TO THE ATTENTION OF:

Capsugel
A Lonza Company

CERTIFICATE OF ANALYSIS

The capsules are produced under carefully controlled conditions. Controls are performed continuously throughout the process and guarantee that capsules conform to the highest quality standards. The capsules described below conform to the specifications as defined in the current edition of the Capsugel "Technical Reference File".

PRODUCT DESCRIPTION — Empty Vcaps® Capsules

Customer:	Euromar Ltd	Lot Number:	5425814
Product Name:	VCAPS SIZE 0 NAT TR	Customer Reference:	PO24000050
Product Code:	001389.66	Product Size:	Size 0, Coni-Snap, Standard
Manufacturing Date:	11-Oct-2024		
Expiration Date:	10-Oct-2029		

BODY

		CAP	
Code:	V43.700	Code:	V43.700
Name:	NATURAL TR. V700	Name:	NATURAL TR. V700
Print Type:	Non-Print		

Body Composition		**Cap Composition**	
Hypromellose	qsp 100 %	Hypromellose	qsp 100 %

Due to the nature of raw materials, their sourcing, and technology improvements, the colorant composition data indicated are target values and actual values may vary to insure the consistency of lot color. Capsugel supports the expiry date if precautions for warehousing and transportation are observed (recommended: 15°C - 25°C and 35% - 65% relative humidity).

Ingredient / Reference	**E Nr**	**C.I. Nr**	**Function**	**Regulatory References**
Hypromellose	E464		Structure	(EU) 231/2012, EP, JP, USP/NF, CHP

ANALYTICAL DATA

Characteristics	**Test Method**	**Units**	**Specifications**	**Results**
Identification of Hypromellose	TRF 002C		Positive	pass *
Disintegration time	TRF 300A	min/sec	Less than 10 minutes	03:31 *
Average weight	TRF 100A	mg	89 to 101	95.0
Loss on drying	TRF 101A	%	Not more than 9.0%	4.8
Sulphated ash	TRF 200A	%	Less than 6	pass *
lubricant content	TRF 202B	%	Less than 0.5%	0.02 *
Total Aerobic Microbial Count	TRF 500A	cfu / g	Less than 1000	< 20
Escherichia coli	TRF 520A		Absence in 1 gram	pass *
Salmonella	TRF 550A		Absence in 10 gram	pass *
Staphylococcus aureus	TRF 530A		Absence in 1 gram	pass *
Total Yeasts/Moulds Count	TRF 510A	cfu / g	Less than 100	< 10 *
Pseudomonas aeruginosa	TRF 540A		Absence in 1 gram	pass *
Customer specific tests				
Solubility and acidity or alkalinity	TRF 103A		Odorless and neutral or slightly acidic	pass *

*** Reduced frequency testing**

Elemental Impurities / Heavy Metals

With reference to ICH Q3D and other applicable standards controlling levels of elemental impurities in drug products and food supplements, Capsugel empty capsule products are meeting below levels of applicable elements. Monitoring testing is in place under validated methods, as described in the current edition of Capsugel's applicable Technical Reference File. A documented risk assessment based on the ICH Q3D principles is available on www.mycapsugel.com.

Element	**Unit**	**Acceptance Level**
Arsenic	ppm	Not more than 1
Lead	ppm	Not more than 1
Cadmium	ppm	Not more than 0.5
Mercury	ppm	Not more than 0.1
Cobalt	ppm	Not more than 5
Vanadium	ppm	Not more than 10
Nickel	ppm	Not more than 20

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חתימה

CERTIFICATE OF ANALYSIS

Lot Nr: 5425814

Customer Name: Euromar Ltd

Residual Solvent Statement

In accordance with ICH Q3C residual solvent guideline, Class 3 solvents may be used according to good manufacturing practices such that their cumulative value does not exceed 5000ppm or 0.5%, under option 1 as defined in ICH Q3C, USP<467>, and EP General Text 5.4.

Physical Characteristics

Defect levels are in conformance with the Coni-Snap® specification for Visual attributes, as defined in the table below.

Defect Group	Class I	Class II	Class III
	Visual	Visual	Visual
Sigma Level	4.9	4.7	4.2
PPM	<290	<670	<3600

Appearance - Clean empty capsules, meeting the specified requirements of color and size.
Odor - Free of disagreeable odor.
The reported disintegration time is subjective, and is provided to indicate Pass/Fail status for 10 minutes.
Composition Notes :
Below gelling agents are processing aids used during production in amounts which are in accordance with, and not exceeding, good manufacturing practices for what is necessary for their intented purpose. Processing aids have a technological purpose in the manufacturing process, but do not have an ongoing function in the empty hard capsule and do not impact the quality, performance or specifications of the capsule product.

Processing aids (gelling agents)	E Nr	References
Gellan gum (not to exceed 1.0%)	E418	(EU) 231/2012, USP/NF, FCC, 21 CFR, JPE, JSFA
Potassium acetate (not to exceed 0.5%)	E261	(EU) 231/2012, EP, USP/NF, JPE

Manufacturing Processes:

No Addition of Preservatives
No Ethylene Oxide Treatment
No Irradiation Treatment

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Digitally approved by Chantal Hirtz (Nov 27 2024, 17:37:24)

Authorized Signer