CERTIFICAT DE CONFORMITE

DATE

VERSION N°1

POUR LE CLIENT NUV

NOVOMA SARL

Je soussigné certifie que le produit cité ci-après est conforme aux spécifications établies.
Nous vous rappelons qu'il vous appartient de vérifier les conditions de distribution et d'utilisation de ces produits conformément à la législation en vigueur.

Code interne	NUVLYS01
Désignation interne	L-LYSINE 90 GVT0T
Code client	3 770025 711300
Désignation client	L-LYSINE

Numéro de lot		Numéro de BL	
Date de fabrication		DDM	

Conditions de conservation: A conserver à l'abri de l'oxygène et de la lumière à une température comprise entre 15 et 25°C dans son emballage d'origine

Le produit contient de(s) Allergène(s): Non

Liste des allergène(s) dans le produit

Non applicable

Le produit contient de(s) Additif(s): Non

Liste de(s) additif(s) dans le produit

Non applicable

Le produit est BIO: Non

*(*Produit issu de l'algriculture biologique FR-BIO-01 et process conforme à la fabrication de produits biologiques)*

Le produit est sans OGM	Oui	Le produit est Ionisé	Non
Le produit est sans Gluten	Non		
Conforme Végétarien	Oui	Conforme Végétalien	Oui
Conforme Halal	Oui	Conforme Casher	Oui

CONDITIONNEMENT PRODUIT

Type de produit	Gélules HPMC	Couleur	Transparente
PV interne gélules	[illegible]	Taille	Taille 0
Lot Fournisseur gélules	[illegible]	Dosage	500mg

Type de conditionnement	Piluliers	Quantité par colis	56*50
Quantité conditionnée	2818	Cartons incomplets	1*18

Autres (dont fond de bol)	

COMPOSITION PRODUIT

INGREDIENT(S)	DOSAGE	PV interne	N°LOT FOURNISSEUR
L-Lysine	500mg	[illegible]	[illegible]

[illegible]

Service qualité

[redacted]

CERTIFICATE OF ANALYSIS

BUYER		PRODUCT	L-Lysine.HCl 99.5% Fine Powder
QUANTITY	10,000 / KG	DATE OF MANUFACTURE	[redacted]
NUMBER OF A VEHICLE		EXPIRATION DATE	[redacted]
INSPECTOR	Yeongkwang Kim	DATE OF PUBLICATION	[redacted]
DECISION	Pass	LOT NO	[redacted]

INSPECTION RESULT

TEST ITEMS	UNIT	SPECIFICATION	RESULT	METHOD
Appearance		WHITE FINE POWDER	CONFIRM	U.S.P
Identification Test		CONFORM TO FCC TEST	CONFIRM	F.C.C
Assay	%	MIN.99.5% TO MAX. 101.5%	99.87	U.S.P
pH(10% soln)		5.0 ~ 6.0	5.71	U.S.P(791)
Transmittance(10% soln)	%	MORE THAN 95.0%	96.7	AT 430NM
Ammonium		LESS THAN 200 PPM	CONFIRM	U.S.P
Lead		LESS THAN 1 PPM	CONFIRM	F.C.C
Arsenic		LESS THAN 1 PPM	CONFIRM	K.P
Particle size distrbution		MAX. 5%	CONFIRM	ON MESH(# 60)
Specific rotation		+ 20.4 ~ +21.4	20.88	U.S.P(781S)
Loss on drying	%	LESS THAN 0.4%	0.27	U.S.P(731)
Content of Chloride	%	19.0 ~ 19.6%	19.30	U.S.P(541)
Residue on ignition	%	Less than 0.1%	0.01	U.S.P(281)
Iron		Less than 30 PPM	CONFIRM	U.S.P(231)
Heavy metals		Less than 10 PPM	CONFIRM	U.S.P(231)
Sulfate		Less than 0.03%	CONFIRM	U.S.P(221)
Individual impurities		Less than 0.5%	CONFIRM	U.S.P(621)
Total impurities		Less than 2.0%	CONFIRM	U.S.P(621)
Insoluble Foreign Matter		Foreign Matter NMT 5mg/100g	CONFIRM	F.C.C
TPC		Less than 1000 cfu/g	CONFIRM	U.S.P
Staphylococcus aureus		Negative	CONFIRM	U.S.P
Salmonella Species		Negative	CONFIRM	U.S.P
Escherichia coli		Negative	CONFIRM	U.S.P
Mold and Yeast		Less than 100 cfu/g	CONFIRM	U.S.P

WE HEREBY CERTIFY THAT L-LYSINE MONOHYDROCHLORIDE MENTIONED ABOVE WAS ANALYZED AND APPROVED BY THE DEPARTMENT OF QUALITY MANAGEMENT IN KOREA. THE PRODUCT COMPLIED WITH THE REQUIREMENTS OF SPECIFICATION THE CURRENT USP & FCC MONOGRAPH.

