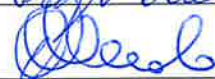


 olon	SPECIFICHE ANALITICHE		N°: MP-SP-0956 Revisione: 1
	Prodotto: L-ASPARAGINA MONOIDRATO AJI92 25KG BAG L-ASPARAGINA MONO. EMPROVE 10 KG BAG	N° Codice: 10000046259 818008	Pag: 1 di : 1

AUTORIZZAZIONI

	nome	funzione	firma	data
Compilato da:	N. Cesarini	CQC Analyst		02/03/2024
Verificato da:	G. Pragliola	CQC Supervisor		01/03/2024
	L. Piccolo	QC Manager		01-03-24
	M. Evangelista	QA Training & Supplier Qualification Specialist		04/03/2024
Approvato da:	V. Marotta	Quality Manager		04 Mar 24

Valido dal: 07/03/2024	Data e firma: 07/03/2024 
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Change control n°:	CH20240219/0001	Descrizione:	Introduzione fornitore alternativo
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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	$C_4H_8N_2O_3 \cdot H_2O$
Peso molecolare	150.14
Numero di CAS	7594-13-8

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

SI AGGIUNGE CoA NUOVO FORNITORE FLAMMASPA 

SI AGGIUNGE CoA FORNITORE H&B&L

SI AGGIUNGE CoA KERR. Agalabs  30/07/25

CONFIDENTIAL

CERTIFICATE OF ANALYSIS

L-ASPARAGINE MONOHYDRATE F. (2S)-2,4-diamino-4-oxobutanoic acid;hydrate (1:1)

BATCH:	0021004063	QUANTITY:	325 KG
MANUFACTURING SITE:	CHIGNOLO D'ISOLA		
MANUFACTURING DATE:	01/16/2022	RETEST DATE:	12/21/2026
CODE MATERIAL:	3102001700	REF.:	FCC/EP
ANALYSIS REF. NO.:	040000014155	SPEC.REV.:	20
CAS NO. :	5794-13-8		

<u>TESTS</u>	<u>SPECIFICATIONS</u>	<u>UM</u>	<u>RESULTS</u>	<u>ANALYTICAL METHOD</u> <u>REFERENCES</u>
Aspect	Crystalline powder		Crystalline Powder	
Colour	White		White	
Identification (First)	Must comply		Complies	EP
Solubility (2% w/v)	Complete		Complete	EP
Solution Appearance	Clear and colourless		Clear and colourless	EP
pH (2% w/v)	4.0 - 6.0		5.2	EP
S.O.R. (10% w/v HCl 6N)	33.0 - 36.5	°	34.4	FCC
S.O.R. (10% w/v HCl 3N)	33.7 - 36.0	°	34.4	EP
Loss On Drying (130°C)	11.5 - 12.5	%	11.9	FCC/EP
Assay (HClO ₄ , Potentiometric)	99.0 - 101.0	% d.b.	99.8	EP
Chlorides	≤ 200	ppm	< 200	
Sulphates	≤ 200	ppm	< 200	
Ammonium	≤ 500	ppm	< 500	
Sulphated Ash	≤ 0.1	%	0.1	FCC/EP
Impurity A (HPLC)	≤ 0.5	% W/W	0.0	EP
Impurity C (HPLC)	≤ 0.1	% W/W	0.0	EP
Each Unspecified Impurity (HPLC)	≤ 0.05	% W/W	< 0.03	EP
Total Impurities (HPLC)	≤ 0.8	% W/W	0.0	EP

Note:

test N°883-885-1032 : <0.03%

Electronically signed by:

Chiara Galimberti
 Quality Control
 04/28/2022 - APPROVED

Laura Zappa
 Quality Assurance
 05/05/2022 - APPROVED

Printed on 12/17/2024
 Document date format: mm/dd/yyyy

OLON S.P.A. / P.O. 202413757

ALL. MRSP-0956
20/07/25



河北昌昊生物科技有限公司
HEBEI CHANGHAO BIOTECHNOLOGY CO., LTD

ADD: EAST OF YUELIANG VILLAGE, JIZHOU TOWN, JIZHOU DISTRICT, HENGSHUI CITY, HEBEI PROVINCE, CHINA
PHONE: +86-318-8696119 FAX: +86-318-8696118

