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® (Pure Bovine Origin)

Customer:	CAPATREX EU	Lot Number:	3626408
Product Name:	SIZE 0 SCARLET	Customer Reference:	Hgc 0 scarlet
Product Code:	005392-01	Product Size:	Size 0, Coni-Snap, Standard
Manufacturing Date:	04-Oct-2024		
Expiration Date:	Oct 2028		

BODY		**CAP**	
Code:	32.364	Code:	32.364
Name:	SCARLET OP. C364	Name:	SCARLET OP. C364
Print Type:	Non-Print		

Body Composition		**Cap Composition**	
Azorubine - Carmoisine	0.1400 %	Azorubine - Carmoisine	0.1400 %
Red Iron Oxide	0.2000 %	Red Iron Oxide	0.2000 %
Titanium dioxide	0.5000 %	Titanium dioxide	0.5000 %
Yellow iron oxide	0.4500 %	Yellow iron oxide	0.4500 %
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
Azorubine - Carmoisine	E122	14720	Colorant	(EU) 231/2012
Yellow iron oxide	E172	77492	Colorant	(EU) 231/2012, 21 CFR, JPE, USP/NF
Red Iron Oxide	E172	77491	Colorant	(EU) 231/2012, 21 CFR, JPE, USP/NF
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	CP010		Positive	pass *
Identification of TiO2	CP011		Conforms to composition	pass *
Identification of dyestuffs	CP012		Conforms to composition	pass
Identification of iron oxides	CP013		Conforms to composition	pass *
Sulphated ash	CP015	%	Less than 7	pass *
Lubricant content	CP019	%	Less than 0.5	0.05 *
Sulphur dioxide	CP020	ppm	Less than 50	3 *
Disintegration time	CP001	min/sec	Less than 15:00	02:33 *
Loss on drying	CP014	%	13.0 to 16.0	14.6
Average weight	CP003	mg	90 to 102	98.7
Total Aerobic Microbial Count	CP031	cfu / g	Less than 1000	< 10
Escherichia coli	CP033		Absence in 1 gram	pass *
Salmonella	CP034		Absence in 10 gram	pass *
Staphylococcus aureus	CP035		Absence in 1 gram	pass *
Pseudomonas aeruginosa	CP036		Absence in 1 gram	pass *
Total Yeasts/Moulds Count	CP032	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

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CERTIFICATE OF ANALYSIS

Customer Name: Vladislav Vanek

Lot Nr: 3626408

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 Hard Gelatin Coni-Snap Sigma Series specifications for Physical attributes, as defined in the Capsugel's Hard Gelatin Coni–Snap Sigma Series Technical Reference File addendum.
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.
The reported disintegration time is subjective, and is provided to indicate Pass/Fail status for 15 minutes.
Empty hard gelatin capsules are conform with the Japanese Pharmacopoeia monograph for capsules.

TSE/BSE Regulations

Capsugel can use blends of several pharmaceutical gelatins. When bovine gelatin is used by Capsugel, it is in full compliance with all pharmaceutical regulatory statutes.
Specifically, Capsugel fully complies with the following where applicable:

- Commission Directive 2003/63/EC/ Note for guidance EMA/410/01 compliance demonstrated by "Certificate of Suitability".
- Regulation (EC) No 853/2004 on specific hygiene rules for food of animal origin.
- Regulation (EC) No 999/2001 as regards specified risk material.
- United States FDA - 21 CFR Parts 211, 226, 300, 500, 530, 600, 895, and 1271 related to Use of Materials Derived from Cattle in Medical Products.
- United States FDA - 21 CFR Parts 189 and 700 related to Use of Materials Derived From Cattle in Human Food and Cosmetics.
- Japanese Ministry of Health, Labor Welfare (MHLW) - "Food Sanitation Law", MHLW Notice No.0327-2 of March 27, 2015.
- Japanese Ministry of Health, Labor and Welfare - Notification No. 210, Notification No. 1002-27 as of November 25th 2014.
- The raw material is derived from healthy animals slaughtered in a slaughterhouse, which have been inspected by an official veterinarian and have been deemed fit for human consumption.

Capsugel currently manufactures capsules under any (or all) of the following Certificates of Suitability:

- Rousselot R1 CEP 2000-029
- Rousselot R1 CEP 2010-043
- Tessenderlo Group R1 CEP 2000-045
- Gelita group R1 CEP 2001-424
- Sterling Gelatin R1 CEP 2001-211
- Nitta Gelatin R1 CEP 2000-344
- Nitta Gelatin R1 CEP 2005-217

Manufacturing Processes:

No Addition of Preservatives
No Ethylene Oxide Treatment
No Irradiation Treatment

Capsugel Belgium NV
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Digitally approved by Tom Van Den Bossche (Oct 25 2021, 07:22:11)

Authorized Signer