ISO 9001 : 2015
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

Format No.STP/QC/71/FM02

CERTIFICATE OF ANALYSIS

Name of Product: ISONIAZID
Batch No : 19420/INH
Mfg. Date : 11/11/2019
Exp. Date : 10/11/2024
Sample quantity : 50 gm

A.R. No : AC/INH/420/2019
Batch size : 1000 kgs
Date of Receipt : 14/11/2019
Date of Completion : 19/11/2019
Analysed as per : BP/EP 9.5/USP/IP/IN HOUSE

Sr. No.	*TESTS*	*PHARMACOPOEIAL SPECIFICATION & RESULTS*		
		EP / BP	USP	IP
1.	Description / Characters	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 ethanol (96 %)	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	171.5 °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
	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

10/12/19
Analysed by
(QC Chemist)
(Jaydeep Patel)

10/12/19
Checked by
(QC Manager)
(Umesh Patel)

19/12/19
Approved by
(Sr. QA Officer)
(Anil Patel)

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Format No.STP/QC/71/FM02

CERTIFICATE OF ANALYSIS

Name of Product: ISONIAZID

A.R. No : AC/INH/420/2019

Sr. No.	TESTS	PHARMACOPOEIAL SPECIFICATION & RESULTS		
		EP / BP	USP	IP
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	7.12	NA	NA
6.	Related Substances (by TLC)			
	Any other single max	NA	NA	0.05%
	Result	NA	NA	NA
	Hydrazine	NA	NA	NA
	Result	NA	NA	NA
7.	Impurity E by HPLC	Maximum 15 ppm	NA	NA
	Result	4.70 ppm	NA	NA
8.	Related Substances As perEP/BP/IP/USP (HPLC Method)	Impurity-A (Isonicotinic Acid) - Maximum 0.15 % Impurity-B (Isonicotinamide) - Maximum 0.15 % Unspecified Impurities - Maximum 0.10 % Total Impurities - Maximum 0.5 %	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 %	Any individual impurity is not more than 0.20%. Sum of all impurities found is not more than 1.0 %.
	Result	Impurity-A - ND Impurity-B - ND Unspecified Impurity - ND Total Impurities - ND	NA	NA

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Format No.STP/QC/T1/FM02 **CERTIFICATE OF ANALYSIS**

Name of Product: ISONIAZID A.R. No : AC/INH/420/2019

Sr. No.	TESTS	PHARMACOPOEIAL SPECIFICATION & RESULTS		
		EP / BP	USP	IP
9.	Heavy Metals	NA	Not more than 0.002% Pb	Not more than 20 ppm Pb
	Result	NA	NA	NA
10.	Loss on Drying	Not more than 0.5 %	Not more than 1.0%.	Not more than 0.50%
	Result	0.23 %	NA	NA
11.	Sulphated Ash	Not more than 0.10%.	NA	Not more than 0.10%
	Result	0.03 %	NA	NA
12.	Residue on Ignition	NA	Not more than 0.20%	NA
	Result	NA	NA	NA
13.	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	99.9 %	NA	NA

SR. NO	TESTS	SPECIFICATION	Results
	ADDITIONAL TESTS		
14.	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.	198 ppm
15.	Particle Size (by Sieve analysis) NA	NA	NA
16.	Related Substances (In-House HPLC Method):		
	Isonicotinic Acid	Not more than 0.05%	0.0054 %
	Isonicotinamide	Not more than 0.10%	ND
	Nicotinoyl Hydrazide	Not more than 0.10 %	ND
	Diisonicotinoyl Hydrazine	Not more than 0.10%	0.0046 %
	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%	0.0044 %
	Total Impurities	Not more than 0.20%	0.0143 %

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Name of Product: ISONIAZID A.R. No : AC/INH/420/2019

SR. NO	TESTS	SPECIFICATION	Results
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 brasiliensis	Should be absent.	-
	Clostridium sporogenes	Should be absent.	-
	Shigella boydii	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 9.5 /BP/USP/IP and the In-House specification.

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

Remark: This batch COA is reprint on 10.12.2019.

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