CERTIFICAT DE CONFORMITE

DATE

VERSION N°1

POUR LE CLIENT | NUV

Je soussigné [redacted] 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	NUVSOM01
Désignation interne	COMPLEXE SOMMEIL
Code client	3 052361 247983
Désignation client	FORMULE SOMMEIL

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

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	429,3mg

Type de conditionnement	Piluliers	Quantité par colis	30*50
Quantité conditionnée	1545	Cartons incomplets	1*45

Autres (dont fond de bol)	

COMPOSITION PRODUIT

INGREDIENT(S)	DOSAGE	PV interne	N°LOT FOURNISSEUR
ES Passiflore feuille	100mg	[illegible]	[illegible]
ES Melisse feuille	100mg	[illegible]	[illegible]
Amidon de riz	100mg	[illegible]	[illegible]
ES Escholzia	75mg	[illegible]	[illegible]
ES Houblon cône	50mg	[illegible]	[illegible]
Mélotime (Mélatonine granular)	4,3mg	[illegible]	[illegible]

[illegible]

Service qualité

[redacted]

K-CAPS®
Capsules of Vegetable Origin

CERTIFICATE OF ANALYSIS
EMPTY HARD CAPSULES OF VEGETABLE ORIGIN

CUSTOMER: [redacted]
LOT No.: [redacted] **PRODUCT CODE:** K00003G **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	106.7
Loss on drying	DCC-MA-P027	3.00-8.00 %	4.1
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	170
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] (Valid since [redacted])
Edition 9

[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	7	g/100g	ISO 712		≤ 14
Protein content (N*6,25) on DM	4,7	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%	78	°C	Brabender	≥ 60	
End viscosity, pH as is, 6%	627	BU	Brabender	≥ 500	
Microbiological Parameters					
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

(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 .

Quality Control Department

Certificate of Analysis

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.	:	Mfg Date	:
Report Date	:	Best Before	:

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%

[redacted]

Handed over By: [redacted]

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.	: [redacted]	Mfg Date	: [redacted]
Report Date	: [redacted]	Best Before	: [redacted]

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

[redacted]

Handed over by: [redacted]

Quality Control Department

Certificate of Analysis

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.	: [redacted]	Mfg Date	: [redacted]
Report Date	: [redacted]	Best Before	: [redacted]

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
[redacted]	[redacted]
Section Head -QC	Head-QC

Disclaimer: Software generated document with electronic signature Print Date and Time : [redacted]

CERTIFICATE OF ANALYSES

HOPS CO 0.035% DE
PR1968

Batch: [redacted] COA Version:1 Edition date: [redacted]
Manufactured: [redacted] Best before: [redacted]

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	*Powder*		*Powder*
Color	*Light brown to dark brown*		*Beige*
Solubility	*To be tested following the degree of incorporation*		*Not done*

ANALYSES

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

CONTAMINANTS

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

[redacted]

CERTIFICATE OF ANALYSES

HOPS CO 0.035% DE
PR1968

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

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

CERTIFICATE OF ANALYSES

CALIFORNIA POPPY AP 2 500 PPM DE PR1704

Batch: [redacted] COA Version:1 Edition date: [redacted]

Manufactured: [redacted] Best before: [redacted]

Botanical kind: *Papaveraceae Eschscholzia californica Cham.*

Part of the plant: *Aerial part*

Extraction solvent(s): *Water*

Carrier(s): *Wheat maltodextrin*

Silicon dioxide [nano] if needed ≤ 2%

DESCRIPTION

	Specifications	Method and reference	Result
Appearance	*Powder*		*Powder*
Color	*Beige to brown*		*Brown greenish*
Solubility	*To be tested following the degree of incorporation*		*Not done*

