

	<b>CERTIFICAT DE CONFORMITE</b>	DATE
		03/06/19
		VERSION N°1

POUR LE CLIENT

NOVOMA SARL  
BATIMENT ZEPHYR AVENUE BERNARD  
31 400 TOULOUSE

Je soussigné M. WACRENIER, Président de Laboratoire PHYTOCOSMA SAS 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   
 Désignation interne

Code client   
 Désignation client

Numéro de lot  Numéro de BL

Date de fabrication  DDM

Conditions de conservation

Le produit contient de(s) Allergène(s)

Liste des allergène(s) dans le produit

Le produit contient de(s) Additif(s)

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

Le produit est BIO

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

Le produit est sans OGM  Le produit est Ionisé

Le produit est sans Gluten

Conforme Végétarien  Conforme Végétalien

Conforme Halal  Conforme Casher

**CONDITIONNEMENT PRODUIT**

Type de produit	Gélules HPMC	Couleur	Transparente
PV interne gélules	25550	Taille	Taille 0
Lot Fournisseur gélules	1-000759	Dosage	429,3mg

Type de conditionnement	Piluliers	Quantité par colis	38*50
Quantité conditionnée	1413+500	Cartons incomplets	1*13

Autres (dont fond de bol)

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**COMPOSITION PRODUIT**

INGREDIENT(S)	DOSAGE	PV interne	N°LOT FOURNISSEUR
ES Passiflore feuille	100mg	25660	P24052408
ES Mélisse feuille	100mg	25633	P24030738
Es Eschlozia	75mg	24866	
ES Houblon	50mg	25632	P24022904
Mélatonine végétale issue du millepertuis	4,3mg	24943	N05223003
Amidon de riz	100mg	25343	2320341590

PHYTOSMA Laboratoires  
23 Route du Burgaud  
82600 AUCAMVILLE  
Tél. : 05 63 02 71 07  
phytocosma@orange.fr  
SAS au capital de 13 720 41 euros  
RCS MONTAUBAN 432 894 354

09/07/24

Service qualité



**CERTIFICATE OF ANALYSES**

**PASSION FLOWER AP 3.5% DE  
PR3137**

Batch: P24052408  
Manufactured: Fri, 07 Jun 2024

COA Version:1

Edition date: Mon, 10 Jun 2024  
Best before: Sun, 07 Jun 2026

**Botanical kind:** *Passifloraceae Passiflora incarnata L. (= Passiflora edulis Sims)*  
**Part of the plant:** *Aerial part*  
**Extraction solvent(s):** *Ethanol, water 30 : 70 (V/V)*  
**Carrier(s):** *Wheat maltodextrin*

**DESCRIPTION**

	Specifications	Method and reference	Result
Appearance	<i>Powder</i>		<i>Powder</i>
Color	<i>Brown to brown greenish</i>		<i>Brown</i>
Solubility	<i>To be tested following the degree of incorporation</i>		<i>Not done</i>

**ANALYSES**

	Specifications		Method and reference	Result
	Min	Max		
Total flavonoids, expressed as vitexin content [%]	> 3.50	-	MO-09 - UV-Vis, Fr. Ph. (1993), "Extrait de passiflore (sec)" monograph	3.51
Vitexin content [%] (4)	<i>Indicative value</i>		AE-37 - HPLC, internal method	<i>Complies (4)</i>
Hyperosid content [%] (4)	<i>Indicative value</i>		AE-23 - HPLC, internal method	<i>Complies (4)</i>
Identification (raw material) (4)	<i>Complies</i>		MO-71 - TLC, Eur. Ph. (01/2008 :1882), "Passion flower dry extract" monograph	<i>Complies (4)</i>
Loss on drying [%]	-	8.00	MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)	<i>Complies</i>
Bulk density	0.30	0.70	MO-181 - Eur. Ph. (04/2019:20934)	0.51
Total ash content [%]	-	< 15.00	MO-01 - Muffle furnace, Eur. Ph. (01/2008:20416), "Total ash" adapted monograph	<i>Complies</i>
pH (1% in demineralized water)	3.0	6.5	MO-03 - pH-meter, Eur. Ph. (07/2016:20203), "Potentiometric determination of pH" monograph	<i>Complies</i>
Screening [ % < 180 µm]	95.0	-	MO-184 - Granulometer, internal method	98.6

