



PRODUCT DOSSIER

Nutrimea

Complex anti-cellulite

GALENIC FORM

Capsules Tablets Soft capsules Powder Liquid

PACKAGING

Vrac Pill jar Blister Paper bag Glass bottle Pill case

Batch num.

2405917

DLUO.

05.2027

Purchase Order

-

Code	PCC6
Edition	1
Date	18.07.2023

Validated by	Cristina Camó
Date	: 08.07.2024

BATCH CERTIFICATE

Product name	Complex anti-cellulite
Batch number	2405917
Customer batch number	-
Manufacturing date	05.2024
Expiry date	05.2027
Description	Brown

Component	Description	Batch number	Amount	Units
CAP0000000	Capsulas T0 HPMC Transparente	202302042	200845	uds
MP00000329	Harina de arroz	2420394630	29700	g
MP00000393	Guarana 12% cafeina	LOT00002516	16499,34	g
MP00003162	Sinetrol Xpur C	XPURC230918	41580	g
MP00003163	Marc de Raisin en polvo	99158	26401,32	g

Component	Description	Batch number	Amount	Units
150AmbNut	Bote 150 ml Ambar Rosca 38 mm Nutrimea	669HEIS	2237	uds
BOL6010060	Bolsa plastico 60 x 100 cm 60 micras	12301367A	12	uds
SE00003159	Complexe Anti-cellulite Nutrimea	2405917	200845	uds
Tapa38PNut	Tapa Rosca 38mm Plateado Nutrimea	M23000667Nutrim	2246	uds

Validated by Cristina Camó Date : 08.07.2024

CERTIFICATE OF ANALYSIS

Product name	Complex anti-cellulite
Batch number	2405917
Customer batch number	-
Manufacturing date	05.2024
Expiry date	05.2027
Description	Brown

MICROBIOLOGICAL TEST RESULTS

Microbiology	Specification (Ph. Eur. 5.1.4)	Results	Test method
Total plate count	< 20.000 cfu/g	1.600 cfu/g Complies	Ph. Eur.
Yeast and mold	< 200 cfu/g	20 cfu/g Complies	Ph. Eur.
<i>Eschericia Coli</i>	Absence/1g	< 10 cfu/g Complies*	Ph. Eur.
<i>Staphylococcus aureus</i>	Absence/1g	< 10 cfu/g Complies*	Ph. Eur.
<i>Salmonella</i>	Absence/10g	Absence 10g Complies	Ph. Eur.
Enterobacteria	< 100 cfu/g	< 10 cfu/g Complies	Ph. Eur.

* There were no growth of E. Coli nor St. Aureus in the -1 concentration plates. Result <10 cfu/g can be considered as absence.

Date of issue	June 03, 2024
Conclusion	Conform



ISO 22000: 2018

<p>Report electronically validated by Cristina Camó - Quality control Date : 08.07.2024</p>
--

Compliance Certificate	
Weighing/mixing	X
Manufacturing	X
Packing	X
Microbiological analysis	X (03.06.2024)

BATCH VALIDATION	
Conforms	X
Non conforms	

<p>Date: 08.07.2024</p> <p>Attachments:</p> <p>- Product specification</p>	<p>PHYTEXTRA, S.L. C/ Banyoles, 12 Vilamalla 17469 CIF. B-55087738 Tel. +34 972 50 69 81</p> <p>Validated by Cristina Camó</p>
--	---

PRODUCT SPECIFICATION	0.1	Product:	Complex Anti-cellulite Nutrimea
	0.2	Version:	08
	0.3	Date:	03 10 2022

1	RESPONSIBILITY: Manufacturing (sieving and mixing) and packaging of food supplements in capsules and powder			
1.1	Name:	PHYTEXTRA, SL		
1.2	Adress:	C. Banyoles Nº12, Subsector B, Vilamalla 17469		
1.3	Approved by:	Administrator: Maribel Puig		
2	PRODUCT IDENTIFICATION			
2.1	GROUP:	Powder/powder mix encapsulated and packaged		
2.2	Commercial Name:	According to customer (Complex Anti-cellulite Nutrimea)		
2.3	Product description:	150AmbNut SE00003159 Tapa38PNut	Bote 150 ml Ambar Rosca 38 mm Nutrimea Complexe Anti-cellulite Nutrimea Tapa Rosca 38mm Plateado Nutrimea	1 unit 90 capsules 1 unit
3	PRODUCT DESCRIPTION			
3.1	Process:	Wheighing, sieving and mixing of raw materials, encapsulation of the mixture in capsules, polishing of capsules and packaging in jars.		
3.2	Raw materials and auxiliary substances:	CAP0000000 MP00000329 MP00000393 MP00003162 MP00003163	Capsulas T0 HPMC Transparente Harina de arroz Guarana 12% cafeina Sinetrol Xpur C Marc de Raisin en polvo	1 unit (90 mg) 150 mg 83,33 mg 210 mg 133,33 mg
3.3	Shelf life:	Generalmente 2-3 años; según estudios de cliente.		
4	REGULATIONS AND REQUIREMENTS			
4.1	Requirements	Parameters	Standard referenced	According to contract
	Physical	Appearance	Visual	Capsules
		Colour*	Visual	Brown*
		Taste	Organoleptic	Characteristic
	* May vary due to raw materials of vegetal origin			
	Chemical	Heavy metals and contaminants	< Limits according to Regulation 1881/2006 and subsequent modifications	
		Pesticides	< Limits according to Regulation 396/2005 and subsequent modifications	
	Biological	<i>Aerobic count</i>	cfu/g	10 ⁴
		<i>Yeast and mould</i>	cfu/g	10 ²
		<i>E. Coli</i>	g	Absence in 1
		<i>Staphylococcus Aureus</i>	g	Absence in 1
		<i>Salmonella</i>	g	Absence in 10
		<i>Enterobacteria</i>	cfu/g	No more than 100
	* Acceptance criteria according to European Pharmacopoeia 5.1.4.			
4.2	Intended use of the product:	Only oral and direct use, without previous dilution.		
4.3	Unintended use:	Not for topical use (Product to be ingested exclusively orally)		
4.4	Risk/vulnerable population:	Not suitable for children, pregnant women and in breastfeeding period and allergens described in section 6.2.		
4.5	Storage conditions:	In dry places at a temperature of <30°C and out of direct light.		
4.6	Packing:	Cardboard box.		
4.7	Transport conditions:	At the customer expense.		
5	LABEL			
	The manufacturer and client name and address (recipient); the product name; the production batch number; the number of jars and boxes, if necessary, the packaging date and expedition date. The design and information in the final product label are responsibility of the customer.			

PRODUCT SPECIFICATION	0.1	Product:	Complex Anti-cellulite Nutrimea
	0.2	Version:	08
	0.3	Date:	03 10 2022

6	ALLERGENS		
6.1	Allergens in the manufacturer place:	Food supplements that may contain food allergens are made in the manufacturer place: Soy, fish and derivatives, crustaceans, gluten, milk and derivatives, egg, celery, nuts, molluscs and derivatives, sesame seeds, mustard and sulphur dioxide and sulphites in concentrations above 10 ppm.	
6.2	Allergens in the product:	Sulphur dioxide and sulphites in concentration above 10 ppm.	
7	MONITORING: According to Quality control plan ISO 22000:2018		
	Internal code of traceability system: 000003159.		

Modifications with the previous version: The composition is specified. Chemical regulations are added. Section 5 of the previous version is divided into two (5. Label and 6. Allergens).