ANALYSES

	Specifications		Method and reference	Result
	Min	Max		
Total alkaloids expressed as californidine content [ppm]	*> 2 500*	*-*	*AE-38 - Titrimetry, Fr. Ph. (January 1996 adapted), "Eschscholtzia (partie aérienne fleurie)" monograph*	*2 509*
Californidine content [%] *(4)*	*Indicative value*		*AE-139 - LC-MS, internal method*	*Complies (4)*
Identification (raw material) *(4)*	*Complies*		*MO-81 - TLC, Fr. Ph. (1996),"Eschscholtzia (parties aériennes fleuries d')" monograph*	*Complies (4)*
Silica [nano] content (if necessary) [%]	*-*	*< 2.00*		*0.00*
Loss on drying [%] *(11)*	*-*	*< 8.00*	*MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)*	*Not done*
Bulk density	*0.30*	*0.70*	*MO-181 - Eur. Ph. (04/2019:20934)*	*0.52*
pH (1% in demineralized water) *(11)*	*3.0*	*6.5*	*MO-03 - pH-meter, Eur. Ph. (07/2016:20203),"Potentiometric determination of pH" monograph*	*6.5*
Screening [% < 500 µm]	*95.0*	*-*	*MO-184 - Granulometer, internal method*	*100.0*

CONTAMINANTS

	Specifications		Method and reference	Result
	Min	Max		

[redacted]

CERTIFICATE OF ANALYSES

CALIFORNIA POPPY AP 2 500 PPM DE PR1704

Batch: [redacted] COA Version:1 Edition date: [redacted]

Manufactured: [redacted] Best before: [redacted]

Pb content [ppm] *(4)*	-	*< 3.00*	*AE-01 - ICP, internal method*	*Complies (4)*
Cd content [ppm] *(4)*	-	*< 1.00*	*AE-01 - ICP, internal method*	*Complies (4)*
Hg content [ppm] *(4)*	-	*< 0.10*	*AE-01 - ICP, internal method*	*Complies (4)*
As content [ppm] *(4)*	-	*< 1.00*	*AE-01 - ICP, internal method*	*Complies (4)*
Pesticides content [ppm] *(4)*	*< Residual Maximum Limit fixed in European regulation 396/2005 and its modifications*		*AE-02 - GC-MSMS/LC-MSMS, internal method*	*Complies (4)*
Benzo(a)pyrene content [ppb] *(4)*	-	*< 10.0*	*AE-03 - GC-MS-MS, internal method*	*Complies (4)*
Pahs (sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene) content [ppb] *(4)*	-	*< 50.0*	*AE-03 - GC-MS-MS, internal method*	*Complies (4)*
Pyrrolizidine alkaloids content [ppb]	-	*< 3 800*	*AE-61 - LC-MSMS, internal method*	*633*

MICROBIOLOGY	**Specifications**		**Method and reference**	**Result**
	Min	**Max**		
Total aerobic microbial count [CFU/g] *(1)*	-	*< 10 000*	*MO-191 - Pétrifilm TM / ISO 4833*	*1 062*
Total yeasts/moulds count [CFU/g] *(1)*	-	*< 100*	*MO-192 - Pétrifilm TM / AOAC 997.02*	*12*
Salmonella content [/25g]	*Absent*		*MO-193 - TECRA TM / ISO 6579*	*Absent*
Enterobacteria content [CFU/g]	-	*< 100*	*MO-194 - Pétrifilm TM ISO 21528-2*	*< 10*
Escherichia coli content [CFU/g]	-	*< 10*	*MO-195 - Pétrifilm TM / ISO 16649-2*	*< 10*

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

[redacted]

CERTIFICATE OF ANALYSES

CALIFORNIA POPPY AP 2 500 PPM DE PR1704

Batch: [redacted] COA Version:1 Edition date: [redacted]

Manufactured: [redacted] Best before: [redacted]

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

[redacted]

CERTIFICATE OF ANALYSES

LEMON BALM LE 5% DE
PR1096

Batch: [redacted] COA Version:1 Edition date: [redacted]

Manufactured: [redacted] Best before: [redacted]

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	*Powder*		*Powder*
Color	*Beige to brown*		*Light brown*
Solubility	*To be tested following the degree of incorporation*		*Not done*

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)*	*Indicative value*		*AE-22 - GC-MS, internal method for aromatic substances*	*Complies (4)*
Methyleugenol content [ppm] *(4)*	*Indicative value*		*AE-22 - GC-MS, internal method for aromatic substances*	*Complies (4)*
Identification (raw material) *(4)*	*Complies*		*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		

CERTIFICATE OF ANALYSES

LEMON BALM LE 5% DE
PR1096

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

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

CERTIFICATE OF ANALYSES

LEMON BALM LE 5% DE
PR1096

Batch: [redacted] COA Version:1 Edition date: [redacted]

Manufactured: [redacted] Best before: [redacted]

