IAS-ANZ

ISO 9001-2008
Reg. No : RQ91/1030

ANSAL 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. : 09072 / INH
Mfg. Date : 09 / 08 / 2009
Exp. Date : 08 / 08 / 2014
Sample quantity : 50 gm.

A.R. No. : AC / INH / 072 / 2009-10
Batch size : 1000 kgs
Date of Receipt : 11 / 08 / 2009
Date of Completion : 11 / 08 / 2009
Analysed as per : EP VI

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 very slightly soluble in ether.	Passes.
03	Identification A- Melting point B- Infrared absorption Spectrum C- Melting point of Derivative	170 °C to 173 °C Should be concordant with IR spectrum of Isoniazid CRS 226 °C to 231 °C	172.8 °C complies. 227.7 °C
04	Appearance of Solution	A solution is clear and not more intensely coloured than ref.soln.BY6.	Passes
05	PH (5% w/v solution)	6.0 to 8.0	6.85
06	Hydrazine & Related substances	Not more than 0.05 % w/w Not more than 0.2 % w/w	Less than 0.05 % 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	0.25 % w/w
09	Sulphated ash	Not more than 0.1 % w/w	0.042 % w/w
10	Assay (Chemical-Titrimetric)	99.0 to 101.0 % w/w on dried basis.	99.60 % w/w on dried basis
	Additional Test:-		
01	As per ICH Guidelines Residual Solvent: Methanol	Not more than 3000 ppm	280.39 ppm

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

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:
09108-806
Director Técnico