

	CERTIFICAT DE CONFORMITE	DATE 
		VERSION N°1

POUR LE CLIENT

NUV



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	NUVSOM01		
Désignation interne	COMPLEXE SOMMEIL		
Code client	3 052361 247983		
Désignation client	FORMULE SOMMEIL		
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'agriculture 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		Taille	Taille 0
Lot Fournisseur gélules		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		
ES Melisse feuille	100mg		
Amidon de riz	100mg		
ES Escholzia	75mg		
ES Houblon cône	50mg		
Mélotime (Mélatonine granular)	4,3mg		

 Service qualité

CERTIFICATE OF ANALYSIS

EMPTY HARD CAPSULES OF VEGETABLE ORIGIN

CUSTOMER: XXXXXXXXXX			
LOT No.: XXXXXXXXXX	PRODUCT CODE: K00003G	SIZE: 0	
PURCHASE ORDER NUMBER: XXXXXXXXXX	CHARGE No.: XXXXXXXXXX	ART No.: XXXXXXXXXX	
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 XXXXXXXXXX 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	%	
<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. 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>			

Date of Manufacture: XXXXXXXXXX

Expiration Date: XXXXXXXXXX

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 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.

Approval by: XXXXXXXXXX

Quality Assurance

Date: XXXXXXXXXX

Code: XXXXXXXXXX

(Valid since XXXXXXXXXX)

Edition 9



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

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.	:	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%

Quality Control Department

Certificate of Analysis

Handed over by

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.	:	Mfg Date	:
Report Date	:	Best Before	:

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.	:	Mfg Date	:
Report Date	:	Best Before	:

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
	
Section Head -QC	Head-QC

CERTIFICATE OF ANALYSES

HOPS CO 0.035% DE PR1968

Batch:
Manufactured:

COA Version:1

Edition date:
Best before:

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 [%]	> 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)

CERTIFICATE OF ANALYSES

HOPS CO 0.035% DE PR1968

Pesticides content [ppm] (4)	< <i>Residual Maximum Limit fixed in European regulation 396/2005 and its modifications</i>		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/ 24

DMD (in months) :

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 $\leq 2\%$

DESCRIPTION

DESCRIPTION	Specifications	Method and reference	Result
Appearance	<i>Powder</i>		<i>Powder</i>
Color	<i>Beige to brown</i>		<i>Brown greenish</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 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		

CERTIFICATE OF ANALYSES

CALIFORNIA POPPY AP 2 500 PPM DE PR1704

Batch: _____

COA Version:1

Edition date: _____

Manufactured: _____

Best before: _____

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/ 24

DMD (in months) :

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

CERTIFICATE OF ANALYSES

CALIFORNIA POPPY AP 2 500 PPM DE PR1704

Batch:

COA Version:1

Edition date:

Manufactured:

Best before:

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	<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)	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/ 24
DMD (in months) :
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	<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)	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/ 24
DMD (in months) :
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:

COA Version:1

Edition date:

Manufactured:

Best before:

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	3.52
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		

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/ 24

DMD (in months) :

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

CERTIFICATE OF ANALYSES

PASSION FLOWER AP 3.5% DE PR3137

Batch:

COA Version:1

Edition date:

Manufactured:

Best before:

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:

COA Version:1

Edition date:

Manufactured:

Best before:

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)	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		

CERTIFICATE OF ANALYSES

PASSION FLOWER AP 3.5% DE PR3137

Batch: [REDACTED]

COA Version:1

Edition date: [REDACTED]

Manufactured: [REDACTED]

Best before Sun, [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/ 24
DMD (in
months) :

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