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	*Powder*		*Powder*
Color	*Beige to brown*		*Light brown*
Solubility	*To be tested following the degree of incorporation*		*Not done*

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)*	*Indicative value*		*AE-22 - GC-MS, internal method for aromatic substances*	*Complies (4)*
Methyleugenol content [ppm] *(4)*	*Indicative value*		*AE-22 - GC-MS, internal method for aromatic substances*	*Complies (4)*
Identification (raw material) *(4)*	*Complies*		*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		

[redacted]

CERTIFICATE OF ANALYSES

LEMON BALM LE 5% DE
PR1096

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

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

CERTIFICATE OF ANALYSES

PASSION FLOWER AP 3.5% DE
PR3137

Batch: [redacted] COA Version:1 Edition date: [redacted]

Manufactured: [redacted] Best before: [redacted]

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	*Powder*		*Powder*
Color	*Brown to brown greenish*		*Brown*
Solubility	*To be tested following the degree of incorporation*		*Not done*

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*	*3.52*
Vitexin content [%] *(4)*	*Indicative value*		*AE-37 - HPLC, internal method*	*Complies (4)*
Hyperosid content [%] *(4)*	*Indicative value*		*AE-23 - HPLC, internal method*	*Complies (4)*
Identification (raw material) *(4)*	*Complies*		*MO-71 - TLC, Eur. Ph. (01/2008 :1882), "Passion flower dry extract" monograph*	*Complies (4)*
Loss on drying [%]	-	*8.00*	*MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)*	*3.87*
Bulk density	*0.30*	*0.70*	*MO-181 - Eur. Ph. (04/2019:20934)*	*0.57*
Total ash content [%]	-	*< 15.00*	*MO-01 - Muffle furnace, Eur. Ph. (01/2008:20416), "Total ash" adapted monograph*	*Complies*
pH (1% in demineralized water)	*3.0*	*6.5*	*MO-03 - pH-meter, Eur. Ph. (07/2016:20203),"Potentiometric determination of pH" monograph*	*5.5*
Screening [% < 180 µm]	*95.0*	-	*MO-184 - Granulometer, internal method*	*97.5*

CONTAMINANTS

	Specifications		Method and reference	Result
	Min	Max		

[redacted]

CERTIFICATE OF ANALYSES

PASSION FLOWER AP 3.5% DE

PR3137

Batch: [redacted] COA Version:1 Edition date: [redacted]

Manufactured: [redacted] Best before: [redacted]

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

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

[redacted]

CERTIFICATE OF ANALYSES

PASSION FLOWER AP 3.5% DE
PR3137

Batch: [redacted] COA Version:1 Edition date: [redacted]

Manufactured: [redacted] Best before: [redacted]

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

[redacted]

CERTIFICATE OF ANALYSES

PASSION FLOWER AP 3.5% DE
PR3137

Batch: [redacted] COA Version:1 Edition date: [redacted]

Manufactured: [redacted] Best before: [redacted]

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	*Powder*		*Powder*
Color	*Brown to brown greenish*		*Brown*
Solubility	*To be tested following the degree of incorporation*		*Not done*

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)*	*Indicative value*		*AE-37 - HPLC, internal method*	*Complies (4)*
Hyperosid content [%] *(4)*	*Indicative value*		*AE-23 - HPLC, internal method*	*Complies (4)*
Identification (raw material) *(4)*	*Complies*		*MO-71 - TLC, Eur. Ph. (01/2008 :1882), "Passion flower dry extract" monograph*	*Complies (4)*
Loss on drying [%]	-	*8.00*	*MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)*	*Complies*
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*	*Complies*
pH (1% in demineralized water)	*3.0*	*6.5*	*MO-03 - pH-meter, Eur. Ph. (07/2016:20203),"Potentiometric determination of pH" monograph*	*Complies*
Screening [% < 180 µm]	*95.0*	-	*MO-184 - Granulometer, internal method*	*98.6*

OTHER ANALYSIS

	Specifications		Method and reference	Result
	Min	Max		

[redacted]

CERTIFICATE OF ANALYSES

PASSION FLOWER AP 3.5% DE
PR3137

Batch: [redacted] COA Version:1 Edition date: [redacted]

Manufactured: [redacted] Best beforeSun, [redacted]

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

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

[redacted]

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)
- 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