[redacted]

Head of Quality Management

[redacted]

[redacted]

K-CAPS®
Capsules of Vegetable Origin

CERTIFICATE OF ANALYSIS
EMPTY HARD CAPSULES OF VEGETABLE ORIGIN

CUSTOMER: [redacted]
LOT No.: [redacted] **PRODUCT CODE:** [redacted] **SIZE:** 0
PURCHASE ORDER NUMBER: [redacted] **CHARGE No.:** [redacted] **ART No.:** [redacted]
CAPSULE COLOR / CODE: **CAP -** NATURAL 1-0K **/ BODY -** NATURAL 1-0K
PRINT: N/A **TEXT:** N/A **INK COLOR:** N/A

THIS IS TO CERTIFY THAT: The hard capsules of vegetable origin (K-CAPS) manufactured by [redacted] are made from cellulose ethers, which are polymers derived from vegetable sources. Our capsules are certified as Kosher and Halal, and meet all requirements of current European Pharmacopoeia (EP) and United States Pharmacopoeia(USP). Hypromellose used in the manufacturing of capsules meet specifications as described in the current United States Pharmacopoeia. Cellulose ethers are considered as Generally Recognized As Safe(GRAS) by the FDA.

(% Ingredients to % Cellulose)

Cap	%	Body	%

Colorant and ingredients used in capsules are officially approved for use as dye in Foods, Drugs and Cosmetics and/or Drugs and Cosmetics, in the country of destination.
Some changes in color are due to natural colorants or can occur/are within the specification. The above specifications apply to all capsules having the same size and code numbers, unless otherwise stipulated.

Date of Manufacture: [redacted] Expiration Date: [redacted]

CRITERIA	METHOD / REFERENCE	SPECIFICATIONS	RESULTS
PHYSICAL			
Average Capsule Weight	DCC-MI-P003/ USP<2091>	103.00-115.00 mg	107.0
Loss on drying	DCC-MA-P027	4.00-8.00 %	4.9
Disintegration	DCC-MA-P063/ USP<701>	N.M.T. 15 min	PASSES
Residue on Ignition *	USP	N.M.T. 1.5% Transparent Capsules N.M.T. 6.0% Colored Capsules	PASSES
Identification of HPMC	DCC-MA-P073 / USP	Meets USP Requirements	PASSES
ANALYTICAL			
Arsenic *	EXTERNAL	N.M.T. 0.8 ppm	PASSES
Chromium *	EXTERNAL	N.M.T. 2 ppm	PASSES
Cadmium *	EXTERNAL	N.M.T. 0.5 ppm	PASSES
Lead *	EXTERNAL	N.M.T. 0.5 ppm	PASSES
Mercury *	EXTERNAL	N.M.T. 0.1 ppm	PASSES
Cobalt *	EXTERNAL	N.M.T. 5.0 ppm	PASSES
Vanadium *	EXTERNAL	N.M.T. 10.0 ppm	PASSES
Nickel *	EXTERNAL	N.M.T. 20.0 ppm	PASSES
Total Aerobic Microbial Count	DCC-MA-P031 / USP <61>	N.M.T. 1000 cfu/g	9
Total Yeasts and Molds Count	DCC-MA-P040 / USP <61>	N.M.T. 100 cfu/g	<10
Total Coliforms	DCC-MA-P036 / USP <62>	Absence / 1 g	Absence
Salmonella	DCC-MA-P039 / USP <62>	Absence / 10 g	Absence
Escherichia Coli	DCC-MA-P036 / USP <62>	Absence / 1g	Absence
Staphylococcus aureus	DCC-MA-P037 / USP <62>	Absence / 1g	Absence
Pseudomonas aeruginosa	DCC-MA-P033 / USP <62>	Absence / 1g	Absence

*Reduced Frecuency Testing Storage Conditions: Temperature: 15°C - 30°C / Relative Humidity: 35 % - 70 % RH N.M.T. = No More Than

NOTE: The VISUAL QUALITY is superior to the established figures in the sampling plans of the ANSI/ASQ Z1.4-2013 "Procedure of sampling to inspect for attributes", using simple sampling with level III of General Inspection and Acceptable Level of Quality (AQL) of 0.010 for Critical defects, 0.040 for Major defects and 0.250 for Minor defects. They also fulfill the specifications established in the Technical Information Manual in force.

Quality Assurance

Date: [redacted]

Code: [redacted]

Edition 7

[redacted]