**OTHER ANALYSIS**

	Specifications		Method and reference	Result
	Min	Max		

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Z.A.C. de la Noue Rousseau - 6, rue d'Alembert - CS 50006 - 91241 SAINT MICHEL SUR ORGE CEDEX - FRANCE  
SAS au capital de 1.700.000 € - SIRET : 37755926500030 - RCS : Evry B 377 559 265 - APE 1089Z - TVA N° FR 77 377 559 265



**CERTIFICATE OF ANALYSES**

**PASSION FLOWER AP 3.5% DE  
PR3137**

Batch: P24052408  
Manufactured: Fri, 07 Jun 2024

COA Version:1

Edition date: Mon, 10 Jun 2024  
Best before Sun, 07 Jun 2026

CONTAMINANTS	Specifications		Method and reference	Result
	Min	Max		
<b>Pb content [ppm] (4)</b>	-	< 3.00	AE-01 - ICP, internal method	Complies (4)
<b>Cd content [ppm] (4)</b>	-	< 1.00	AE-01 - ICP, internal method	Complies (4)
<b>Hg content [ppm] (4)</b>	-	< 0.10	AE-01 - ICP, internal method	Complies (4)
<b>As content [ppm] (4)</b>	-	< 1.00	AE-01 - ICP, internal method	Complies (4)
<b>Pesticides content [ppm] (4)</b>	< Residual Maximum Limit fixed in European regulation 396/2005 and its modifications		AE-02 - GC-MSMS/LC-MSMS, internal method	Complies (4)
<b>Benzo(a)pyrene content [ppb] (4)</b>	-	< 10.0	AE-03 - GC-MS-MS, internal method	Complies (4)
<b>Pahs (sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene) content [ppb] (4)</b>	-	< 50.0	AE-03 - GC-MS-MS, internal method	Complies (4)

MICROBIOLOGY	Specifications		Method and reference	Result
	Min	Max		
<b>Total aerobic microbial count [CFU/g] (1)</b>	-	< 10 000	AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)	< 100
<b>Total yeasts/moulds count [CFU/g] (1)</b>	-	< 100	AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)	< 10
<b>Salmonella content [ /25g]</b>	Absent		AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)	Absent
<b>Bile-tolerant Gram negative bacteria content [CFU/g]</b>	-	< 100	AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)	< 10
<b>Escherichia coli content [ /g]</b>	Absent		AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)	Absent

(1) Acceptable maximal count: 5 times the acceptance criterion according to Eur. Ph. VIII° Ed. 5.1.8 Category B  
(4) HACCP based control plan defined annually according to risk analysis

**Best before/** 24  
**DMD (in**  
**months) :**



**CERTIFICATE OF ANALYSES**

**LEMON BALM LE 5% DE  
PR1096**

Batch: P24030738

COA Version:1

Edition date:

Tue, 26 Mar 2024

Manufactured: Mon, 25 Mar 2024

Best before:

Wed, 25 Mar 2026

**Botanical kind:** *Lamiaceae Melissa officinalis L.*  
**Part of the plant:** *Leaf*  
**Extraction solvent(s):** *Ethanol, water 30 : 70 (V/V)*  
**Carrier(s):** *Wheat maltodextrin*

**DESCRIPTION**

	Specifications	Method and reference	Result
Appearance	<i>Powder</i>		<i>Powder</i>
Color	<i>Beige to brown</i>		<i>Light brown</i>
Solubility	<i>To be tested following the degree of incorporation</i>		<i>Not done</i>

**ANALYSES**

	Specifications		Method and reference	Result
	Min	Max		
Total hydroxycinnamic derivatives expressed as rosmarinic acid content [%]	5.00	-	MO-29 - UV-Vis, Eur. Ph. (01/2008:1447), "Melissa leaf" monograph	5.02
Eucalyptol content [ppm] (4)	<i>Indicative value</i>		AE-22 - GC-MS, internal method for aromatic substances	Complies (4)
Methyleugenol content [ppm] (4)	<i>Indicative value</i>		AE-22 - GC-MS, internal method for aromatic substances	Complies (4)
Identification (raw material) (4)	<i>Complies</i>		MO-87 - TLC, Eur. Ph. (01/2011:1447), "Melissa leaf" monograph	Complies (4)
Loss on drying [%]	-	8.00	MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)	2.67
Bulk density	0.40	0.80	MO-181 - Eur. Ph. (04/2019:20934)	0.59
pH (1% in demineralized water)	4.0	6.5	MO-03 - pH-meter, Eur. Ph. (07/2016:20203), "Potentiometric determination of pH" monograph	5.5
Screening [ % < 500 µm]	95.0	-	MO-184 - Granulometer, internal method	100

