CERTIFICAT DE CONFORMITE

DATE

VERSION N°1

POUR LE CLIENT NUV

NOVOMA SARL

Je soussigné [illegible] 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	NUVVIT10
Désignation interne	QUATREFOLIC
Code client	
Désignation client	ACIDE FOLIQUE VIT B9

Numéro de lot	[illegible]	Numéro de BL	[illegible]
Date de fabrication	[illegible]	DDM	[illegible]

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	250,4mg

Type de conditionnement	Piluliers	Quantité par colis	82*50
Quantité conditionnée	4130	Cartons incomplets	1*30

Autres (dont fond de bol)	

COMPOSITION PRODUIT

INGREDIENT(S)	DOSAGE	PV interne	N°LOT FOURNISSEUR
Vitamine B9 quatrefolic	400µg	[illegible]	[illegible]
Fibre acacia	250mg	[illegible]	[illegible]

[illegible]

[illegible]
Service qualité

CERTIFICATE OF ANALYSIS

Quatrefolic®
The 4th generation folate

QUATREFOLIC (6S)-5-Methyltetrahydrofolic acid, Glucosamine Salt

Batch Nr.: **Manufacturing date:** **Retest date:**

Code:

TESTS	SPECIFICATIONS	UM	RESULTS	ANALYTICAL METHOD REFERENCES
Appearance	Creamy to light brown powder	-	Complies	Visual
Identification (IR) §	Positive	-	Complies	USP < 197A>
Water Content (K.F.)	<=8,0	%	5,5	USP < 921>MethodIA
Glucosamine assay on d.b. (HPLC)	34 - 46	%	44	GN QT-005
5-Methyltetrahydrofolic ac assay on d.b.	54 - 59	%	57	GN QT-001
4-Aminobenzoylglutamic ac. (ABGA)	<=0,3	%	0,1	GN QT-002
HOMeTHFA	<=1,0	%	0,2	GN QT-002
(6S)-Pyrazino-s-triazine derivate	<=0,3	%	Not determinable	GN QT-002
5-Methyltetrahydropteroic acid (MeT	<=0,3	%	0,1	GN QT-002
Any other individual impurity	<=1,0	%	0,1	GN QT-002
Total impurities	<=2,5	%	0,5	GN QT-002
Lead	<=0,5	ppm	< 0,5	EP 2.2.58 or 2.2.57/USP < 233>
Cadmium	<=0,5	ppm	< 0,5	EP 2.2.58 or 2.2.57/USP < 233>
Mercury	<=0,1	ppm	< 0,0	Ph.Eur.2.2.58/USP< 233>
Arsenic	<=1,5	ppm	< 0,5	EP 2.2.58 or 2.2.57/USP < 233>
Boron	<=10	ppm	< 5	EP 2.2.58 or 2.2.57/USP < 233>
Diastereoisomeric purity:(6S)5-MTHF acid	>= 99,0	%	99,0	GN QT-003
Total aerobic microbial count	<= 10^2	cfu/g	< 10	USP< 2021>
Total combined yeast and molds count	<= 10^2	cfu/g	< 10	USP< 2021>
E. Coli	Absent /10g	-	Complies	USP< 2022>

- 10^2 CFU: MAXIMUM ACCEPTABLE COUNT= 100
- 10^2 CFU: MAXIMUM ACCEPTABLE COUNT= 100

Storage: <25°C

§ Spectrum comparable with the reference standard

Released by:
Title: QU Director & Qualified Person
Date:

[redacted]

Name of product **INAVEA ORIGINAL**

Lot number [redacted]

Date of manufacture [redacted] **Expiry date** [redacted]

Place of manufacture [redacted]

CERTIFICATE OF ANALYSIS

Test	Method	Specifications	Result
Description		Yellowish-white to yellow powder	Yellowish-white to yellow powder
Total dietary fibers (on dry weight) (%)	AOAC 985.29	≥ 90%	≥ 90%
pH of 25% solution	Eur.Ph	4.0 to 5.0	4,30
Viscosity of 25% solution (mPa.s)	Brookfield LVF 60 rpm	70 to 130 mPa.s	90
Moisture (5H-105°C) (%)	USP 921 Method III	≤ 10%	8,70
Acid insoluble matters (%)	Eur.Ph	≤ 0.5%	0,02
Total ashes (%)	Eur.Ph	≤ 4.0%	3,00
Acid insoluble ashes (%)	USP 561	≤ 0.5%	≤ 0.5%
Mesh size through 63 µm (%)	Vibro sieving	≤ 15%	≤ 15%
Solubility and reaction*	Eur.Ph	Passes test	Passes test
Glucose and fructose*	Eur.Ph	Passes test	Passes test
Starch, dextrin and agar*	Eur.Ph	Passes test	Passes test
Sterculia gum*	Eur.Ph	Passes test	Passes test
Tragacantha*	Eur.Ph	Passes test	Passes test
Tannins*	Eur.Ph	Passes test	Passes test
Identification*	Eur.Ph	Passes test	Passes test
Lead* (ppm)	ICP-OES/ICP-MS	≤ 0.1 ppm	≤ 0.1 ppm
Arsenic* (ppm)	ICP-OES/ICP-MS	≤ 0.5 ppm	≤ 0.5 ppm
Mercury* (ppm)	SAA	≤ 0.1 ppm	≤ 0.1 ppm
Cadmium* (ppm)	ICP-OES/ICP-MS	≤ 0.1 ppm	≤ 0.1 ppm
Total heavy metal* (ppm)	FCC Method II	≤ 5 ppm	≤ 5 ppm
Total plate count (CFU per g)	ISO 4833-1	≤2000/g	≤2000/g
Yeast and molds (CFU per g)	ISO 6611	≤100/g	≤100/g
E.coli	NF ISO 7251	ABS/5g	ABS/5g
Salmonella	NF EN ISO 6579-1	ABS/25g	ABS/25g

ORGANIC ACACIA GUM USA-NOP CERTIFIED BY ECOCERT SA F32600
PRODUIT ISSU DE L'AGRICULTURE BIOLOGIQUE CERTIFIE PAR FR-BIO-01

/**/ periodicity of the analysis as defined on the Technical Data Sheet**

Comply with the EC regulation, 231/2012
Conform to Eur.Ph, USP/NF, BP

[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:** 1

PURCHASE ORDER NUMBER: [redacted] **CHARGE No.:** 1-000832 **ART No.:** 56-000108

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	79.6
Loss on drying	DCC-MA-P027	3.00-8.00 %	4.4
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	20
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: _____ Quality Assurance

Date: [redacted]

Code: [redacted]

Edition 8

[redacted]