METAPHARMACEUTICAL IND SL
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ISONIAZIDA (EUR. PH.)

PRODUCT CODE: 1146	CAS Nº: 54-85-3	ANALYSIS Nº: 220/25	
MANUFACTURER BATCH:	25033/INH	CERTIFICATE ID:	47.401
SUPPLIER BATCH:	----	MANUFACTURING DATE:	13/02/2025
METAPH BATCH:	0180725	EXPIRY DATE:	12/02/2030

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder or colourless crystals	White crystalline powder
Solubility	Freely soluble in water, sparingly soluble in ethanol (96 %)	Complies (*)
Melting point	170 - 174 ºC	172 ºC
Identification A	Complies	Complies
Identification B	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY7	Complies
pH	6.0 - 8.0	6.8
Impurity E	=< 15 ppm	1.1 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 on drying	=< 0.5 %	0.2 %
Sulfated ash	=< 0.1 %	0.04 %
Assay	99.0 - 101.0 %	99.7 %

COMPLIES WITH

European Pharmacopoiea 11.3

REMARKS

Product fully analyzed within the EU, in compliance with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Isoniazid is subjected to the requirements of the ICH Q3D "Elemental Impurities" and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.
(*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Store in a cool and dry place. Keep container tightly closed.

Analysis date: 17/07/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000416
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