**CONTAMINANTS**

	Specifications		Method and reference	Result
	Min	Max		

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**CERTIFICATE OF ANALYSES**

**LEMON BALM LE 5% DE  
PR1096**

<b>Pb content [ppm] (4)</b>	-	< 3.00	AE-01 - ICP, internal method	Complies (4)
<b>Cd content [ppm] (4)</b>	-	< 1.00	AE-01 - ICP, internal method	Complies (4)
<b>Hg content [ppm] (4)</b>	-	< 0.10	AE-01 - ICP, internal method	Complies (4)
<b>As content [ppm] (4)</b>	-	< 1.00	AE-01 - ICP, internal method	Complies (4)
<b>Pesticides content [ppm] (4)</b>	< Residual Maximum Limit fixed in European Regulation 396/2005 and its modifications		AE-02 - GC-MSMS/LC-MSMS, internal method	Complies (4)
<b>Benzo(a)pyrene content [ppb] (4)</b>	-	< 10.0	AE-03 - GC-MS-MS, internal method	Complies (4)
<b>PaHs (sum of benzo(a) pyrene, benz(a) anthracene, benzo(b) fluoranthene and chrysene) content [ppb] (4)</b>	-	< 50.0	AE-03 - GC-MS-MS, internal method	Complies (4)

<b>MICROBIOLOGY</b>	<b>Specifications</b>		<b>Method and reference</b>	<b>Result</b>
	<b>Min</b>	<b>Max</b>		
<b>Total aerobic microbial count [CFU/g] (1)</b>	-	< 10 000	AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)	< 100
<b>Total yeasts/moulds count [CFU/g] (1)</b>	-	< 100	AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)	35
<b>Salmonella content [ /25g]</b>	Absent		AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)	Absent
<b>Bile-tolerant Gram negative bacteria content [CFU/g]</b>	-	< 100	AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)	< 10
<b>Escherichia coli content [ /g]</b>	Absent		AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)	Absent

(1) Acceptable maximal count: 5 times the acceptance criterion according to Eur. Ph. VIII° Ed. 5.1.8 Category B

(4) HACCP based control plan defined annually according to risk analysis

**Best before/  
DMD (in  
months) :**

24

**Storage  
conditions:**

Store in closed original packaging at 5 to 25°C in a dry place and protected from light.





**CERTIFICATE OF ANALYSES**

**LEMON BALM LE 5% DE  
PR1096**

**Complementary  
data**

*This reference is neither an Active Pharmaceutical Ingredient nor an excipient for pharmaceutical use  
Responsibility of final labelling lies with the company placing the final product on the market.*

*- Complies with French decrees (2006-352 and 24th June 2014)*

*- According to Regulation 1999/3/EC, and its modifications, has not been ionized.*

*- According to the Regulations 2001/18/EC, 1829/2003 and 1830/2003, and its modifications, the above mentioned item does not contain deliberately added GMO. (fortuitous or technically inevitable traces could be detected at less than 0,9%)*

*- The product does not contain TSE/BSE substances*

**Laboratory Manager  
Aude ATTICOT**



**CERTIFICATE OF ANALYSES**

**PASSION FLOWER AP 3.5% DE  
PR3137**

**Storage  
conditions:**

*Store in closed original packaging at 5 to 25°C in a dry place and protected from light.*

**Complementary  
data**

*This reference is neither an Active Pharmaceutical Ingredient nor an excipient for pharmaceutical use  
Responsibility of final labelling lies with the company placing the final product on the market.*

*- Complies with French decrees (2006-352 and 24th June 2014)*

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**Laboratory Manager**

**Aude ATTICOT**



# CERTIFICATE OF ANALYSIS



Natural  
EXTRACT

## Product and Batch Informations

### CALIFORNIAN POPPY AERIAL PART EXTRACT 4/1

REF : ESCH4\_1001

DT V03 - 05/11/2021

Latin name	<i>Eschscholtzia californica Cham.</i>	Plant part	Aerial part
Solvent (%)	100% water	Carrier (%)	20-60% maltodextrin
Extract ratio	4/1	Country of plant origin	Europe
Batch	C3108401	Country of manufacturing	Europe
MF date	08/03/2023	Expiration date	06/03/2028

