METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

1146-TDS-ENG-2024

ISONIAZIDA (EUR. PH.)		
DESCRIPTION DCI: isoniazid	DESCRIPTION DOE: ISONIAZIDA	
CAS Nº: 54-85-3	EC Nº: 200-214-6	AEMPS CODE: 1637A
MOL. WEIGHT: 137,14	MOL. FORMULA: C6H7N3O	ARTICLE CODE: 1146

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder or colourless crystals
Solubility	Freely soluble in water, sparingly soluble in ethanol (96 %)
Melting point	170 - 174 ºC
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY7
pH	6.0 - 8.0
Impurity E	=< 15 ppm
Related substances	
Impurity A	=< 0.15 %
Impurity B	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %
Residual solvents [In-house]	
Methanol	=< 3000 ppm
Benzene	=< 2 ppm
Pyridine	=< 200 ppm
Microbiological control	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
Escherichia coli	Absent
Salmonella	Absent
Staphylococcus aureus	Absent
Pseudomonas aeruginosa	Absent
Candida Albicans	Absent
Aspergillus brasilensis	Absent
Clostridium sporogenes	Absent
Shigella boydii	Absent

COMPLIES WITH

European Pharmacopoiea 11.0

STORAGE

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

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REMARKS

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

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.