Productos Químicos Gonmisol S.A.
T: (+34) 93 313 61 18
Av. Diagonal, 458 3º 1ª
08006, Barcelona, Spain
info@gonmisol.com
https://gonmisol.suannutra.com/

Certificate of analysis

Certificado de análisis

NICOTINIC ACID
BP USP

Batch	Manufacturer	Manufactured	Expiration
24-25/NCN[P]/00055	37WDRX	01/05/2024	30/04/2029

BP2023		
Appearance	White or almost white crystalline powder	White crystalline powder
Solubility	Sparingly soluble in water, soluble in boiling water and in boiling ethanol (96%) and in dilute solution of alkali hydroxides and carbonates	Complies
Identification		
- Melting point	234º to 240 ºC	236.3ºC
- IR Test	IR Spectrum to match with Reference standard no.2	Matches
Related Substance (by HPLC)	Any individual impurity ≤0.05%	Any individual impurity =0.03%
Related Substance (by HPLC)	Total impurity ≤0.05%	Total impurity =0.03%
Loss on Drying	≤1.0% w/w	0.20% w/w
Sulphated Ash/Residue on Ignition	≤0.1% w/w	0.03% w/w
Chloride	≤200 PPM	<200 PPM
Assay (On Dried Basis)		
- Aqueous Titration	99.5 to 100.5%w/w	99.84% w/w
Special Requirement		
Heavy Metals:		
Lead	Less than 3 mg/kg	*<3 mg/kg
Arsenic	Less than 1 mg/kg	*<1 mg/kg
Cadmium	Less than 1 mg/kg	*<1 mg/kg
Mercury	Less than 0.1 mg/kg	*<0.1 mg/kg
Microbiological Limit Test:		

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a) Total Plate Count	<10,000 cfu/gram	<30 cfu/gram
b) Yeast / Moulds	<100 cfu/gram	<10 cfu/gram
c) Salmonella	Absent/10 gram	Absent/10 gram
d) Enterobactgeriaceaes	Absent/gram	Absent/gram
e) Staphylococcus aureus	Absent/gram	Absent/gram
f) E.coli	Absent/gram	Absent/gram
Heavy Metals	≤ 20 PPM	<20 PPM
USP-NF 2023		
Appearance	White crystals and crystalline powder	White crystalline powder
Identification		
- UV Test - Ratio A239 to A263 nm	0.46 to 0.52	0.483
- IR Test	IR spectrum to match with Refernce standard No. 2	Matches
- By HPLC-RT of major peaks in sample and standart	RT of the sample & standard solution corresponds in major peaks	Complies
Related Substance (By HPLC)	Any individual impurity ≤0.05%	Any individual impurity =0.03%
Related Substance (By HPLC)	Total impurity ≤0.20%	Total impurity =0.03%
Loss on Drying	≤1.0% w/w	0.20% w/w
Sulphated Ash/Residue on Ignition	≤0.1% w/w	<0.03%w/w
Chloride	≤ 0.02%	<0.02%
Sulphate	≤ 0.02%	<0.02%
Assay (On Dried Basis)		

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- HPLC Method	98.0 to 102.0% w/w	100.50% w/w

Note: *Based on testing at regular interval.

Report: Certified that the material referred above confirms to the following specifications:
1.- Manufacturing specifications of WDL.
2.- BP 2023 for Niacin (Nicotinic Acid)
3.- USP-NF 2023 for Niacin