## ANALYSIS ITEM

## SPECIFICATION

## RESULT

## TEST METHOD

### Active Ingredients/Substance to control

#### Assay

Substance to control *	Isoquinoline alkaloids (californidine)	Not tested	-
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### Physical/Chemical Control

Appearance**	Light-brown to brown powder	Complies	Visual inspection
Identification*	Positive	Complies	TLC
Sieve analysis	NLT 97% through 300 microns	Complies	Circular Vibrating Screener
Loss on drying	NMT 6%	2,30%	105°C - 3 hours

### Contaminant Control\*

Lead (Pb)	NMT 3ppm	Complies	Atomic absorption
Cadmium(Cd)	NMT 1ppm	Complies	Atomic absorption
Arsenic	NMT 1ppm	Complies	Atomic absorption
Mercury (Hg)	NMT 0,1ppm	Complies	Atomic absorption
Pesticides Residues	<MRL	Complies	Reg EC 396/2005
Benzo(a)pyrene	NMT 50ppb	Complies	GC-MS
PAHs	NMT 10ppb	Complies	GC-MS

### Microbiological Control

Total aerobic microbial	NMT 50 000 cfu/g	Complies	As per Eur.Ph
Tot. yeast and mould	NMT 500 cfu/g	Complies	As per Eur.Ph
Enterobacteria*	NMT 100 cfu/g	Complies	As per Eur.Ph
Salmonella	Negative/25g	Not detected	As per Eur.Ph
E.Coli	Negative/g	Not detected	As per Eur.Ph
Staphylococcus aureus	Negative/g	Not detected	As per Eur.Ph

### Statements

Allergens	Allergen free
GMO	No OGM
Irradiation	No irradiation
BSE/TSE	BSE/TSE free
Nanomaterials	Nanomaterials free

### Packing and Storage

Packing	Suitable for food industry
Storage	Store in dry places and keep away from strong direct light and heat.

\*According to a control plan

\*\*Depending to variations of raw material

\*\*\*Sum of ethylene oxide and 2-chloro-ethanol expressed as ethylene oxide



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07/04/2023  
ALLAIRE Laurène  
Quality Department



**CERTIFICATE OF ANALYSES**

**HOPS CO 0.035% DE  
PR1968**

Batch: P24022904

COA Version:1

Edition date:

Thu, 07 Mar 2024

Manufactured: Thu, 07 Mar 2024

Best before:

Sat, 07 Mar 2026

**Botanical kind:** *Cannabaceae Humulus lupulus L.*

**Part of the plant:** *Cone*

**Extraction solvent(s):** *Food grade Ethanol, Water 25-30 : 70-75 (V/V)*

**Carrier(s):** *Wheat maltodextrin*

**DESCRIPTION**

	Specifications	Method and reference	Result
Appearance	<i>Powder</i>		<i>Powder</i>
Color	<i>Light brown to dark brown</i>		<i>Beige</i>
Solubility	<i>To be tested following the degree of incorporation</i>		<i>Not done</i>

**ANALYSES**

	Specifications		Method and reference	Result
	Min	Max		
Isoquercitrin content [%]	<i>&gt; 0.035</i>	<i>-</i>	<i>AE-74 - HPLC, internal method</i>	<i>0.036</i>
8-Prenylnaringenin content [ppm]	<i>-</i>	<i>&lt; 200.00</i>	<i>AE-73 - HPLC, internal method</i>	<i>54.2</i>
Identification (raw material)	<i>Complies</i>		<i>MO-136 - TLC, Eur. Ph. (01/2011:1222), "Hop strobile" monograph</i>	<i>Complies</i>
Loss on drying [%]	<i>-</i>	<i>7.00</i>	<i>MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)</i>	<i>Complies</i>
Bulk density	<i>0.45</i>	<i>0.70</i>	<i>MO-181 - Eur. Ph. (04/2019:20934)</i>	<i>0.65</i>
pH (1% in demineralized water)	<i>3.0</i>	<i>6.5</i>	<i>MO-03 - pH-meter, Eur. Ph. (07/2016:20203), "Potentiometric determination of pH" monograph</i>	<i>Complies</i>
Screening [ % < 500 µm]	<i>95.0</i>	<i>-</i>	<i>MO-184 - Granulometer, internal method</i>	<i>100</i>

