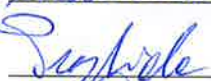


Prodotto:
L-SERINA EP/USP 25 KG BAGN° Codice:
10000046026

Pag: 1 di: 1

AUTORIZZAZIONI

	<i>nome</i>	<i>funzione</i>	<i>firma</i>	<i>data</i>
Compilato da:	N. Cesarini	CQC Analyst		02/06/2024
Verificato da:	G. Pragliola	CQC Spv		02/06/2024
	L. Piccolo	QC Manager		02-06-24
	M. Evangelista	QA Training & Supplier Qualification Specialist		03-06-24
Approvato da:	V. Marotta	Quality Manager		08 APR 24

Valido dal: 30/01/2024

Data e firma: 30/01/2024 

Change control n°:	CC/23/015	Descrizione:	Introduzione nuovo spettrofotometro FT-IR
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Il prodotto viene accettato sulla base del Certificato di analisi (CoA) del fornitore (vedi certificato allegato), dopo aver verificato la conformità della “Descrizione” ed effettuato il test di “Identificazione”

Fonti	Olon Spa - Stabilimento di Capua
Formula bruta	$C_3H_7NO_3$
Peso molecolare	105.1
Numero di CAS	56-45-1

Test	Riferimento	Specifiche
Descrizione	IL-MA-0192	Polvere bianca cristallina
Identificazione (IR)	E_WI CPU CQC 00047	Positiva

**SHANGHAI KYOWA AMINO ACID CO.,LTD.**

No. 158 Xintuan Road, Qingpu Industrial Zone, Shanghai 201707 China
Phone: 86-21-5970-1998 Fax: 86-21-5970-1135

CERTIFICATE OF ANALYSIS

Commodity: L-SERINE
Lot No.: 20090903
Manufacturing date: Sep-26-2020
Analysis date: Oct-27-2020
Retest date: Sep-26-2023

SPECIFICATION	ACCEPTANCE CRITERIA	RESULT
APPEARANCE	WHITE CRYSTALS OR CRYSTALLINE POWDER	WHITE CRYSTALS
IDENTIFICATION (IR)	PASS TEST	PASS TEST
STATE OF SOLUTION	COLORLESS AND CLEAR	COLORLESS AND CLEAR
STATE OF SOLUTION (T%)	NOT LESS THAN 98.0%	100.0%
pH	5.2 ~ 6.2	5.8
SPECIFIC ROTATION (AT 20°C)	+14.4 ~ +15.5°	+15.3°
SPECIFIC ROTATION (AT 25°C)	+14.0 ~ +15.6°	+14.9°
AMMONIUM (NH ₄)	NOT MORE THAN 0.020%	NOT MORE THAN 0.020%
CHLORIDE (Cl)	NOT MORE THAN 0.020%	NOT MORE THAN 0.020%
SULFATE (SO ₄)	NOT MORE THAN 0.020%	NOT MORE THAN 0.020%
IRON (Fe)	NOT MORE THAN 10ppm	NOT MORE THAN 10ppm
HEAVY METALS (as Pb)	NOT MORE THAN 5ppm	NOT MORE THAN 5ppm
ARSENIC (As ₂ O ₃)	NOT MORE THAN 1ppm	NOT MORE THAN 1ppm
LOSS ON DRYING	NOT MORE THAN 0.20%	0.03%
RESIDUE ON IGNITION	NOT MORE THAN 0.10%	0.00%
RELATED SUBSTANCES		
UNSPECIFIED IMPURITY	NOT MORE THAN 0.2%	NOT DETECTED
TOTAL IMPURITIES	NOT MORE THAN 0.5%	NOT DETECTED
ASSAY (DRY BASIS)	99.0 ~ 101.0%	99.7%
TOTAL AEROBIC MICROBIAL COUNT	NOT MORE THAN 100 CFU/g	NOT MORE THAN 100 CFU / g
TOTAL YEASTS AND MOULDS COUNT	NOT MORE THAN 10 CFU/g	NOT MORE THAN 10 CFU / g
E.COLI	NEGATIVE/g	NEGATIVE/g
ENDOTOXIN	LESS THAN 3.0EU/g	LESS THAN 3.0EU/g

THIS SPECIFICATION MEETS THE CURRENT CP, JP, USP AND EP PRODUCT MONOGRAPHS AND THE CURRENT RESIDUAL SOLVENTS REQUIREMENT AS PER USP AND EP.
NO ANIMAL ORIGIN RAW MATERIALS/ADDITIVES ARE USED THROUGHOUT THE MANUFACTURING PROCESS.

MADE IN CHINA.

The undersigned affirms that contents mentioned above are truly reported in accordance with the analysis by Quality Control Department.

Lu Yazhou

Date of issue: Dec-07-2020

QA Manager