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	NUVHAY02
Désignation interne	ACIDE HYALURONIQUE
Code client	3 770025 711324
Désignation client	ACIDE HYALURONIQUE + Vitamine C

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 1
Lot Fournisseur gélules	[illegible]	Dosage	230mg

Type de conditionnement	Piluliers	Quantité par colis	150*50
Quantité conditionnée	7500	Cartons incomplets	

Autres (dont fond de bol)	

COMPOSITION PRODUIT

INGREDIENT(S)	DOSAGE	PV interne	N°LOT FOURNISSEUR
Acide Hyaluronique – Exception HYAL	100mg	[illegible]	[illegible]
Vitamine C L-acide ascorbique	50mg	[illegible]	[illegible]
Amidon de riz	80mg	[illegible]	[illegible]

[illegible]

Service qualité

CERTIFICATE OF ANALYSIS

ExceptionHYAL® Star

Batch n.		[illegible]
Production date		[illegible]
Period of best use		[illegible]

Parameter	Unit	Requirement	Method	Result
PHYSICAL-CHEMICAL				
Appearance	-	Powder	IO 07-06A	Powder
Colour	-	White	IO 07-06A	White
Odour	-	Characteristic	IO 07-06A	Characteristic
pH (0,1% solution)	-	6,0 – 8,0	IO 07-06B	6,5
Transparency (0,1% solution,550 nm)	%	≥99	Ph.Eur. 2.2.25	Complies
Loss on drying (105°C)	%	≤10	IO 07-06K	7
Ashes	%	≤15	Ph.Eur. 2.4.16	Complies
Bulk density	g/cm3	0,3 -0,5	Ph.Eur. 2.9.34	0,3
Glucuronic acid assay	%	≥46	S.H. Ph.Eur.Monograph	47
Sodium Hyaluronate assay	%	≥95	S.H. Ph.Eur.Monograph	97
Lead (Pb)	ppm	≤3	IO 07-06AG	Complies
Cadmium (Cd)	ppm	≤1	IO 07-06AG	Complies
Mercury (Hg)	ppm	≤0,1	IO 07-06AG	Complies
Water activity	-	≤0,5	IO 07-06AL	0,0
MICROBIOLOGICAL				

CERTIFICATE OF ANALYSIS

ExceptionHYAL® Star

Total bacterial count	CFU/g	≤100*	Ph.Eur. 2.6.12/USP (current edition)	<100
Yeasts & Moulds	CFU/g	≤100*	Ph.Eur. 2.6.12/USP (current edition)	<100
Enterobacteriaceae	CFU/g	≤100	UNI ISO 21528-2	<100
Escherichia coli	g	Absence	Ph.Eur. 2.6.13/USP (current edition)	Absence
Staphylococcus aureus	g	Absence	Ph.Eur. 2.6.13/USP (current edition)	Absence
Salmonella	10g	Absence	Ph.Eur. 2.6.13/USP (current edition)	Absence

* 2x (as per Ph.Eur.5.1.4)

Date: [redacted]

[redacted] HPC Technical Department

The analyses are performed on a representative sample and are referred to the product at the time of release. The information included in this Certificate of Analysis does not discharge the user from the control of the product before the use. Roelmi HPC SRL does not take liability for any damage due to improper use. This document refers to the latest version of the specification data sheet and it has been prepared by electronic processing not requiring signature and the traceability to the original signature is managed by internal quality assurance system.

CERTIFICATE OF ANALYSIS

ExceptionHYAL® Star

Batch n.	[illegible]
Production date	[illegible]
Period of best use	[illegible]

Parameter	Unit	Requirement	Method	Result
PHYSICAL-CHEMICAL				
Appearance	-	Powder	IO 07-06A	Powder
Colour	-	White	IO 07-06A	White
Odour	-	Characteristic	IO 07-06A	Characteristic
pH (0,1% solution)	-	6,0 – 8,0	IO 07-06B	7,0
Transparency (0,1% solution,550 nm)	%	≥99	Ph.Eur. 2.2.25	Complies
Loss on drying (105°C)	%	≤10	IO 07-06K	6
Ashes	%	≤15	Ph.Eur. 2.4.16	Complies
Bulk density	g/cm3	0,3 -0,5	Ph.Eur. 2.9.34	0,4
Glucuronic acid assay	%	≥46	S.H. Ph.Eur.Monograph	47
Sodium Hyaluronate assay	%	≥95	S.H. Ph.Eur.Monograph	98
Lead (Pb)	ppm	≤3	IO 07-06AG	Complies
Cadmium (Cd)	ppm	≤1	IO 07-06AG	Complies
Mercury (Hg)	ppm	≤0,1	IO 07-06AG	Complies
Water activity	-	≤0,5	IO 07-06AL	0,0
MICROBIOLOGICAL				

