



## Specification

Concerning Product:	
Article number	54853NPEUI
Trade name / designation / denomination	Isoniazid, EP/USP/IP
CAS number	54-85-3
Other names / synonyms	•4-pyridinecarbohydrazide; •Hidranizil / Isoniazid / Isonicotinic acid hydrazide; •Isonicotinohydrazide; •Pyridin-4-carbonsäurehydrazid; •isoniazid;
EC number	200-214-6
Customs tariff number / CN code / TARIC	29333999
Molecular weight [g / mol]	137,14
Formula	C <sub>6</sub> H <sub>7</sub> N <sub>3</sub> O
<b>Warning</b>	
Harmful if swallowed. Do not get in eyes, on skin, or on clothing.	

Parameter	Test Method	Specification	Unit
<b>Organoleptic test</b>			
Appearance of solution	EP/BP, IP	A 5 % w/v solution is clear and not more intensely colored than reference Solution BY <sub>7</sub> .	
Colour	EP/BP, USP, IP	colorless, white or almost white	
Odour	USP	odourless	
<b>Physical parameter</b>			
Form	EP/BP, USP, IP	crystalline powder or crystals	
Loss on drying	IP	≤ 1,0	%
Loss on drying	EP/BP, IP	≤ 0,50	%
pH value	USP	(10% w/v): 6,0 – 7,5	
pH value	EP/BP, IP	(5 % w/v): 6,0 – 8,0	
Solubility	USP, IP	in Chloroform: slightly soluble	
Solubility	EP/BP, USP, IP	in ethanol (96%): sparingly soluble	
Solubility	USP, IP	in Ether: very slightly soluble	
Solubility	EP/BP, USP, IP	in water: easily soluble	
<b>Identity</b>			
Assay	IP (HPLC)	98,0 – 101,0	%
Assay	USP (HPLC)	98,0 – 102,0	%
Assay	EP/BP (Titrimetry)	99,0 – 101,0	%
Identification	USP (HPLC)	Ident. (D): The retention time of the Isoniazid peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.	
Infrared absorption spectrometry	EP/BP, IP	Ident. (B): Should be concordant with IR spectrum of Isoniazid CRS/RS	
Melting Point (identity)	EP/BP, IP	Ident. (A): 170 – 174	°C
Melting Point (identity)	EP/BP, IP	Ident. (C) of Derivative: 226 – 231	°C
<b>Impurities</b>			
Residue on ignition	USP	≤ 0,20	%
Heavy Metals (as Pb)	USP, IP	≤ 20	ppm
Sulphated ash	EP/BP, IP	≤ 0,10	%
Impurity	EP/BP (HPLC)	(E): ≤ 15	ppm
Impurity	IP (HPLC)	any individual: ≤ 0,20	%

Impurity	EP/BP, USP, In-house (HPLC)	any other / unspecified impurities: $\leq 0,10$	%
Impurity	In-house (HPLC)	total impurities: $\leq 0,20$	%
Impurity	USP (HPLC)	total impurities: $\leq 2,0$	%
Impurity	EP/BP (HPLC)	total impurities: $\leq 0,50$	%
Impurity	IP (HPLC)	total impurities: $\leq 1,0$	%
Related substances	EP/BP (HPLC)	(A) Isonicotinic Acid: $\leq 0,15$	%
Related substances	EP/BP (HPLC)	(B) Isonicotinamide: $\leq 0,15$	%
Related substances	In-house (HPLC)	2-Isoniacid $\leq 0,10$	%
Related substances	In-house (HPLC)	4-Cyanopyridine	%
Related substances	IP (TLC)	any other single: $\leq 0,05$	%
Related substances	In-house (HPLC)	Benzoyl Hydrazine	%
Related substances	In-house (HPLC)	Diisonicotinol Hydrazide $\leq 0,10$	%
Related substances	USP (HPLC)	Isoniacin: $\leq 0,10$	%
Related substances	USP, In-house (HPLC)	Isonicotinamide: $\leq 0,10$	%
Related substances	In-house (HPLC)	Isonicotinic Acid: $\leq 0,05$	%
Related substances	USP (HPLC)	Isonicotinonitrile: $\leq 0,10$	%
Related substances	In-house (HPLC)	Nicotinoyl Hydracide: $\leq 0,10$	%
Related substances	USP (HPLC)	Picolinohydracin: $\leq 0,10$	%
<b>Residual Solvents</b>			
Residual solvents	In-house (GC)	Benzene: $\leq 2$	ppm
Residual solvents	In-house (GC)	Methanol: $\leq 3000$	ppm
Residual solvents	In-house (GC)	Pyridine: $\leq 200$	ppm
<b>Elemental Impurities</b>			
Chromium (Cr)		$\leq 3$	ppm
Molybdenum (Mo)		$\leq 3$	ppm
Nickel (Ni)		$\leq 3$	ppm
Vanadium (V)		$\leq 3$	ppm
<b>Microbiological data</b>			
Aerobic microorganisms		1000	CFU/g
Aspergillus brasiliensis		neg.	
Candida albicans		neg.	
Clostridium sporogenes		neg.	
Escherichia Coli.		neg.	
Pseudomonas aeruginosa		neg.	
Salmonella		neg.	
Yeast and Mould		$\leq 100$	CFU/g

#### **Supplemental information:**

**Shelf life:** 5 years

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 24. Aug. 2021

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