AMSAL CHEM PVT. LTD.
QUALITY CONTROL LABORATORY
The Drugs & Cosmetic Act 1940 & the rules thereunder
CERTIFICATE OF ANALYSIS

A-1 401, 402 & 403,
G.I.D.C. Industrial Estate,
Ankleshwar-393 002.
District : Bharuch, Gujarat, India.
CIN : U24231GJ1992PTC018289

METAPHARMACEUTICAL

N DE LOTE: 0190425

Format No : SOP/QC/111/FM01

Name of Product : **ISONIAZID EP**
Batch No : **25008/INH**
Mfg. Date : **09/01/2025**
Exp. Date : **08/01/2030**
Sample quantity : **50 gm**
CAS NO. : **54-85-3**

A.R. No : **AC/INH/008/2025**
Batch size : **2100.0 kgs**
Date of Sampling : **13/01/2025**
Date of Release : **16/02/2025**
Analysed as per : **EP 11.3 / In House**

Sr. No.	TEST	SPECIFICATION	RESULT
1.	Appearance	White or almost white, crystalline powder or colourless crystals.	Complies
2.	Solubility	Freely Soluble in water, sparingly soluble in ethanol (96%), practically insoluble in heptane.	Complies
3.	Identification	First identification: A, B Second identification: A, C	
	A. Melting point	170°C to 174°C	171.2°C
	B. Infrared absorption spectrophotometry	Should be concordant with IR spectrum of Isoniazid WS.	Complies
	C. Melting point of Derivative	226°C to 231°C	-
4.	Appearance of solution	5% w/v solution is clear and not more intensely coloured than reference solution BY_7.	Complies
5.	pH	The pH of a 5% W/V solution is 6.0 to 8.0	7.28
6.	Impurity E by HPLC	Not more than 15 ppm.	2.14 ppm
7.	Loss on Drying	Not more than 0.5%	0.24 %
8.	Sulfated ash	Not more than 0.1%	0.03 %
9.	Assay by (Titrimetric)	99.0% to 101.0% (dried substance)	99.8 %
ADDITIONAL TEST			
10.	Related substances by HPLC (In-House Method)		
	Isonicotinic Acid	Not more than 0.05%	0.01 %
	Isonicotinamide	Not more than 0.10%	0.01 %
	Nicotinoyl Hydrazide	Not more than 0.10%	ND
	Diisonicotinoyl Hydrazine	Not more than 0.10%	0.01 %
	2-Isoniazid	Not more than 0.10%	ND
	4-CYanopyridine	Not more than 0.10%	ND
	Benzoyl Hydrazine	Not more than 0.10%	ND
	Single Maximum Unknown Impurity.	Not more than 0.10%	0.01 %
	Total Impurities	Not more than 0.20%	0.05 %
11.	Residual Solvents (In-House GC Method)		
	Methanol	Not more than 3000 ppm.	263 ppm
	Benzene	Not more than 2 ppm.	ND
	Pyridine	Not more than 200 ppm.	ND

20/03/2025
Analysed by
(QC Officer)
(Sagar Modi)

20/03/2025
Checked by
(Asst. QC Manager)
(A.R. Rajput)

20/03/2025
Approved by
(Asst. QA Manager)
(Anil Patel)

AMSAL CHEM PVT. LTD.
QUALITY CONTROL LABORATORY
The Drugs & Cosmetic Act 1940 & the rules thereunder
CERTIFICATE OF ANALYSIS

A-1 401, 402 & 403,
G.I.D.C. Industrial Estate,
Ankleshwar-393 002.
District : Bharuch, Gujarat, India.
CIN : U24231GJ1992PTCO18289

Format No : SOP/QC/111/FM01

Name of Product : **ISONIAZID EP** A.R. No : **AC/INH/008/2025**

Sr. No.	TEST	SPECIFICATION	RESULT
12.	**Particle Size (by Sieve analysis)**		
	NA	NA	NA
13.	**Microbiological Analysis**		
	Total viable Aerobic count		
	a) Total Bacterial count	Not more Than 1000 CFU/gm	-
	b) Total Fungal Count (Yeasts +Moulds)	Not more than 100 CFU/gm	-
	Pathogens:		
	Escherichia coli	Should be absent.	-
	Salmonella abony	Should be absent.	-
	Staphylococcus aureus	Should be absent.	-
	Pseudiomonas aeruginosa	Should be absent.	-
	Candida albicans	Should be absent.	-
	Aspergillus brasiliensis	Should be absent.	-
	Clostridium sporogenes	Should be absent.	-
	Shigella boydii	Should be absent.	-
14.*	**Metal impurities**		
	Molybdenum (Mo)	Not more than 150 ppm	-
	Nickel (Ni)	Not more than 2.0 ppm	-
	Chromium (Cr)	Not more than 110 ppm	-
	Vanadium (V)	Not more than 1.0 ppm	-
15.*	**Acetaldehyde Content By GC**	Not more than 0.1 %	-

Report:

In the opinion of the undersigned the sample referred to above complies / ~~does not comply~~ with the requirement as per EP 11.3 and the In-House specification.

* Test No.14 Metal impurities 'Skip test' and Test No.15 Acetaldehyde Content 'Skip test '.

Remark: This batch COA is reprint on 20/03/2025.

Modi 20/03/2025
Analysed by
(QC Officer)
(Sagar Modi)

20/03/2025
Checked by
(Asst. QC Manager)
(A.R. Rajput)

20/03/2025
Approved by
(Asst. QA Manager)
(Anil Patel)