CERTIFICATE OF ANALYSIS

ExceptionHYAL® Star

Total bacterial count	CFU/g	≤100*	Ph.Eur. 2.6.12/USP (current edition)	<100
Yeasts & Moulds	CFU/g	≤100*	Ph.Eur. 2.6.12/USP (current edition)	<100
Enterobacteriaceae	CFU/g	≤100	UNI ISO 21528-2	<100
Escherichia coli	g	Absence	Ph.Eur. 2.6.13/USP (current edition)	Absence
Staphylococcus aureus	g	Absence	Ph.Eur. 2.6.13/USP (current edition)	Absence
Salmonella	10g	Absence	Ph.Eur. 2.6.13/USP (current edition)	Absence

* 2x (as per Ph.Eur.5.1.4)

Date: [redacted]

[redacted] HPC Technical Department

The analyses are performed on a representative sample and are referred to the product at the time of release. The information included in this Certificate of Analysis does not discharge the user from the control of the product before the use. Roelmi HPC SRL does not take liability for any damage due to improper use. This document refers to the latest version of the specification data sheet and it has been prepared by electronic processing not requiring signature and the traceability to the original signature is managed by internal quality assurance system.

Certificate of Analysis

Contract No : [redacted] Container No: [redacted]

Invoice No: [redacted] Report No: [redacted]

Production Name	Ascorbic acid	Production Code	[redacted]
Batch No	[redacted]	Manufacture Date	[redacted]
Quantity	5000kg	Analysis Date	[redacted]
Foundation	USP42/EP11.0/EU231/2012	Expiry Date	[redacted]

Results of Analysis:

Items	Standards	Results
Appearance	White or almost white, crystalline powder or colourless crystals.	Qualified
Identification	Positive Reaction	Qualified
Specific optical rotation	+20.5°~+21.5°	+20.88°
pH(with 5% water solution)	2.1~2.6	2.4
pH(with 2% water solution)	2.4~2.8	2.6
Impurity E*	≤0.20%	Conform
Clarity of solution	Clear	Clear
Colour of solution	≤BY_7	<BY7
Assay($C_6H_8O_6$)	99. 0%~100.5%	99.9%
Melting point	190~192℃	190.7~191.8℃
Particle size	Not less than 95% through 100mesh	96.2%
Residue on ignition**	≤0.1%	<0.1%
Loss of Drying*	≤0.4%	Conform
Heavy metal**	≤10.0 mg/kg	Conform
Iron**	≤2.0 mg/kg	Conform
Copper**	≤5.0 mg/kg	Conform
Lead**	≤0.5 mg/kg	Conform
Arsenic**	≤1.0 mg/kg	Conform
Cadmium(Cd)**	≤0.5 mg/kg	Conform
Mercury**	≤0.1 mg/kg	Conform
Impurities C，D*	≤0.15%	Conform
Unspecified impurities (each impurity)*	≤0.10%	Conform
Sum of impurities other than C and D*	≤0.20%	Conform
Residual Solvents(as methanol)*	≤200mg/kg	Conform
Total Plate Counts*	≤1000 cfu/g	Conform
Yeasts and Moulds*	≤100 cfu/g	Conform
Staphylococcus Aureus*	Negative in 25g	Conform
Salmonella*	Negative in 25g	Conform
Escherichia coli*	Negative in 10g	Con[redacted]

*Test once every three months.

**Test once every six months.

Reporter: 刘晓玉 Reviewer: 王帅杰 Approv[redacted] 郑乐友

QC Manager: [redacted]

Certificate of Analysis

General Information

Product	Remy O DR6	**Production Date**	(dd/mm/yyyy)
Batch		**Best before**	(dd/mm/yyyy)
Issued by	Quality Control Management	**Date CoA Issued**	(dd/mm/yyyy)

Results of analyses

Parameter	Result	Unit	Method (1)	LSL	USL
Physical and Chemical Parameters					
Moisture	6	g/100g	ISO 712		≤ 14
Protein content (N*6,25) on DM	4,4	g/100g d.m.	ISO 1871 (1)		≤ 7,0
Ash content on DM	0,2	g/100g d.m.	ISO 3593		≤ 1,0
Rheological Parameters					
Starting gel point, pH as is, 6%	82	°C	Brabender	≥ 60	
End viscosity, pH as is, 6%	640	BU	Brabender	≥ 500	
Microbiological Parameters					
Salmonella (/375g)	Negative	/375g	ISO 6579		Negative
Total mesophilic bacteria (aerobic)	20.000	cfu/g	ISO 4833		≤ 100.000
Yeasts and Moulds	270	cfu/g			≤ 1.000
Enterobacteriaceae	80	cfu/g			≤ 100

(1) or (acknowledged and) validated equivalent

Remarks

We herewith confirm that the product complies with the corresponding guarantees listed in its Product Sheet .

Rice starch issued from organic farming, Certisys BE-BIO-01

This certificate is issued automatically, it does not need a signature .

FORM

LIMS: 117.731

[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:** 1
PURCHASE ORDER NUMBER: [redacted] **CHARGE No.:** 1-000843 **ART No.:** 56-000992
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>	75.00-85.00 mg	77.5
Loss on drying	DCC-MA-P027	3.00-8.00 %	4.3
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.

Approval by: [redacted]
Quality Assurance

Date: [redacted]

Code: [redacted]

Edition 8

[redacted]