Product Specification Sheet

Empty Vcaps® Capsules

Capsugel® A Lonza Company

Customer	Acef S.p.A.		
Product Name:	0 VC VEGETALE TRASPARENTE	Product Size:	Size 0, Coni-Snap, Standard
Product Code:	001522-59		

BODY		CAP	
Colour			
Code:	V43.700	Code:	V43.700
Name:	NATURAL TR. V700	Name:	NATURAL TR. V700

Qualitative and Quantitative composition*

Composition per unprinted capsule part

Body represents about 60% of the capsule weight

		Body (V43.700)		Cap (V43.700)		Total Capsule	
Name of ingredient(s)	Function	%	mg/body	%	mg/cap	%	mg/capsule
Hypromellose	Structure	QSP 100%	57.0000	QSP 100%	38.0000	QSP 100%	95.0000
		100	57.0000	100	38.0000	100	95.0000

*The quantities given are based on the theoretical calculations of the average specification weight of the capsule.
Due to the nature of raw materials, their sourcing and technology improvements, the dyestuff content data indicated are target values and actual values may vary.

Specifications

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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

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Characteristics	Specifications	Units
Disintegration time	Less than 30:00	min/sec
Average weight	89 to 101	mg
Hypromellose identification	Positive	
Loss on drying	Less than 9.0%	%
Sulphated ash	Less than 6	%
Lubricant content	Less than 0.5	%
Total Aerobic Microbial Count	Less than 1000	cfu / g
Escherichia coli	Absence in 1 gram	
Salmonella	Absence in 10 gram	
Staphylococcus aureus	Absence in 1 gram	
Total Yeasts/Moulds Count	Less than 100	cfu / g
Pseudomonas aeruginosa	Absence in 1 gram	

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

- Arsenic: not more than 1.5 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

Additional Information

Storage Conditions / Shelf life

Capsugel recommends that our capsules be stored in the closed containers in which they are dispatched in areas where the ambient temperature is 15°C to 25°C and the relative humidity 35% to 65%.
Shelf life: 5 years

General Commitment

As the supplier of this product, Capsugel will notify of any significant changes that would affect the integrity of the product. Typically this is defined as Level II changes by the International Pharmaceutical Excipient Council's Significant Change Guide for Bulk Pharmaceutical Excipients.

Manufacturing Processes

No Addition Of Preservatives
No Ethylene Oxide Treatment
No Irradiation Treatment

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Regulatory information

Regulatory References

Name of ingredient(s)	E Nr.	C.I. Nr.	Function	Reference / Monograph standard
Hypromellose	E464		Structure	(EU) 231/2012, EP, JP, USP/NF, CHP

Capsugel has made every effort to ensure suitability of the capsule compostion. However, capsule constituents, such as colorants, may be restricted in terms of their application we recommend that you give careful consideration to your final composition and ensure compliance with the regulations of the market and countries in which the product will be launched. A crosscheck by your regulatory people as well as appropriate authorities in these countries is advised.

Below table provides the regulatory status of the empty unprinted capsules (V43.700/V43.700) based on the colorants present.

Food Supplement	Medicinal Products

Customer Approval Signature/ Date:

Capsugel Belgium NV, Rijksweg 11 - 2880 Bornem - Belgium
Capsugel France SAS, Rue Timken 10 - F68027 Colmar - France

For questions please contact your Account Solutions Representative.