

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.**

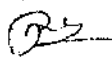
A.R. No. : **AC / INH / 062 / 12**
Batch size : **1050 kgs**
Date of Receipt : **06 / 03 / 2011**
Date of Completion : **10 / 03 / 2011**
Analysed as per : **EP VII**

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 B- Infrared absorption Spectrum C- Melting point of Derivative	172.2 °C Complies. --
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

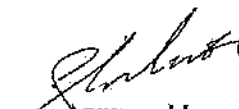
Additional Test:-

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