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 : U24231GJ1992PTC018269

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 : **17057/INH**
Mfg. Date : **24/02/2017**
Exp. Date : **23/02/2022**
Sample quantity : **50 gm**

A.R. No : **AC/INH/057/2017**
Batch size : **1050 kgs**
Date of Receipt : **27/02/2017**
Date of Completion : **20/02/2018**
Analysed as per : **BP/EP 9 /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 and is slowly affected by exposure to air and light.	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	170 °C to 173 °C	170 °C to 174 °C
	Result	171 °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

20/02/18
Analysed by
(QC Chemist)
(Asmita Bhayani)

20/02/18
Checked by
(QC Asst. Manager)
(Nilesh Shah)

20/02/18
Approved by
(QA Asst. Manager)
(Kamal Bhatt)

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CERTIFICATE OF ANALYSIS

Format No.STP/QC/71/FM02

Name of Product: ISONIAZID A.R. No : AC/INH/057/2017

Sr. No.	*TESTS*	*PHARMACOPOEIAL SPECIFICATION & RESULTS*		
		EP / BP	USP	IP
	D. Ultraviolet Absorption Spectrum	NA	Should be concordant with UV spectrum of Isoniazid USP RS.	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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Sr. No.	*TESTS*	*PHARMACOPOEIAL SPECIFICATION & RESULTS*		
		EP / BP	USP	IP
8.	Heavy Metals	Not more than 10 ppm Pb	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	0.28 %	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	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.	*ADDITIONAL TESTS*		
	TESTS	*SPECIFICATION*	*Results*
13.	Related Substances (In-House HPLC Method):		
	Isonicotinic Acid	Not more than 0.05%	0.0169 %
	Isonicotinamide	Not more than 0.10%	0.0081 %
	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
	Any Other Single Impurity	Not more than 0.10%	ND
	Total Impurities	Not more than 0.20%	0.0250 %

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Sr. No.	ADDITIONAL TESTS TESTS	SPECIFICATION	Results
14.	Residual Solvents (In-House GC Method):		
	Benzene:	Not more than 2 ppm.	ND
	Pyridine:	Not more than 200 ppm.	ND
	Methyl Alcohol:	Not more than 3000 ppm.	246 ppm
15.	Particle Size (by Sieve analysis)		
	NA	NA	NA
16.	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 boyadii	Should be absent.	-
17	*Metal Impurities: Skip test*		
	Molybdenum	Not more than 3 ppm	Not detected
	Nickel	Not more than 3 ppm	Not detected
	Chromium	Not more than 3 ppm	2.48 ppm
	Vanadium	Not more than 3 ppm	Not detected

Conclusion:

In the opinion of the undersigned the sample referred to above complies / ~~does not comply~~ with the requirement as per EP 9 /~~BP/USP/IP~~ and the In-House specification.

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