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 : U24231GJ1992PTC018289

METAPHARMACEUTICAL

N DE LOTE: 0970123

11/01/2023

Format No. STP/QC/137/FM02

Name of Product : ISONIAZID EP
Batch No : 22229/INH
Mfg. Date : 01/08/2022
Exp. Date : 31/07/2027
Sample quantity : 50 gm

A.R. No : AC/INH/229/2022
Batch size : 1000 Kg
Date of Receipt : 04/08/2022
Date of Completion: 09/08/2022
Analysed as per : EP 10 / In House

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	171.3°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	7.11
6.	Impurity E by HPLC	Not more than 15 ppm.	2.01 ppm
7.	Related Substances by HPLC		
	Impurity-A (Isonicotinic Acid)	Not more than 0.15 %	ND
	Impurity-B (Isonicotinamide)	Not more than 0.15 %	ND
	Unspecified Impurity	Not more than 0.10 %	ND
	Total Impurities	Not more than 0.5 %	ND
8.	Loss on Drying	Not more than 0.5%	0.22 %
9.	Sulfated ash	Not more than 0.1%	0.03 %
10.	Assay by Titrimetric	99.0% to 101.0% (dried substance)	100.2 %
ADDITIONAL TEST			
11.	Related substances by HPLC (In-House Method)		
	Isonicotinic Acid	Not more than 0.05%	0.0014 %
	Isonicotinamide	Not more than 0.10%	0.0058 %
	Nicotinoyl Hydrazide	Not more than 0.10%	ND
	Diisonicotinoyl Hydrazine	Not more than 0.10%	ND
	2-Isoniazid	Not more than 0.10%	ND
	4-Cyanopyridine	Not more than 0.10%	ND
	Benzoyl Hydrazine	Not more than 0.10%	ND
	Single Maximum Unknown Impurity.	Not more than 0.10%	0.0260 %
	Total Impurities	Not more than 0.20%	0.0332 %

Modi 21/12/2022

Analysed by
(QC Chemist)
(Sagar Modi)

21/12/2022

Checked by
(Asst. QC Manager)
(A.R. Rajput)

22/12/2022

Approved by
(Head-QA)
(Bhavesh Dhrangdhria)

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CIN : U24231GJ1992PTC018289

Format No. STP/QC/137/FM02

Name of Product : **ISONIAZID EP** A.R. No : **AC/INH/229/2022**

Sr. No.	TEST	SPECIFICATION	RESULT
12.	Residual Solvents (In-House GC Method)		
	Methanol	Not more than 3000 ppm.	114 ppm
	Benzene	Not more than 2 ppm.	ND
	Pyridine	Not more than 200 ppm.	ND
13.	Particle Size (by Sieve analysis)		
	NA	NA	NA
14.	Microbiological Analysis		
	Total viable Aerobic count a) Total Bacterial count	Not more Than 1000 CFU/gm	-
	b) Total Fungal Count (Yeasts +Moulds)	Not more than 100 CFU/gm	-
	Pathogens:		
	Escherichia coli	Should be absent.	-
	Salmonella abony	Should be absent.	-
	Staphylococcus aureus	Should be absent.	-
	Pseudiomonas aeruginosa	Should be absent.	-
	Candida albicans	Should be absent.	-
	Aspergillus brasiliensis	Should be absent.	-
	Clostridium sporogenes	Should be absent.	-
	Shigella boydii	Should be absent.	-
15.	Metal impurities*		
	Molybdenum	Not more than 150 ppm	-
	Nickel	Not more than 2.0 ppm	-
	Chromium	Not more than 100 ppm	-
	Vanadium	Not more than 1.0 ppm	-

Conclusion:

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

*** Test No.15 Metal impurities 'Skip test'. (Frequency: Three batches are tested once in a year)**

Remark: This batch COA is reprint on 21/12/2022.

Modi 21/12/2022

Analysed by
(QC Chemist)
(Sagar Modi)

21/12/2022

Checked by
(Asst. QC Manager)
(A.R. Rajput)

21/12/2022

Approved by
(Head-QA)
(Bhavesh Dhrangdhria)