

G. AMPHRAY LABORATORIES

E-mail : info@amphray.com

Sambava Chambers, 4th Floor, Sir P. M. Road, Mumbai – 400 001, INDIA.

Web : www.amphray.com

CERTIFICATE OF ANALYSIS

Name of Product	:	ISONIAZID USP	A.R. No.	:	INH/110/08
Batch No.	:	INH/06110	Batch Size	:	1000 Kgs.
Date of Manufacture	:	16/06/2008	Date of Receipt	:	16/06/2008
Date of Expiry	:	15/06/2013			

RESULTS OF ANALYSIS

TEST	SPECIFICATION	RESULT
CHARACTERS	A White, Crystalline Powder, or colourless crystalline.	A white, crystalline powder.
SOLUBILITY	Freely soluble in water, sparingly soluble in alcohol very slightly soluble in ether.	Passes.
IDENTIFICATION		
A.	Infrared Absorption.	
B.	The U. V. absorption spectrum of obtained exhibits maxima and minima only at the same wave lengths as that of a similar solution of USP Isoniazid RS.	Complies.
MELTING RANGE	170 ° C to 173 ° C.	171.7 ° C
pH (10 % w/v SOLUTION)	6.5 to 7.5	6.94
LOSS ON DRYING	Not more than 1 % w/w	0.18 % w/w
RESIDUE ON IGNITION	Not more than 0.2 % w/w	0.045 % w/w
HEAVY METALS	Not more than 20 ppm.	L. T. 20 ppm
ORGANIC VOLATILE IMPURITIES (METHANOL)	Meets the requirement as per USP.	Complies.
ASSAY	98 to 102 % w/w on dried basis.	99.42 % w/w on dried basis.

REPORT: IN THE OPINION OF THE UNDERSIGNED THE SAMPLE REFERRED TO ABOVE IS OF STANDARDS QUALITY AS PER USP 26.

Certified True Copy
For G. AMPHRAY LABORATORIES

AUTHORISED SIGNATORY

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CERTIFICATE OF ANALYSIS

Name of Product	:	ISONIAZID EP		
Batch No.	:	INH/06110	A.R. No.	: INH/110/08
Date of Manufacture	:	16/06/2008	Batch Size	: 1000 Kgs.
Date of Expiry	:	15/06/2013	Date of Receipt	: 16/06/2008

RESULTS OF ANALYSIS

TEST	SPECIFICATION	RESULT
CHARACTERS	A White, Crystalline Powder, or colourless crystals	A white crystalline powder.
SOLUBILITY	Freely soluble in water, sparingly soluble in alcohol very slightly soluble in ether.	Passes.
IDENTIFICATION A) MELTING POINT B) INFARRED ABSORPTION SPECTRUM C) MELTING POINT OF DERIVATIVE	170 °C to 174° C Should be Concordant with IR spectrum of Isoniazid CRS. 226° C to 231°C	171.7 °C 228.5 °C
APPEARANCE OF SOLUTION	Solution is clear and not more intensely coloured than ref. solution BY ₇	Passes
pH	6.0 to 8.0	6.94
HYDRAZINE & RELATED SUBSTANCES	Not more than 0.05 % w/w Not more than 0.20 % w/w	L.T. 0.05 % w/w L.T. 0.20 % w/w
HEAVY METALS	Not more than 10 ppm	L.T. 10 ppm
LOSS ON DRYING	Not More than 0.5% w/w	0.18 % w/w
SULPHATED ASH	Not more than 0.1%	0.045 % w/w
ASSAY (On Dried Basis)	99 to 101 % of Isonicotinoylhydrazine	99.42 % w/w on dried basis.
ADDITIONAL TEST ICH Guidelines Residual Solvent Methanol.	 NMT 3000 PPM.	 Less than 3000 ppm.

REPORT: IN THE OPINION OF THE UNDERSIGNED THE SAMPLE REFERRED TO ABOVE IS OF STANDARDS QUALITY AS PER EP V.

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CERTIFICATE OF ANALYSIS

Name of Product	:	ISONIAZID BP	A.R. No.	:	INH/110/08
Batch No.	:	INH/06110	Batch Size	:	1000 Kgs.
Date of Manufacture	:	16/06/2008	Date of Receipt	:	16/06/2008
Date of Expiry	:	15/06/2013			

RESULTS OF ANALYSIS

TEST	SPECIFICATION	RESULT
CHARACTERS	A White, Crystalline Powder, or colourless crystalline.	A white, crystalline powder.
SOLUBILITY	Freely soluble in water, sparingly soluble in alcohol very slightly soluble in ether.	Complies
IDENTIFICATION A) MELTING POINT B) INFARRED ABSORPTION SPECTRUM C) MELTING POINT OF DERIVATIVE	170 °C to 174° C Should be Concordant with IR spectrum of Isoniazid CRS. 226° C to 231°C	171.7 °C 228.5 °C
APPEARANCE OF SOLUTION	A solution is clear and not more intensely coloured than ref. solution BY ₇	Complies
pH (5 % w/v Solution)	6.5 to 8.0	6.94
HYDRAZINE & RELATED SUBSTANCES	Not more than 0.05% w/w Not more than 0.2% w/w	L.T. 0.05 % w/w L.T. 0.2 % w/w
HEAVY METALS	Not more than 10 ppm	L.T. 10 ppm
LOSS ON DRYING	Not More than 0.5% w/w	0.18 % w/w
SULPHATED ASH	Not more than 0.1%	0.045 % w/w
ASSAY [Chemical – Titrimetric]	99 to 101 % w/w on dried basis	99.42 % w/w on dried basis.

REPORT: IN THE OPINION OF THE UNDERSIGNED THE SAMPLE REFERRED TO ABOVE IS OF STANDARDS QUALITY AS PER BP 2000.

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