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AMSAL CHEM PVT. LTD.
QUALITY CONTROL LABORATORY
The Drugs & Cosmetic Act 1940 & the rules thereunder

CERTIFICATE OF ANALYSIS

A-1 401, 402 & 403,
G.I.D.C. Industrial Estate,
Ankleshwar-393 002.
District : Bharuch, Gujarat, India.
CIN : U24231GJ1992PTCO18289

META PHARMACEUTICAL

Format No : SOP/QC/111/FM01

Name of Product	: ISONIAZID EP	A.R. No	: AC/INH/279/2022
Batch No	: 22279/INH	Batch size	: 2007.0 Kg
Mfg. Date	: 14/11/2022	Date of Receipt	: 18/11/2022
Exp. Date	: 13/11/2027	Date of Completion	: 12/11/2022
Sample quantity	: 50 gm	Analysed as per	: EP 10

Sr. No.	TEST	SPECIFICATION	RESULT
1.	Appearance	White or almost white, crystalline powder or colourless crystals.	Complies
2.	Solubility	Freely Soluble in water, sparingly soluble in ethanol (96%).	Complies
3.	Identification	First identification: A, B Second identification: A, C	
	A. Melting point	170°C to 174°C	171.2°C
	B. Infrared absorption spectrophotometry	Should be concordant with IR spectrum of Isoniazid WS.	Complies
	C. Melting point of Derivative	226°C to 231°C	-
4.	Appearance of solution	5% w/v solution is clear and not more intensely coloured than reference solution BY_7	Complies
5.	pH	The pH of a 5% W/V solution is 6.0 to 8.0	7.15
6.	Impurity E by HPLC	Not more than 15 ppm.	4.66 ppm
7.	Related Substances by HPLC		
	Impurity-A (Isonicotinic Acid)	Not more than 0.15 %	0.0066 %
	Impurity-B (Isonicotinamide)	Not more than 0.15 %	0.0079 %
	Unspecified Impurity	Not more than 0.10 %	0.0202 %
	Total Impurities	Not more than 0.5 %	0.0346 %
8.	Loss on Drying	Not more than 0.5%	0.20 %
9.	Sulfated ash	Not more than 0.1%	0.03 %
10.	Assay by Titrimetric	99.0% to 101.0% (dried substance)	99.8 %
11.	Residual Solvents (In-House GC Method)		
	Methanol	Not more than 3000 ppm.	206 ppm
	Benzene	Not more than 2 ppm.	ND
	Pyridine	Not more than 200 ppm.	ND

Conclusion:

In the opinion of the undersigned the sample referred to above complies / ~~does not comply~~ with the requirement as per EP 10 specification.

Remark: This batch COA is reprint on 14/07/2023.

14/07/2023
Analysed by
(QC Chemist)
(Jagdish Patel)

14/07/2023
Checked by
(Asst. QC Manager)
(A.R. Rajput)

14/07/2023
Approved by
(Asst. QA Manager)
(Anil Patel)