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 Hard Gelatin Capsules - Coni-Snap® (Porcine)

Customer:	Next PharmaPack LLC	Lot Number:	3663711
Product Name:	HGC PORCINE SIZE 0 WHITE	Customer Reference:	51/2024-Darnitsa
Product Code:	6171940-09	Product Size:	Size 0, Coni-Snap, Standard
Manufacturing Date:	12-Aug-2024		
Expiration Date:	11-Aug-2029		

BODY		**CAP**	
Code:	44.000	Code:	44.000
Name:	WHITE OP.	Name:	WHITE OP.
Print Type:	Non-Print		

Body Composition		Cap Composition	
Titanium dioxide	2.0000 %	Titanium dioxide	2.0000 %
GELATIN	qsp 100 %	GELATIN	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
Titanium dioxide	E171	77891	Opacifier	(EU) 231/2012, 21 CFR, EP, JP, USP/NF
GELATIN			Structure	EP, JP, USP/NF, CHP

ANALYTICAL DATA

Characteristics	Test Method	Units	Specifications	Results
Identification of gelatin	TRF 001A		Positive	pass *
Identification of TiO2	TRF 007A		Conforms to composition	pass *
Sulphated ash	TRF 200A	%	Less than 7	pass *
Lubricant content (Soxtherm)	TRF 202B	%	Less than 0.5	0.03 *
Sulphur dioxide	TRF 201A	ppm	Not more than 10	2 *
Disintegration time	TRF 300A	min/sec	Less than 10:00	02:11 *
Loss on drying	TRF 101A	%	13.0 to 16.0	14.4
Average weight	TRF 100A	mg	90.0 to 102.0	94.2
Solubility and acidity or alkalinity	TRF 103A		Odorless and neutral or slightly acidic	pass *
Total Aerobic Microbial Count	TRF 500A	cfu / g	Less than 1000	< 10
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 *
Pseudomonas aeruginosa	TRF 540A		Absence in 1 gram	pass *
Total Yeasts/Moulds Count	TRF 510A	cfu / g	Less than 100	< 10 *

*** 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
Chromium	ppm	Not more than 2

CERTIFICATE OF ANALYSIS

Customer Name: Next PharmaPack LLC

Lot Nr: 3663711

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® Sigma Series specification for Visual attributes, as defined in the table below.

Defect Group	Class I	Class II	Class III
	Visual	Visual	Visual
Sigma Level	5.4	5.1	4.3
PPM	<50	<150	<2500

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.
Empty hard gelatin capsules are conform with the Japanese Pharmacopoeia monograph for capsules.

TSE/BSE Regulations

For the production of this product, no components are used which have been derived from TSE/BSE-relevant animal species. Consequently, we herewith confirm that this empty capsule product is not subject to any TSE/BSE regulations.

Manufacturing Processes:

No Addition of Preservatives
No Ethylene Oxide Treatment
No Irradiation Treatment