

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.**

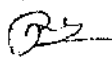
A.R. No. : **AC / INH / 062 / 12**
Batch size : **1050 kgs**
Date of Receipt : **06 / 03 / 2011**
Date of Completion : **10 / 03 / 2011**
Analysed as per : **EP VII**

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 & Related substances	Not more than 0.05 % w/w	Less than 0.05 % w/w
07	Heavy Metals	Not more than 0.2 % w/w	Less than 0.2 % w/w
08	Loss on Drying	Not more than 10 ppm	Less than 10 ppm
09	Sulphated ash	Not more than 0.5 % w/w	0.29 % w/w
10	Assay (Chemical-Titrimetric)	Not more than 0.1 % w/w 99.0 to 101.0 % w/w on dried basis.	0.026 % w/w 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 Impurities	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:
12D10-803

14-10-11 Director Técnico S.