

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 Capsugel "Technical Reference File".

PRODUCT DESCRIPTION Empty DRcaps™ Capsules			
Customer:	CAPSUGEL Belgium NV	Lot Number:	53425701
Product Name:	/	Customer Reference:	
Product Code:	/	Product Size:	2
Manufacturing Date:	22-Nov-2015	Type:	CONI-SNAP
Expiration Date:	Nov 2020		
BODY		CAP	
Code:	V43.700	Code:	V43.700
Name:	NATURAL TR. V700	Name:	NATURAL TR. V700

Body Composition		Cap Composition	
Hypromellose	qsp 100 %	Hypromellose	qsp 100 %
Gellan gum	5.0000 %	Gellan gum	5.0000 %

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. Capsugel supports the expiry date if recommendations 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
Gellan gum	E418		Gelling agent	(EU) 231/2012, JSFA, 21 CFR

ANALYTICAL DATA

Characteristics	Test Method	Units	Specifications	Results
Hypromellose identification	VCP010		Positive	pass *
Average weight	VCP003	mg	56 to 64	60.5
Loss on drying	VCP012	%	Less than 9.0%	6.0
Sulphated ash	VCP013	%	Less than 6	pass *
Arsenic	VCP015A	ppm	Less than 1.5	pass *
Cadmium	VCP015B	ppm	Less than 0.5	pass *
Lead	VCP015C	ppm	Less than 1	pass *
Mercury	VCP015D	ppm	Less than 0.1	pass *
Lubricant content	VCP016	%	Less than 0.5	0.06 *
Total Aerobic Microbial Count	VCP031	cfu / g	Less than 1000	< 20
Escherichia coli	VCP032		Absence in 1 gram	pass *
Salmonella	VCP033		Absence in 10 gram	pass *
Staphylococcus aureus	VCP034		Absence in 1 gram	pass *
Total Yeasts/Moulds Count	VCP035	cfu / g	Less than 100	< 10 *
Pseudomonas aeruginosa	VCP036		Absence in 1 gram	pass *

Customer specific tests				
Identification of gellan gum	VCDRP002		Positive	pass *
Disintegration time	VCDRP001	min/sec	Greater than 30:00	Pass *

* Reduced frequency testing

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

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.

Manufacturing Processes:
No Addition of Preservatives
No Ethylene Oxide Treatment
No Irradiation Treatment