

CERTIFICATE OF ANALYSIS

The capsules are produced under very 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 Lonza Technical Reference File for empty hard capsules.

PRODUCT DESCRIPTION Empty Plantcaps® Capsules

Customer: Stock
 Product Name:
 Product Code:
 Manufacturing Date: 24-Jun-2026
 Expiration Date: 24-Jun-2031

Capsugel Lot Number: 9065237
 Customer Reference:
 Product Size: Size 00, CS
 Type: Coni-Snap
 Capsugel Part Number: 10000190

BODY

Code: C43.1005
 Name: NATURAL TR

CAP

Code: C43.1005
 Name: NATURAL TR

IMPRINTING

Logo:

Design / Roll Code:

Ink:

Body Composition

PULLULAN

qsp 100%

Cap Composition

PULLULAN

qsp 100%

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

Ingredient / Reference

PULLULAN

E Nr

E1204

C.I. Nr**Function**

STRUCTURE

Regulatory References

(EU) 231/2012, EP, JP, JSFA,
USP/NF, FCC

ANALYTICAL DATA

Characteristics	Test Method	Units	Specifications	Results
Identification of Pullulan	TRF 004A		Positive	pass
Disintegration time	TRF 300A	min/sec	Less than 10:00	0:57
Sulphated Ash	TRF 200A	%	Less than 4	2
Solubility and acidity or alkalinity	TRF 103A		Conforms	pass
Loss on drying	TRF 101A	%	Between 10.0 to 14.0	10.8
Average weight	TRF 100A	mg	Between 115 to 129	128
Escherichia coli	TRF 520A		Absence in 1 gram	pass
Pseudomonas aeruginosa	TRF 540A		Absence in 1 gram	pass
Salmonella	TRF 550A		Absence in 10 grams	pass
Staphylococcus aureus	TRF 530A		Absence in 1 gram	pass
Total Aerobic Microbial Count	TRF 500A	cfu/g	Less than 1000	<10
Total Yeast and Mold Count	TRF 510A	cfu/g	Less than 100	<10

* Reduced frequency testing

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Physical Characteristics:

This product conforms to established A.Q.L.'s for Physical Attributes.

Appearance - Clean empty capsules, meeting the specified requirements of color and size.

Odor - Free of disagreeable odor.

Empty Plantcaps® Capsules conform with the JP monograph for Pullulan capsules.

The reported disintegration time is subjective, and is provided to indicate Pass/Fail status.

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 intended 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
Carrageenan (not to exceed 0.5%)	E407	(EU) 231/2012, EP, 21 CFR, JPE, JSFA, USP/NF
Potassium chloride (not to exceed 2.0%)	E508	(EU) 231/2012, EP, 21 CFR, JP, USP/NF

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, and Indian Pharmacopeia Residual Solvents 5.4.

Elemental Impurities / Heavy Metals:

With reference to ICH Q3D and other applicable standards controlling levels of elemental impurities in drug products and food supplements, Lonza 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 Lonza's applicable Technical Reference File. A documented risk assessment based on the ICH Q3D principles is available on www.mycapsugel.com

- * Arsenic: not more than 1 ppm
- * Lead: not more than 1 ppm
- * Cadmium: not more than 0.5 ppm
- * Mercury: not more than 0.1 ppm
- * Cobalt: not more than 5 ppm
- * Vanadium: not more than 10 ppm
- * Nickel: not more than 20 ppm

Preservative Status:

Capsules are manufactured without the addition of preservatives

Capsules are manufactured without ethylene oxide treatment or (Ethylene Oxide is not used for terminal microbial control of empty capsule)

Capsules are manufactured without irradiation treatment

Country of Origin: Made in Mexico

**Capsugel de México S.
de R.L. de C.V.**

Quality Assurance
F0009065237004004

Digitally Signed By: Viviana Cruz
Date & Time Signed: 10 Jul 2026 02:24:13 PM

Signer: Viviana Cruz
QA Lab Analyst

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