分 析 报 告

CERTIFICATE OF ANALYSIS

产品名称: L-天门冬酰胺 Product Name: L-Asparagine Monohydrate	数量: Quantity: 325kg	批号: Batch No.: 20250511
参考标准: Reference standard: AJI92	产品包装: Packing: 25KG/袋	生产日期: Sampling date: 2025.05.11
取样日期: Sampling date: 2025.05.12	报告日期: Send out date: 2025.03.01	有效期: Expiry date: 2027.05.10

检测项目 Items	标准 Standard	检测结果 Result
货物描述 Description	白色结晶或结晶性粉末 White crystals or crystalline powder	合格 Conforms
旋光度 Specific rotation	+34.3° ~ +36.5°	+35.4°
溶液颜色(透光率), % State of solution (transmittance), %	透明无色 Clear and colorless: ≥98.0	99.0
氯化物 Chloride, %	≤0.02	<0.02
硫酸盐 Sulfate, %	≤0.02	<0.02
铁盐 Iron, %	≤10ppm	<10ppm
重金属 Heavy metals, %	≤10ppm	<10ppm
其他氨基酸 Other amino acids, %	conforms	conforms
干燥失重 Loss on drying, %	11.5~12.5	12.0
炽灼残渣 Residue on ignition, %	≤0.1	0.06
含量 Assay, %	99.0~101.0	99.8
铵盐 Ammonium (NH ₄), %	≤0.10	<0.10
砷盐 Arsenic, %	≤1ppm	<1ppm
酸度 PH	4.4~6.4	4.50
结论: 产品符合参考标准 AJI92. Conclusion: The goods conforms to reference standard of AJI92.		

检验员: 丁春红
Inspector: Ding Chunhong

复核人: 朱琳琳
Checker: Zhu Linlin

批准人: 王树丽
Director: Wang Shuli

All to #4 HP-SP-0956_R01
COB 818008
Oja (12 h 00)



Certificate of Analysis

1.01565.9010 L-Asparagine monohydrate EMPROVE® EXPERT Ph Eur,NF
Batch K55326165

	Spec. Values		Batch Values	
Assay (perchloric acid titration, calculated on dried substance)	99.0 - 101.0	%	99.6	%
Assay (HPLC, calculated on dried substance)	95.5 - 102.0	%	99.7	%
Identity (IR-spectrum)	passes test		passes test	
Identity (specific rotation)	passes test		passes test	
Identity (HPLC)	passes test		passes test	
Identity (loss on drying)	passes test		passes test	
Appearance	white to almost white crystalline powder or colorless crystals		passes test	
Appearance of solution (20 g/l, CO ₂ -free water)	clear and not more intense in color than reference solution B ₉		passes test	
pH (20 g/l, CO ₂ -free water)	4.0 - 6.0		5.4	
Spec. rotation (α 20/D, 100 g/l, hydrochloric acid 3 mol/l, calc. on dried substance)	+33.7 to +36.0	*	+35.1	*
Spec. rotation (α 20/D, 10 g/l, hydrochloric acid 6 mol/l, calc. on dried substance)	+33.0 to +36.5	*	+34.8	*
Chloride (Cl)	≤ 200	ppm	≤ 200	ppm
Sulfate (SO ₄)	≤ 200	ppm	≤ 200	ppm
Fe (Iron)	≤ 10	ppm	≤ 10	ppm
Pb (Lead)	≤ 5	ppm	≤ 5	ppm
NH ₄ (Ammonium)	≤ 0.1	%	≤ 0.1	%
Related substances (HPLC) (impurity A)	≤ 0.5	%	≤ 0.5	%
Related substances (HPLC) (impurity C)	≤ 0.1	%	≤ 0.1	%
Related substances (HPLC) (any unspecified impurity)	≤ 0.05	%	≤ 0.05	%
Related substances (HPLC) (total impurities)	≤ 0.8	%	≤ 0.8	%
Organic Impurities (HPLC) (Asparagine related compound A (2,2'-(3,6-Dioxopiperazine-2,5-diyl) diacetamide))	≤ 1.0	%	≤ 1.0	%
Organic Impurities (HPLC) (Aspartic acid)	≤ 1.0	%	≤ 1.0	%
Organic Impurities (HPLC) (any unspecified impurity)	≤ 0.5	%	≤ 0.5	%
Organic Impurities (HPLC) (total impurities)	≤ 3.0	%	≤ 3.0	%
Ethanol (HS-GC)	≤ 5000	ppm	< 500	ppm
Other residual solvents (ICH Q3C)	excluded by manufacturing process		excluded by manufacturing process	
Sulfated ash (600 °C)	≤ 0.1	%	< 0.1	%
Loss on drying (130 °C, 3 h)	11.5 - 12.5	%	12.0	%
Bacterial endotoxins	≤ 3.0	I.U./g	≤ 3.0	I.U./g