**CONTAMINANTS**

	Specifications		Method and reference	Result
	Min	Max		
Pb content [ppm] (4)	<i>-</i>	<i>&lt; 3.00</i>	<i>AE-01 - ICP, internal method</i>	<i>Complies (4)</i>
Cd content [ppm] (4)	<i>-</i>	<i>&lt; 1.00</i>	<i>AE-01 - ICP, internal method</i>	<i>Complies (4)</i>
Hg content [ppm] (4)	<i>-</i>	<i>&lt; 0.10</i>	<i>AE-01 - ICP, internal method</i>	<i>Complies (4)</i>

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**CERTIFICATE OF ANALYSES**

**HOPS CO 0.035% DE  
PR1968**

<b>Pesticides content [ppm] (4)</b>	< Residual Maximum Limit fixed in European regulation 396/2005 and its modifications		AE-02 - GC-MSMS/LC-MSMS, internal method	Complies (4)
<b>Benzo(a)pyrene content [ppb] (4)</b>	-	< 10.0	AE-03 - GC-MS-MS, internal method	Complies (4)
<b>Pahs (sum of benzo(a) pyrene, benz(a) anthracene, benzo(b) fluoranthene and chrysene) content [ppb] (4)</b>	-	< 50.0	AE-03 - GC-MS-MS, internal method	Complies (4)

<b>MICROBIOLOGY</b>	<b>Specifications</b>		<b>Method and reference</b>	<b>Result</b>
	<b>Min</b>	<b>Max</b>		
<b>Total aerobic microbial count [CFU/g] (1)</b>	-	< 10 000	AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)	108
<b>Total yeasts/moulds count [CFU/g] (1)</b>	-	< 100	AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)	< 10
<b>Salmonella content [ /25g]</b>	Absent		AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)	Absent
<b>Bile-tolerant Gram negative bacteria content [CFU/g]</b>	-	< 100	AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)	< 10
<b>Escherichia coli content [ /g]</b>	Absent		AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)	Absent

(1) Acceptable maximal count: 5 times the acceptance criterion according to Eur. Ph. VIII° Ed. 5.1.8 Category B

(4) HACCP based control plan defined annually according to risk analysis

**Best before/ DMD (in months) :** 24

**Storage conditions:** Store in closed original packaging at 5 to 25°C in a dry place and protected from light.



**CERTIFICATE OF ANALYSES**

**HOPS CO 0.035% DE  
PR1968**

**Complementary  
data**

*This reference is neither an Active Pharmaceutical Ingredient nor an excipient for pharmaceutical use  
Responsibility of final labelling lies with the company placing the final product on the market.*

*- According to Regulation 1999/3/EC, and its modifications, has not been ionized.*

*- According to the Regulations 2001/18/EC, 1829/2003 and 1830/2003, and its modifications, the above mentioned item does not contain deliberately added GMO. (fortuitous or technically inevitable traces could be detected at less than 0,9%)*

*- The product does not contain TSE/BSE substances*

**Laboratory Manager**

**Aude ATTICOT**

Quality Control Department

Certificate of Analysis

Handed over by:



Product Name	: melotime		
Generic Name	:melotime - Melatonin SR Granules		
AR No	: 40000112384	Page No	: 1 of 3
TDS Reference No.	: NFT0052	Version No.	: 2.0
Batch No.	: N05223003	Mfg Date	: May.2023
Report Date	: 29.05.2023	Best Before	: Apr.2025

Sr. No.	Test	Specification	Results
01	Description	Off-white to pale yellow granular powder	Complies
02	Loss on Drying	Not more than 5.0 % w/w	0.27 % w/w
03	Bulk Density (Tapped)	Not less than 0.5 g/mL	0.629 g/ml
04	Particle Size	Not less than 90% passing through ASTM # 50 sieve	100%
05	Solubility	Insoluble in water	Complies
06	Total Ash	Not more than 5.0%	Complies
07	Assay (By HPLC)	Not less than 45 % w/w	47.6 % w/w
08	In-vitro Dissolution Test		
	1 Hour	Not more than 60%	34%
	4 Hours	Not less than 70%	73%
	8 Hours	Not less than 80%	86%



Handed over by:



Quality Control Department

Certificate of Analysis

Product Name	: melotime		
Generic Name	:melotime - Melatonin SR Granules		
AR No	: 40000112384	Page No	: 2 of 3
TDS Reference No.	: NFT0052	Version No.	: 2.0
Batch No.	: N05223003	Mfg Date	: May.2023
Report Date	: 29.05.2023	Best Before	: Apr.2025

