

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/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	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

Analysed by
(Q.C. Chemist)

Checked by
(Q.C. Incharge)

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 BY 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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16/11/14
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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 ₆ H ₇ N ₃ O. (By Titrimetry)	Not less than 98.0 % and not more than 102.0 % of C ₆ H ₇ N ₃ O. (By HPLC)	Not less than 98.0 % and not more than 101.0% of C ₆ H ₇ N ₃ O. (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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	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:		
	<i>Escherichia coli</i>	Should be absent.	--
	<i>Salmonella abony</i>	Should be absent.	--
	<i>Staphylococcus aureus</i>	Should be absent.	--
	<i>Pseudomonas aeruginosa</i>	Should be absent.	--
	<i>Candida albicans</i>	Should be absent.	--
	<i>Aspergillus brasiliensis</i>	Should be absent.	--
	<i>Clostridium sporogenes</i>	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.

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

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

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

FAGRON IBÉRICA, Q.A.U.
 Corresponde al lote de Fagron:

14L R-003
 Director Técnico