≤ 0.5 %	0.08 %
Sulfated ash	≤ 0.1 %	0.09 %
ASSAY	SPECIFICATION	RESULT
Assay	99.0 – 101.0 %	99.1 %

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: