

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

POUR LE CLIENT

NUV

NOVOMA SARL
3 BIS AVENUE MARCEL LANGER
31 000 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	NUVSOM01
Désignation interne	COMPLEXE SOMMEIL

Code client	
Désignation client	FORMULE SOMMEIL

Numéro de lot	D16219	Numéro de BL	20387-20403-20404
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Date de fabrication	10/01/2023	DDM	31/01/2026
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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
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Le produit contient de(s) Allergène(s)	Non
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Liste des allergène(s) dans le produit

Non applicable

Le produit contient de(s) Additif(s)	Non
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Liste de(s) additif(s) dans le produit

Non applicable

Le produit est BIO	Non
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(*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
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Le produit est sans Gluten	Non
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Conforme Végétarien	Oui	Conforme Végétalien	Oui
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Conforme Halal	Oui	Conforme Casher	Oui
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FOR CTR 01 CC



Type de produit	Gélules HPMC	Couleur	Transparente
PV interne gélules	23701	Taille	Taille 0
Lot Fournisseur gélules	1-000263	Dosage	425,95mg

Type de conditionnement	Piluliers	Quantité par colis	(14+4)*107
Quantité conditionnée	1941 + 443	Cartons incomplets	1*15

Autres (dont fond de bol)

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COMPOSITION PRODUIT

INGREDIENT(S)	DOSAGE	PV interne	N°LOT FOURNISSEUR
ES Passiflore feuille	100mg	22095-23706	P21120823-P22111007
ES Melisse feuille	100mg	22758	P22062402
Amidon de riz	100mg	23673	2220242950
ES Escholzia	75mg	21578-22096	P21081630-P21090905
ES Houblon cône	50mg	21526-23690	P21071216-P22041107
Mélatonine végétale issue du millepertuis	0,95mg	21778	7X0010

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 432 694 354

31/01/23
Service qualité



CERTIFICATE OF ANALYSES

**PASSION FLOWER AP 3.5% DE
PR3137**

Batch: P22111007

COA Version:1

Edition date: Tue, 22 Nov 2022

Manufactured: Mon, 21 Nov 2022

Best before: Thu, 21 Nov 2024

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 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 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)	5.10
Bulk density	0.30	0.70	MO-181 - Eur. Ph. (04/2019:20934)	0.61
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	5.7
Screening [% < 180 µm]	95.0	-	MO-184 - Granulometer, internal method	99.6

CONTAMINANTS

	Specifications		Method and reference	Result
	Min	Max		

Tel. : +33 (0)1 60 16 69 25 - Fax. : 33 (0)1 60 16 69 37

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**

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)
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)
Benzo(a)pyrene content [ppb] (4)	-	< 10.0	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)	9 846
Total yeasts/moulds count [CFU/g] (1)	-	< 100	AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)	69
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)	32
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

**PASSION FLOWER AP 3.5% DE
PR3137**

**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: P21120823

COA Version:1 (Partial)

Edition date: Mon, 13 Dec 2021

Manufactured: Fri, 10 Dec 2021

Shelf life: Sun, 10 Dec 2023

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 [%]	<i>> 3.50</i>	<i>-</i>	<i>MO-09 - UV-Vis, Fr. Ph. (1993), "Extrait de passiflore (sec)" monograph</i>	<i>3.51</i>
Vitexin content [%] (4)	<i>Indicative value</i>		<i>AE-37 - HPLC, internal method</i>	<i>Complies (4)</i>
Hyperosid content [%] (4)	<i>Indicative value</i>		<i>AE-23 - HPLC, internal method</i>	<i>Complies (4)</i>
Identification (raw material) (4)	<i>Complies</i>		<i>MO-71 - TLC, Eur. Ph. (01/2008 :1882), "Passion flower dry extract" monograph</i>	<i>Complies (4)</i>
Loss on drying [%]	<i>-</i>	<i>8.00</i>	<i>MO-183 - Eur. Ph. (01/2008:20817) and (02/2008:20816)</i>	<i>3.69</i>
Bulk density	<i>0.30</i>	<i>0.70</i>	<i>MO-181 - Eur. Ph. (04/2019:20934)</i>	<i>0.60</i>
Total ash content [%]	<i>-</i>	<i>< 15.00</i>	<i>MO-01 - Muffle furnace, Eur. Ph. (01/2008:20416), "Total ash" adapted monograph</i>	<i>Complies</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>5.4</i>
Screening [% < 180 µm]	<i>95.0</i>	<i>-</i>	<i>MO-184 - Granulometer, internal method</i>	<i>97.1</i>

CONTAMINANTS

	Specifications		Method and reference	Result
	Min	Max		

Tel. : +33 (0)1 60 16 69 25 - Fax. : 33 (0)1 60 16 69 37

Z.A.C. de la Noue Rousseau - 6, rue d'Alembert - CS 50006 - 91241 SAINT MICHEL SUR ORGE CEDEX - FRANCE

SAS au capital de 1.7000.000 € - 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**

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)
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)
Benzo(a)pyrene content [ppb] (4)	-	< 10.0	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)	309
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

Shelf life/ DMD 24
(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**

**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: P22062402

COA Version:1

Edition date: Fri, 01 Jul 2022

Manufactured: Mon, 27 Jun 2022

Shelf life: Thu, 27 Jun 2024

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)	4.02
Bulk density	0.40	0.80	MO-181 - Eur. Ph. (04/2019:20934)	0.70
pH (1% in demineralized water)	4.0	6.5	MO-03 - pH-meter, Eur. Ph. (07/2016:20203), "Potentiometric determination of pH" monograph	5.0
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)
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)
Benzo(a)pyrene content [ppb] (4)	-	< 10.0	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)	238
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

Shelf life/ DMD 24
(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

**HOPS CO 0.035% DE
PR1968**

Batch: P22041107

COA Version:2

Edition date: Tue, 17 May 2022

Manufactured: Tue, 12 Apr 2022

Shelf life: Fri, 12 Apr 2024

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>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		
Isoquercitrin content [%]	<i>> 0.035</i>	<i>-</i>	<i>AE-74 - HPLC, internal method</i>	<i>0.039</i>
8-Prenylnaringenin content [ppm]	<i>-</i>	<i>< 200.00</i>	<i>AE-73 - HPLC, internal method</i>	<i>Complies</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>2.41</i>
Bulk density	<i>0.45</i>	<i>0.70</i>	<i>MO-181 - Eur. Ph. (04/2019:20934)</i>	<i>0.56</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>5.7</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>< 3.00</i>	<i>AE-01 - ICP, internal method</i>	<i>Complies (4)</i>
Cd content [ppm] (4)	<i>-</i>	<i>< 1.00</i>	<i>AE-01 - ICP, internal method</i>	<i>Complies (4)</i>
Hg content [ppm] (4)	<i>-</i>	<i>< 0.10</i>	<i>AE-01 - ICP, internal method</i>	<i>Complies (4)</i>



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)
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)
Benzo(a)pyrene content [ppb] (4)	-	< 10.0	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

Shelf life/ DMD 24
(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

**HOPS CO 0.035% DE
PR1968**

Batch: P21071215
Manufactured: Thu, 22 Jul 2021

COA Version:1

Edition date: Fri, 23 Jul 2021
Shelf life: Sat, 22 Jul 2023

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>Light brown orangish</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>> 0.035</i>	<i>-</i>	<i>AE-74 - HPLC, internal method</i>	<i>0.035</i>
8-Prenylnaringenin content [ppm]	<i>-</i>	<i>< 200.00</i>	<i>AE-73 - HPLC, internal method</i>	<i>198</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>2.33</i>
Bulk density	<i>0.45</i>	<i>0.70</i>	<i>MO-181 - Eur. Ph. (04/2019:20934)</i>	<i>0.45</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>5.4</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		
Cd content [ppm] (4)	<i>-</i>	<i>< 1.00</i>	<i>AE-01 - ICP, internal method</i>	<i>Complies (4)</i>
Hg content [ppm] (4)	<i>-</i>	<i>< 0.10</i>	<i>AE-01 - ICP, internal method</i>	<i>Complies (4)</i>
As content [ppm] (4)	<i>-</i>	<i>< 3.00</i>	<i>AE-01 - ICP, internal method</i>	<i>Complies (4)</i>



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>		<i>AE-02 - GC-MSMS/LC-MSMS, internal method</i>	<i>Complies (4)</i>
Pahs (sum of benzo(a) pyrene, benz(a) anthracene, benzo(b) fluoranthene and chrysene) content [ppb] (4)	-	< 50.0	<i>AE-03 - GC-MS-MS, internal method</i>	<i>Complies (4)</i>
Benzo(a)pyrene content [ppb] (4)	-	< 10.0	<i>AE-03 - GC-MS-MS, internal method</i>	<i>Complies (4)</i>

MICROBIOLOGY	Specifications		Method and reference	Result
	Min	Max		
Total aerobic microbial count [CFU/g] (1)	-	< 10 000	<i>AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)</i>	<i>2 403</i>
Total yeasts/moulds count [CFU/g] (1)	-	< 100	<i>AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)</i>	<i>24</i>
Salmonella content [/25g]	<i>Absent</i>		<i>AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)</i>	<i>Absent</i>
Bile-tolerant Gram negative bacteria content [CFU/g]	-	< 100	<i>AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)</i>	<i>< 10</i>
Escherichia coli content [/g]	<i>Absent</i>		<i>AE-04 - Eur. Ph. (07/2010:20612) and (01/2014:20631)</i>	<i>Absent</i>

(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

Shelf life/ DMD 24
(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 ANALYSIS

CALIFORNIAN POPPY AP 0.250%

Ref: PR 1704

Batch: P21081630
Manufactured: 17.08.2021

Date: 2021, August 19th
Shelf life: 17.08.2023

CONTROLS

Botanical kind
Plant part
Extraction solvent
Description

Carriers

Solubility

Bulk density
(Eur. Ph. VIII° Ed. 2.9.34)

Loss on drying
(Eur. Ph. VIII° Ed. 2.8.17)

pH
(Eur. Ph. VIII° Ed. 2.2.3)

Screening
(Internal method)

*Heavy metals (Control plan)**
(ICP, Internal method)

Pb
Cd
Hg
As

*Pesticides (Control plan)**
(GC-MSMS/LC-MSMS, Internal method)

*PAH (Control plan)**

PaHs (sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene)
(GC-MS, internal method)

Benzo(a)pyrene
(GC-MS, internal method)

Identification (On raw material) (Control plan)*
(TLC, Eur. Ph. VIII° Ed. 2.2.27) (=MO-81)

Assay

(Titrimetry, Fr. Ph. XI° Ed. (1996) adapted "Eschscholtzia (aerial parts of)" monograph)

SPECIFICATIONS

Papaveraceae Eschscholtzia californica Cham.

Aerial part

Water

Beige to brown powder

Wheat maltodextrin
Silicon dioxide [nano] if needed ≤ 2%

To be tested following the degree of incorporation

0.30 - 0.70

≤ 8.00%

3.0 – 6.5 (1% in demineralised water)

Min. 95% < 500 µm

< 3.00 ppm
< 1.00 ppm
< 0.10 ppm
< 1.00 ppm

<Residual Maximum Limit fixed in European regulation 396/2005 and its modifications

< 50 µg/kg

< 10 µg/kg

Complies with "Eschscholtzia (aerial parts of)" monograph, Fr. Ph. XI° Ed (1996)

≥ 0.250% Total alkaloids expressed as californidine

RESULTS

Standard
Standard
Standard
Light brown powder
Standard
0.00%
0.53
4.00%
5.5
Standard

*Complies**
*Complies**
*Complies**
*Complies**

*Complies**

*Complies**

*Complies**

*Complies**

0.25%

CERTIFICATE OF ANALYSIS

CALIFORNIAN POPPY AP 0.250%

Ref: PR 1704

Batch: P21081630
Manufactured: 17.08.2021

Date: 2021, August 19th
Shelf life: 17.08.2023

CONTROLS

SPECIFICATIONS

RESULTS

MICROBIOLOGY

(Eur. Ph. VIII° Ed. 2.6.12 and 2.6.31)

Total aerobic microbial count

< 10 000 CFU / g**

1 541 CFU / g

Total yeasts/moulds count

< 100 CFU / g**

< 10 CFU / g

Salmonella

Absent / 25g

Absent / 25g

Bile-tolerant Gram negative bacteria

< 100 CFU / g

< 10 CFU / g

Escherichia coli

Absent / g

Absent / g

* HACCP based control plan defined annually according to risk analysis

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

Storage: Keep in a dry and clean place, protected from light.

QUALITY CONTROL



Laboratory Manager

CERTIFICATE OF ANALYSIS

CALIFORNIAN POPPY AP 0.250%

Ref: PR 1704

Batch: P21090905
Manufactured: 27.10.2021

Date: 2021, December 09th
Shelf life: 27.10.2023

CONTROLS

Botanical kind
Plant part
Extraction solvent
Description

Carriers

Solubility

Bulk density
(Eur. Ph. VIII° Ed. 2.9.34)

Loss on drying
(Eur. Ph. VIII° Ed. 2.8.17)

pH
(Eur. Ph. VIII° Ed. 2.2.3)

Screening
(Internal method)

*Heavy metals (Control plan)**
(ICP, Internal method)

Pb
Cd
Hg
As

*Pesticides (Control plan)**
(GC-MSMS/LC-MSMS, Internal method)

*PAH (Control plan)**

*PaHs (sum of benzo(a)pyrene, benz(a)anthracene,
benzo(b)fluoranthene and chrysene)*
(GC-MS, internal method)

Benzo(a)pyrene
(GC-MS, internal method)

Identification (On raw material) (Control plan)*
(TLC, Eur. Ph. VIII° Ed. 2.2.27) (=MO-81)

Assay

*(Titrimetry, Fr. Ph. XI° Ed. (1996) adapted
"Eschscholtzia (aerial parts of)" monograph)*

SPECIFICATIONS

Papaveraceae Eschscholtzia californica Cham.

