ISO 9001:2008
Reg. No. RQ91/1030

AMSAL CHEM
PRIVATE LIMITED

A-1, 401, 402 & 403,
G.I.D.C. Industrial Estate,
Ankleshwar-393 002.
District : Bharuch, Gujarat, India.
CIN : U24231GJ1992PTC018289

QUALITY CONTROL LABORATORY

The Drugs & Cosmetic Act 1940 & the rules thereunder

CERTIFICATE OF ANALYSIS

Format No.STP/QC/71/FM02

Name of Product: ISONIAZID

Batch No : 18133/INH

Mfg. Date : 10/04/2018

Exp. Date : 09/04/2023

Sample quantity : 50 gm

A.R. No : AC/INH/133/2018

Batch size : 1050 kgs

Date of Receipt : 13/04/2018

Date of Completion : 19/04/2018

Analysed as per : ~~BP/EP 9.0/USP/IP/IN HOUSE~~

Sr. No.	TESTS	PHARMACOPOEIAL SPECIFICATION & RESULTS		
		EP / BP	USP	IP
1.	Description / Characters	A white or almost white crystalline powder or colourless crystals.	Colorless or white crystals or white, crystalline powder. Odorless.	Colourless crystals or a white, crystalline powder.
	Result	Complies	NA	NA
2.	Solubility	Freely soluble in water, sparingly soluble in alcohol.	Freely soluble in water, sparingly soluble in alcohol, slightly soluble in chloroform, and very slightly soluble in ether.	Freely soluble in water, sparingly soluble in ethanol (95%), slightly soluble in chloroform, very slightly soluble in ether.
	Result	Complies	NA	NA
3.	Identification:	(Perform Tests A&B or A&C)	(Perform Tests B&D)	(Perform Tests A & B or A&C)
	A. Melting Point/ Melting Range:	170 °C to 174 °C.	NA	170 °C to 174 °C
	Result	172°C	NA	NA
	B. Infrared Absorption Spectrum	Should be concordant with IR spectrum of Isoniazid CRS / RS.	Should be concordant with IR spectrum of Isoniazid CRS / RS.	Should be concordant with IR spectrum of Isoniazid CRS / RS.
	Result	Complies	NA	NA
	C. Melting Point of Derivative	226 °C to 231°C.	NA	226 °C to 231°C.
	Result	NA	NA	NA

24/04/18
Analysed by
(QC Chemist)
(Asmita Bhayani)

24/04/18
Checked by
(QC Manager)
(Umesh Patel)

20/04/2018
Approved by
(QA Manager)
(S. J. Surati)

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Sr. No.	TESTS	PHARMACOPOEIAL SPECIFICATION & RESULTS		
		EP / BP	USP	IP
	D. By HPLC	NA	The retention time of the Isoniazid peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.	NA
	Result	NA	NA	NA
4.	Appearance of Solution:	A 5% w/v solution is clear and not more intensely colored than reference Solution BY_7	NA	A 5% w/v solution is clear and not more intensely colored than reference Solution BYS_7.
	Result	Complies	NA	NA
5.	pH:	The pH of a 5% w/v solution is 6.0 to 8.0	The pH of a 10% w/v solution is 6.0 to 7.5	The pH of a 5% w/v solution is 6.0 to 8.0
	Result	7.2	NA	NA
6.	Hydrazine and Related Substances (by TLC)			
	Hydrazine	0.05%	NA	0.05%
	Result	Complies	NA	NA
	Total Related Substances (Except Hydrazine)	0.20%	NA	NA
	Result	Complies	NA	NA
7.	Related Substances As per IP (HPLC Method)	NA	NA	Any individual impurity is not more than 0.20%. Sum of all impurities found is not more than 1.0 %.
	Result	NA	NA	NA

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24/5/2018

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Sr. No.	TESTS	PHARMACOPOEIAL SPECIFICATION & RESULTS		
		EP / BP	USP	IP
8.	Heavy Metals	NA	Not more than 0.002% Pb	Not more than 20 ppm Pb
	Result	NA	NA	NA
9.	Loss on Drying	Not more than 0.50 %	Not more than 1.0%.	Not more than 0.50%
	Result	0.27 %	NA	NA
10.	Sulphated Ash	Not more than 0.10 %	NA	Not more than 0.10%
	Result	0.02 %	NA	NA
11.	Residue on Ignition	NA	Not more than 0.20%	NA
	Result	NA	NA	NA
12.	Assay (on dried basis)	Not less than 99.0 % and not more than 101.0 % of $C_6H_7N_3O$. (By Titrimetry)	Not less than 98.0 % and not more than 102.0 % of $C_6H_7N_3O$. (By HPLC)	Not less than 98.0 % and not more than 101.0% of $C_6H_7N_3O$. (By HPLC)
	Result	100.1 %	NA	NA

SR. NO	TESTS	SPECIFICATION	Results
13.	Related Substances By HPLC (%) : As per USP 38		
	Isoniacin	Not more than 0.1 %	--
	Isonicotinamide	Not more than 0.1 %	--
	Picolinohydrazide	Not more than 0.1 %	--
	Isonicotinonitrile	Not more than 0.1 %	--
	Any Unspecified Impurity	Not more than 0.10 %	--
	Total Impurities	Not more than 2.0 %	--
	ADDITIONAL TESTS		
14.	Related Substances (In-House HPLC Method):		
	Isonicotinic Acid	Not more than 0.05%	0.0107 %
	Isonicotinamide	Not more than 0.10%	0.0062 %
	Nicotinoyl Hydrazide	Not more than 0.10 %	ND
	Diisonicotinoyl Hydrazine	Not more than 0.10%	0.0030 %
	2-Isoniazid	Not more than 0.10%	ND
	4-Cyanopyridine	Not more than 0.10%	ND
	Benzoyl Hydrazine	Not more than 0.10%	ND
	Any Other Single Impurity	Not more than 0.10%	0.0074 %
	Total Impurities	Not more than 0.20%	0.0272 %

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SR. NO	TESTS	SPECIFICATION	Results
15	Residual Solvents (In-House GC Method)		
	Benzene	Not more than 2 ppm.	ND
	Pyridine	Not more than 200 ppm.	ND
	Methanol	Not more than 3000 ppm.	299 ppm
16.	Particle Size (by Sieve analysis) NA	NA	NA
17.	Microbiological Analysis Total Viable Aerobic Count:		
	Total Bacterial Count:	Not More Than 1000 CFU/gm	-
	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.	-
	Pseudomonas aeruginosa	Should be absent.	-
	Candida albicans	Should be absent.	-
	Aspergillus brasilinesis	Should be absent.	-
	Clostridium sporogenes	Should be absent.	-
18*	*Metal Impurities: Skip test*		
	Molybdenum	Not more than 3 ppm	-
	Nickel	Not more than 3 ppm	-
	Chromium	Not more than 3 ppm	-
	Vanadium	Not more than 3 ppm	-

Conclusion:

In the opinion of the undersigned the sample referred to above complies / ~~does not comply~~ with the requirement as per EP 9.0 /BP/USP/IP and the In-House specification.

* Test No.18 Metal impurities 'Skip test'.

Remark: This batch COA is reprint on 24.05.2018.

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