Sr. No.	Test	Specification	Results
09	Heavy Metals Content of Lead	Not more than 0.5 ppm	Complies
	Content of Mercury	Not more than 0.1 ppm	Complies
	Content of Arsenic	Not more than 1.0 ppm	Complies
	Content of Cadmium	Not more than 0.5 ppm	Complies
10	Microbiological Analysis Total Plate Count	Less than 1000 CFU/g	Complies
	Total Combined Yeast and Mould Count	Less than 100 CFU/g	Complies
	Escherichia coli	Less than 3 MPN/g	Complies
	Salmonella species	Absent / 25g	Complies
	Staphylococcus species	Less than 10 CFU/g	Complies
	Coliforms	Less than 10 CFU/g	Complies

Quality Control Department

Certificate of Analysis

Handed over by:





Product Name	: melotime		
Generic Name	:melotime - Melatonin SR Granules		
AR No	: 40000112384	Page No	: 3 of 3
TDS Reference No.	: NFT0052	Version No.	: 2.0
Batch No.	: N05223003	Mfg Date	: May.2023
Report Date	: 29.05.2023	Best Before	: Apr.2025

Sr. No.	Test	Specification	Results
11	Residual Solvents Ethanol	Not more than 5000 ppm	Complies

**REMARK :**

Sample conforms as per finished product specification.

Prepared By / Date & Time	Approved By / Date & Time
 Mahendra Tarade 29.05.2023 16:09:56	 Jaya Jadhav 29.05.2023 16:57:05
Section Head -QC	Head-QC



## Certificate of Analysis

### General Information

<b>Product</b>	Remy O DR6	<b>Production Date</b>	06/09/2023	(dd/mm/yyyy)
<b>Batch</b>	2320341590	<b>Best before</b>	05/09/2027	(dd/mm/yyyy)
<b>Issued by</b>	Quality Control Management	<b>Date CoA Issued</b>	21/02/2024	(dd/mm/yyyy)

### Results of analyses

Parameter	Result	Unit	Method <sup>(1)</sup>	LSL	USL
<b>Physical and Chemical Parameters</b>					
Moisture	8	g/100g	ISO 712	≤	14
Protein content (N*6,25) on DM	4,7	g/100g d.m.	ISO 1871 <sup>(1)</sup>	≤	7,0
Ash content on DM	0,3	g/100g d.m.	ISO 3593	≤	1,0
<b>Rheological Parameters</b>					
Starting gel point, pH as is, 6%	80	°C	Brabender	≥	60
End viscosity, pH as is, 6%	600	BU	Brabender	≥	500
<b>Microbiological Parameters</b>					
Salmonella (/375g)	Negative	/375g	ISO 6579		Negative
Total mesophilic bacteria (aerobic)	100	cfu/g	ISO 4833	≤	100.000
Yeasts and Moulds	10	cfu/g		≤	1.000
Enterobacteriaceae	<10	cfu/g		≤	100

<sup>(1)</sup> 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

**CERTIFICATE OF ANALYSIS  
EMPTY HARD CAPSULES OF VEGETABLE ORIGIN**

**CUSTOMER:** GOCAPS GMBH

**LOT No.:** K2311001888      **PRODUCT CODE:** K00003G      **SIZE:** 0

**PURCHASE ORDER NUMBER:** PO2000574      **CHARGE No.:** 1-000759      **ART No.:** 56-000991

**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 C.I. FARMACAPSULAS S.A.S. 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	%
<p><i>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.</i></p> <p><i>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.</i></p>			

Date of Manufacture: 2023-12      Expiration Date: 2028-12

CRITERIA	METHOD / REFERENCE	SPECIFICATIONS	RESULTS
<b>PHYSICAL</b>			
Average Capsule Weight	DCC-MI-P003/ USP<2091>	103.00-115.00 mg	106.7
Loss on drying	DCC-MA-P027	4.00-8.00 %	4.5
Disintegration	DCC-MA-P063/ USP<701>	N.M.T. 15 min	PASSES
Residue on Ignition *	USP	N.M.T. 1.5% Transparent Capsules	PASSES
		N.M.T. 6.0% Colored Capsules	
Identification of HPMC	DCC-MA-P073 / USP	Meets USP Requirements	PASSES
<b>ANALYTICAL</b>			
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 Frequency 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.

*Jina Otero*  
Quality Assurance

Date: 2023/12/26



Code: DCC-032G (Valid since November 1<sup>st</sup>, 2021)  
Edition 7