

TO THE ATTENTION OF:

The World's Leader in Two-Piece Capsules™



# 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 for Empty Vcaps® Capsules"

PRODUCT DESCRIPTION		Empty Vcaps® Capsules	
Customer:	STOCK	Capsugel Lot Number:	90235681
Product Name:		Customer Reference:	
Product Code:		Product Size:	Size 0, CS
Manufacturing Date:	22 Oct 2013	Type:	Coni-Snap
Expiration Date:	22 Oct 2018	Capsugel Part Number:	G0HCS000994
<b>BODY</b>		<b>CAP</b>	
Code:	V43.700	Code:	V43.700
Name:	NATURAL TRANSPARENT	Name:	NATURAL TRANSPARENT
<b>IMPRINTING</b>			
Design / Roll Code:			
Ink:			
<b>Body Composition</b>		<b>Cap Composition</b>	
Hypromellose	qsp 100%	Hypromellose	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 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

## ANALYTICAL DATA

Characteristics	Test Method	Units	Specifications	Results
Identification of hypromellose	WI-0102B		Positive	pass *
Sulphated ash	WI-0108C	%	Less than 6	1 *
Arsenic	WI-0104L	ppm	Less than 1.5	0.000 *
Lead	WI-0104J	ppm	Less than 1	0.000 *
Cadmium	WI-0104I	ppm	Less than 0.5	0.0003 *
Mercury	WI-0104K	ppm	Less than 0.1	0.000 *
Lubricant content	WI-0095B	%	Less than 0.5	0.037 *
Disintegration time	WI-0101C	min/sec	Less than 30:00	4:39 *
Loss on drying	WI-0119	%	Less than 9	3.2
Average weight	WI-0118	mg	Between 89 and 101	93
Escherichia coli	WI-0111		Absence in 1 gram	pass
Salmonella	WI-0113		Absence in 10 grams	pass *
Staphylococcus aureus	WI-0114		Absence in 1 gram	pass
Pseudomonas aeruginosa	WI-0112		Absence in 1 gram	pass
Total Yeast and Mold Count	WI-0116	cfu/g	Less than 100	<10 *
Total Aerobic Microbial Count	WI-0115	cfu/g	Less than 1000	<10

\* Reduced frequency testing

## CERTIFICATE OF ANALYSIS

Customer: STOCK

Capsugel Lot Number: 90235681

### 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."

"The reported disintegration time is subjective, and is provided to indicate Pass/Fail status for 30 minutes."

### 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.

### 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

CAPSUGEL - PUEBLA  
Quality Assurance  
F0090235681001001

21D12183-02FC1103



Approval Date & Time: 31 Oct 2013 05:14:47 PM

Approver  
Luz del Carmen Sanchez  
Lab Department Head

Blvd. 18 de Noviembre 1030 A  
C.P. 72270 Puebla, Pue. México.  
Tel: (52) (222) 372 - 1524  
Fax: (52) (222) 3721504