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

CERTIFICATE OF ANALYSIS

Name of Product : **ISONIAZID EP**
Batch No. : **12062 / INH**
Mfg. Date : **04 / 03 / 2012**
Exp. Date : **03 / 03 / 2015**
Sample quantity : **50 gm.**

A.R. No. : **AC / INH / 062 / 12**
Batch size : **1050 kgs**
Date of Receipt : **06 / 03 / 2011**
Date of Completion : **10 / 03 / 2011**
Analysed as per : **EP VII**

SR.No.	TEST	SPECIFICATION	RESULT
01	Characters	A white, crystalline powder or colourless crystals.	**A white, crystalline powder.**
02	Solubility	Freely soluble in water, sparingly soluble in alcohol slightly soluble in Chloroform & very slightly soluble in ether.	**Passes.**
03	Identification	(Test C omitted as test A&B carried out)	
	A- Melting point	170 °C to 174 ° C	**172. 2 °C**
	B- Infrared absorption Spectrum	Should be concordant with IR spectrum of Isoniazid CRS	**Complies.**
	C- Melting point of Derivative	226 °C to 231 ° C	--
04	Appearance of Solution	A solution is clear and not more intensely coloured than ref.soln.BY_7.	**Passes**
05	PH (5% w/v solution)	6.0 to 8.0	**6. 59**
06	Hydrazine &	Not more than 0.05 % w/w	**Less than 0. 05 % w/w**
	Related substances	Not more than 0.2 % w/w	**Less than 0. 2 % w/w**
07	Heavy Metals	Not more than 10 ppm	**Less than 10 ppm**
08	Loss on Drying	Not more than 0.5 % w/w	**0. 29 % w/w**
09	Sulphated ash	Not more than 0.1 % w/w	**0. 026 % w/w**
10	Assay (Chemical-Titrimetric)	99.0 to 101.0 % w/w on dried basis.	**99. 78 % w/w on dried basis**

Additional Test:-

1	Related substances (BY HPLC)		
	A-Isonicotinic Acid	Not more than 0.05%	**N.D.**
	B-Isonicotinamide	Not more than 0.10%	**N.D.**
	C-Nicotinoyl Hydrazide	Not more than 0.10%	**N.D.**
	D-Single Impuritics	Not more than 0.10%	**0.00004%.**
	E-Total Impurities	Not more than 0.2%	**0.00008%.**
2	Residual Solvents		
	(1) Methanol	Not more than 3000 ppm	**64.99 ppm**
	(2) Benzene	Not more than 2.0 ppm	**N.D.**
	(3) Pyridine	Not more than 200 ppm	**N.D.**

Report: In the opinion of the undersigned the sample referred to above is of standards quality as per EP VII.

Analysed by
(Q.C.Chemist)

Checked by
(Q.C.Incharge)

Approved by
(Q.A.Manager)

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:
12D10-603
Director Técnico