



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Nicotinic Acid (Ph. Eur., USP) pure, pharma grade		Issue Date	March-23
Product Code	A0963		Prepared by	Sr. Tech Lead
CAS NO.	59-67-6		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A0963/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies Ph. Eur., USP</i>	<i>USP 2022</i>	<i>EP Version 11.0</i>	<i>JP 18</i>
1	Description	Solid	White crystals or crystalline powder. Is odorless, or has a slight odor. Melts at about 235°C	White or almost white, crystalline powder	White, crystals or crystalline powder. It is odorless, and has a slightly acid taste.
2	Solubility	Not mentioned	Freely soluble in boiling water, in boiling alcohol, and in solutions of alkali hydroxides and carbonates; sparingly soluble in water; practically insoluble in ether.	Sparingly soluble in water, soluble in boiling water and in boiling ethanol (96 %). It dissolves in dilute solutions of alkali hydroxides and carbonates.	Sparingly soluble in water, slightly soluble in ethanol (95), and very slightly soluble in diethyl ether. It dissolves in NaOH and in sodium carbonate
3	Identification 1	Passes the test	In the assay test, the retention time of the major peak of the Sample solution corresponds to that of the Standard solution	Melting point should be between 234 °C and 240 °C	A dark red color should be produced
4	Identification 2	Passes the test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Nicotinic acid reference standard/working standard.	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Nicotinic acid reference standard/working standard.	UV absorption spectrum obtained with sample should exhibit maxima at the same wavelength as standard
5	Identification 3	Passes the test	UV visible spectrum obtained with sample should show maxima at 263 nm and minima at 239 nm, the ratio of minima to maxima should be between 0.46 and 0.52	UV visible spectrum obtained with sample should show maxima at 262 nm and minima at 237 nm, the ratio of minima to maxima should be between 0.46 and 0.50	Not mentioned
6	Clarity and color of solution	Not mentioned	Not mentioned	Not mentioned	Sample solution should be clear and colorless
7	Melting Range or temperature	Not mentioned	Not mentioned	Not mentioned	Between 234 and 238°C
8	Chlorides	NMT 0.02%	NMT 0.02%	NMT 200 ppm	NMT 0.021%
9	Sulfate	NMT 0.02%	NMT 0.02%	Not mentioned	NMT 0.019%
10	Heavy metals	NA	Not mentioned	Not mentioned	NMT 20 ppm
11	Nitro compounds	Not mentioned	Not mentioned	Not mentioned	Sample solution should not be more intensely colored than matching fluid A
12	pH	Not mentioned	Not mentioned	Not mentioned	Between 3.0 and 4.0

13	Related Compounds	Isocinchomeric acid: NMT 0.05% 6-Hydroxynicotinic acid: NMT 0.05% Isonicotinic acid: NMT 0.05% 6-Methylnicotinic acid: NMT 0.05% 6,6'-Dinicotinic acid: NMT 0.05% 5-Nitronicotinic acid: NMT 0.05% Pyridine: NMT 0.05% 3-Nitropyridine: NMT 0.05% 3,5-Dinitropyridine: NMT 0.05% 3-Ethylpyridine: NMT 0.05% 5-Ethyl-2-methylpyridine: NMT 0.05% Maximum individual unknown impurity: NMT 0.05% Total impurities: NMT 0.20%	Isocinchomeric acid: NMT 0.05% 6-Hydroxynicotinic acid: NMT 0.05% Isonicotinic acid: NMT 0.05% 6-Methylnicotinic acid: NMT 0.05% 6,6'-Dinicotinic acid: NMT 0.05% 5-Nitronicotinic acid: NMT 0.05% Pyridine: NMT 0.05% 3-Nitropyridine: NMT 0.05% 3,5-Dinitropyridine: NMT 0.05% 3-Ethylpyridine: NMT 0.05% 5-Ethyl-2-methylpyridine: NMT 0.05% Maximum individual unknown impurity: NMT 0.05% Total impurities: NMT 0.20%	Maximum individual impurity : NMT 0.05% Total impurities: NMT 0.05%	Not mentioned
14	Sulfated Ash	NMT 0.1%	Not mentioned	NMT 0.1%	Not mentioned
15	Residue on Ignition	Not mentioned	NMT 0.1%	Not mentioned	NMT 0.1%
16	Loss on Drying	NMT 1.0%	NMT 1.0%	NMT 1.0%	NMT 0.5%
17	Assay (dried basis)	Between 98.0% and 102.0% (by HPLC) Between 99.5% and 100.5% (By titrimetry)	Between 98.0% and 102.0%	Between 99.5% and 100.5%	NLT 99.5%
	Storage condition	Keep container tightly sealed at room Temperature	Preserve in well-closed containers	Protected from light	Containers—Well-closed containers
Note - If you need any additional testing, you may use our Additional Testing Feature on the product page or contact your Clyzo representative.					
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