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 : 14207/INH
Mfg. Date : ~~05/08/2014~~
Exp. Date : 04/08/2018
Sample quantity : 50 gm

A.R. No : AC/INH/207/2014
Batch size : 1050 kgs
Date of Receipt : 09/08/2014
Date of Completion : 16/11/2014
Analysed as per : ~~B.P/EP8/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 colour less 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	N. A.	N. A.
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	N. A.	N.A
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	N. A.	N.A
	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	N. A.	N.A
	C. Melting Point of Derivative	226 °C to 231°C.	N. A.	226 °C to 231°C.
	Result	N.A	N.A	N.A

16/11/14
Analysed by
(Q.C. Chemist)

16/11/14
Checked by
(Q.C. Incharge)

17/11/2014
Approved by
(Q.A. Manager)

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Sr. No.	*TESTS*	*PHARMACOPOEIAL SPECIFICATION & RESULTS*		
		EP / BP	**USP**	**IP**
	D. Ultraviolet Absorption Spectrum	N. A.	Should be concordant with UV spectrum of Isoniazid USP RS.	N. A.
	Result	N. A.	N. A.	N. A.
4.	Appearance of Solution:	A 5% w/v solution is clear and not more intensely colored than reference Solution BY_7	N. A.	A 5% w/v solution is clear and not more intensely colored than reference Solution BYS_7.
	Result	Complies	N. A.	N.A
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	N. A.	N.A
6.	Hydrazine and Related Substances (by TLC)			
	Hydrazine	0.05%	N. A.	0.05%
	Result	Complies	N. A.	N.A
	Total Related Substances (Except Hydrazine)	0.20%	N. A.	N. A.
	Result	Complies	N. A.	N. A.
7.	Related Substances As per IP (HPLC Method)	N. A.	N. A.	Any individual impurity is not more than 0.20%. Sum of all impurities found is not more than 1.0 %.
	Result	N. A.	N. A.	N.A

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		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	Complies	N. A.	N.A
9.	Loss on Drying	Not more than 0.50%	Not more than 1.0%.	Not more than 0.50%
	Result	0.28 %	N. A.	N.A
10.	Sulphated Ash	Not more than 0.10%.	N. A.	Not more than 0.10%.
	Result	0.02 %	N.A	N.A
11.	Residue on Ignition	N. A.	Not more than 0.20%	N. A.
	Result	N. A.	N. A.	N. A.
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	99. 8 %	N. A.	N.A

Sr. No.	*ADDITIONAL TESTS*		
	TESTS	*SPECIFICATION*	*Results*
13.	Related Substances (In-House HPLC Method):		
	Isonicotinic Acid	Not more than 0.05%	0.008 %
	Isonicotinamide	Not more than 0.10%	N.D
	Nicotinoyl Hydrazide	Not more than 0.10%	N.D
	Diisonicotinoyl Hydrazine	Not more than 0.10%	N.D
	2-Isoniazid	Not more than 0.10%	N.D
	4-Cyanopyridine	Not more than 0.10%	N.D
	Benzoyl Hydrazine	Not more than 0.10%	0.028 %
	Any Other Single Impurity	Not more than 0.10%	0.017 %
	Total Impurities	Not more than 0.50%	0.056 %

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Sr. No.	*ADDITIONAL TESTS*		
	TESTS	*SPECIFICATION*	*Results*
14.	Residual Solvents (In-House GC Method):		
	Benzene:	Not more than 2 ppm.	N.D
	Pyridine:	Not more than 200 ppm.	N.D.
	Methyl Alcohol:	Not more than 3000 ppm.	161 ppm
15.	Particle Size N.A	N.A	N.A
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 brasilinesis	Should be absent.	--
	Clostridium sporogenes	Should be absent.	--

Conclusion:

In the opinion of the undersigned the sample referred to above complies / ~~does not comply~~ with the requirement as per EP8/~~BP/USP/IP~~ and the In-House specification.

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