Certificate of Analysis

1.01565.9010 L-Asparagine monohydrate EMPROVE® EXPERT Ph Eur,NF
Batch K55326165

Microbiological test (total aerobic microbial count (TAMC))	$\leq 10^2$	CFU/g	$\leq 10^2$	CFU/g
Microbiological test (total yeast and mould count (TYMC))	$\leq 10^2$	CFU/g	$\leq 10^2$	CFU/g

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (*).
Corresponds to Ph. Eur., NF

Date of manufacture (DD.MM.YYYY) 10.03.2022
Date of examination (DD.MM.YYYY) 04.07.2023
Minimum shelf life (DD.MM.YYYY) 31.03.2027

Dr. Michael Memmel
Responsible laboratory manager quality control

This document has been produced electronically and is valid without a signature.

AVVERTENZA 18-SP 0956/1

CD 1000006259

per 01/03/2024



Prodotto	L-ASPARAGINA MONOIDRATA AJI92 (NO A.P.I)
Codice	156200
Lotto	20200723 / 2017187001
Data di produzione 23/07/2020	Data scadenza/Retest 22/07/2022

	SPECIFICHE	RISULTATO
Aspetto	Polvere cristallina bianca	Polvere cristallina bianca
Potere rotatorio (°)	34,2 - 36,5	35,2
Trasmittanza(%)	98,0 min.	99,0
Ammonio (%)	0,1 max.	<0,1
Metalli pesanti(Pb)(ppm)	10 max.	<10
Arsenico(ppm)	1 max.	<1
Ferro(ppm)	10 max.	<5
Solfati(%)	0,02 max.	<0,01
Cloruri(%)	0,02 max.	<0,02
Altri aminoacidi	Conforme	Conforme
Perdita all'essiccamento(%)	11,5 - 12,5	11,98
Residuo alla calcinazione(%)	0,10 max.	0,07
Titolo(%)	99,0-101,0	99,56
pH	4,4 - 6,4	4,6
Il prodotto è conforme a	AJI92	AJI92
VALIDITA' (RE-TEST)	2 anni	2 anni

Data 04/11/2020
Codice 156200
Lotto 20200723 / 2017187001

Versione 00 del 04/11/2020

Il presente documento e' una trascrizione delle informazioni contenute nel documento rilasciato dal nostro fornitore, soggetta a controlli di natura informatica e doppio controllo da parte di operatori Faravelli. Poiche' Faravelli non e' responsabile per gli usi finali del prodotto, la rispondenza dello stesso alla normativa vigente e' responsabilita' del cliente destinatario.

Pagina 1/1 -



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Codice Distributore Far. Exter M202AN01
Soggetta a direzione e coordinamento da parte di Faravelli Holding Srl al sensi dell'art. 2497-bis del C.C.

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