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AMINATURE
AMINO ACID, DELIVERY FROM NATURE

CERTIFICATE OF ANALYSIS

Product name : L-Isoleucine
Production date : 2019.01.12; 2019.02.13; 2019.02.21
Expiry : 2 (two) years
Lot No. : IKAF190112, IKAF190213, IKAF 190221
Quantity : 5 MT
Reference no. : 1000683667
Country of Origin : Ningbo, China

1. Product Information

White crystals or crystalline powder, Odorless, Slightly bitter taste.
Freely soluble in formic acid, Sparingly soluble in water, very slightly soluble in ethanol or in ether.
Dissolves in dilute hydrochloric acid.

2. Specification

Items		Limit	Result	Test Method
Appearance		White or almost white, crystal	conform	/
Assay		98.5% - 101.5%	100.50%	USP 39 <541>
pH		5.5 ~ 7.0	6.79	USP 39 <791>
Identification		Infrared absorption spectrum	conform	USP39<197k>
Specific Test	Specific Rotation	+38.9° - +41.8°	+39.90°	USP 39 <781S>
	Loss on Drying	Not more than 0.3%	0.16%	USP 39 <731>
Inorganic Impurities	Residue on Ignition	Not more than 0.3%	0.04%	USP 39 <281>
	Chloride	Not more than 0.05%	< 0.05%	USP 39 <221>
	Sulfate	Not more than 0.03%	<0.03%	USP 39 <221>
	Ammonium	Not more than 0.02%	< 0.02%	AJI
	Heavy metals	Not more than 15 ppm	< 10ppm	USP 39 <231>
	Lead	Not more than 1 ppm	< 1 ppm	USP 39 <233>
	Arsenic	Not more than 1 ppm	< 1 ppm	USP 39 <233>
	Cadmium	Not more than 1 ppm	< 1 ppm	USP 39 <233>
	Mercury	Not more than 0.1 ppm	<0.1 ppm	USP 39 <261>
	Iron	Not more than 30 ppm	<10 ppm	USP 39 <241>
Related compounds		Any unspecified impurity NMT0.5% Total unspecified impurities NMT 2.0%	<0.5% <2.0%	USP 39 <621>
Microbiology	Total viable count	Not more than 1000 cfu/g	< 1000 cfu/g	USP 39 <2021>
	Yeast & mould	Not more than 100 cfu/g	<100 cfu/g	USP 39 <2021>
	Enterobacteriaceae	Negative/25g	Negative	USP 39 <2021>
	Coliforms bacteria	Negative/g	Negative	USP 39 <2022>
	<i>Escherichia coli</i>	Negative/g	Negative	USP 39 <2022>
	<i>Salmonella sp.</i>	Negative/10g	Negative	USP 39 <2022>
	<i>Staphylococcus aureus</i>	Negative/g	Negative	USP 39 <2022>

This product meets quality requirements of current USP , AJI monograph.

3. Storage Conditions & Shelf life

L-Isoleucine is recommended to store in dry conditions and fresh place in sealed or closed container that is to be protected from water, sunlight and heat. Avoid direct contact with floor and any source of combustion.

Shelf life: We recommend the usage within 2 years.