



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.

QUALITY CONTROL LABORATORY

The Drugs & Cosmetic Act 1940 & the rules thereunder

Format No. STP/QC/71/FM02

Name of Product: ISONIAZID

Batch No : 13228/INH

Mfg. Date : 05/08/2013

Exp. Date : 04/08/2017

Sample quantity : 50 gm

CERTIFICATE OF ANALYSIS

A.R. No : AC/INH/228/2013

Batch size : 1025 kgs

Date of Receipt : 08/08/2013

Date of Completion : 09/08/2013

Analysed as per : BP/EP/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 white, crystalline powder; odourless.
	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)

FAGRION IBÉRICA
Corresponde al lote de Fagron:

L14100165

Director Técnico S.

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