Aerial part

Water

Beige to brown powder

Wheat maltodextrin

Silicon dioxide [nano] if needed ≤ 2%

To be tested following the degree of incorporation

0.30 - 0.70

≤ 8.00%

3.0 – 6.5 (1% in demineralised water)

Min. 95% < 500 µm

< 3.00 ppm

< 1.00 ppm

< 0.10 ppm

< 1.00 ppm

*<Residual Maximum Limit fixed in European regulation
396/2005 and its modifications*

< 50 µg/kg

< 10 µg/kg

*Complies with "Eschscholtzia (aerial parts of)"
monograph, Fr. Ph. XI° Ed (1996)*

≥ 0.250% Total alkaloids expressed as californidine

RESULTS

Standard

Standard

Standard

*Light brown
yellowish powder*

Standard

0.00%

0.59

3.54%

4.0

Standard

*Complies**

*Complies**

*Complies**

*Complies**

*Complies**

*Complies**

*Complies**

*Complies**

0.250%

CERTIFICATE OF ANALYSIS

CALIFORNIAN POPPY AP 0.250%

Ref: PR 1704

Batch: P21090905
Manufactured: 27.10.2021

Date: 2021, December 09th
Shelf life: 27.10.2023

CONTROLS

SPECIFICATIONS

RESULTS

MICROBIOLOGY

(Eur. Ph. VIII° Ed. 2.6.12 and 2.6.31)

Total aerobic microbial count

< 10 000 CFU / g**

4 550 CFU / g

Total yeasts/moulds count

< 100 CFU / g**

< 10 CFU / g

Salmonella

Absent / 25g

Absent / 25g

Bile-tolerant Gram negative bacteria

< 100 CFU / g

< 10 CFU / g

Escherichia coli

Absent / g

Absent / g

* HACCP based control plan defined annually according to risk analysis

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

Storage: Keep in a dry and clean place, protected from light.

QUALITY CONTROL

Laboratory Manager



Certificate of Analysis

General Information

Product	Remy O DR6	Production Date	05/06/2022	(dd/mm/yyyy)
Batch	2220242950	Best before	04/06/2026	(dd/mm/yyyy)
Issued by	Quality Control Management	Date CoA Issued	21/06/2022	(dd/mm/yyyy)

Results of analyses

Parameter	Result	Unit	Method ⁽¹⁾	LSL	USL
Physical and Chemical Parameters					
Moisture	12	g/100g	ISO 712	≤	14
Protein content (N*6,25) on DM	4,9	g/100g d.m.	ISO 1871 ⁽¹⁾	≤	6,0
Ash content on DM	0,2	g/100g d.m.	ISO 3593	≤	1,0
Rheological Parameters					
Starting gel point, pH as is, 6%	83	°C	Brabender	≥	60
End viscosity, pH as is, 6%	571	BU	Brabender	≥	500
Microbiological Parameters					
Total mesophilic bacteria (aerobic)	62.000	cfu/g	ISO 4833	≤	100.000
Yeasts and Moulds	400	cfu/g	ISO 21527	≤	1.000
Enterobacteriaceae	<10	cfu/g	ISO 21528	≤	100
Salmonella (/375g)	Negative	/375g	ISO 6579		Negative

⁽¹⁾ or (acknowledged and) validated equivalent

Remarks

Rice starch issued from organic farming, Certisys BE-BIO-01, Certified Organic NOP by bio.inspecta AG

CERTIFICATE OF ANALYSIS EMPTY HARD CAPSULES OF VEGETABLE ORIGIN

CUSTOMER: GOCAPS GMBH			
LOT No.: K2207002018	PRODUCT CODE: K00003	SIZE: 0	
PURCHASE ORDER NUMBER: 2000179	CHARGE No.: 1-000263	ART No.: 56-000107	
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: 2022-08

Expiration Date: 2027-08

CRITERIA	METHOD / REFERENCE	SPECIFICATIONS	RESULTS
PHYSICAL			
Average Capsule Weight	DCC-MI-P003/ USP<2091>	103.00-115.00 mg	107.2
Loss on drying	DCC-MA-P027	4.00-8.00 %	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	PASSES
		N.M.T. 6.0% Colored Capsules	
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	10
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.


 Quality Assurance

Date: 2022/08/30



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

MANUFACTURER ADDRESS: VIA 40 85-48 BARRANQUILLA - COLOMBIA
TELEPHONE: (57-60-5) 330-4100 FAX: (57-60-5) 330-4105