

## CONSOLIDATION

### Hydroxypropylmethylcellulose Hard Capsules

- Empty (Lock Type) -

	<b>GoCaps GmbH</b>	<b>Farmacapsulas S.A.</b>
<u>Article No.:</u>	56-000107	K00003
<u>Batch No.:</u>	611-440	K1609000423
<u>Production Date:</u>	October 2016	
<u>Expiry Date:</u>	October 2021	
<u>Halal-Status:</u>	The product is Halal-certified.	
<u>Kosher-Status:</u>	The product is Kosher-certified.	
<u>Manufacturer:</u>	Farmacapsulas S.A.	
<u>Country of origin:</u>	Colombia	

Edling, 11 November 2016

This document is valid without signature.

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Christina Reuther, PhD



**CERTIFICATE OF ANALYSIS  
EMPTY HARD CAPSULES OF VEGETABLE ORIGIN**

CUSTOMER : GOCAPS GMBH.

PURCHASER ORDER NUMBER: 72907                      CHARGE No.: 611-440                      ART No.: 56-000107

LOT:K1609000423                      MANUFACTURING DATE: 2016/10                      EXPIRATION DATE: 2021/10

SIZE: 0                      COLOR / CODE : CAP / NATURAL 1-0K                      BODY / NATURAL 1-0K

PHYSICAL	MEASURE UNIT	METHOD	SPECIFICATIONS	RESULTS
Moisture	%	DCC - MA - P027	4,0 - 8,0	4,6
Average Weight	mg	DCC - MI - P003	99,0 - 111,0	108,1
Cap length	mm	DCC - MI - P006	10,50 - 11,20	10,62 - 11,19
Body length	mm	DCC - MI - P006	18,00 - 18,70	18,00 - 18,70
Disintegration	min	DCC - MA - P063	*N.M.T. 15	Passes
Identification of HPMC		USP	Positive	Passes
<b>ANALYTICAL</b>				
Arsenic	ppm	EXTERNAL	*N.M.T. 0,8	Passes
Chromium	ppm	EXTERNAL	*N.M.T. 2,0	Passes
Cadmium	ppm	EXTERNAL	*N.M.T. 1,0	Passes
Lead	ppm	EXTERNAL	*N.M.T. 3,0	Passes
Mercury	ppm	EXTERNAL	*N.M.T. 0,1	Passes
Total viable aerobic count in cfu/g		DCC - MA - P031	< 1000	30
Total Coliforms		DCC - MA - P036	Negative / 10 g	Negative
Escherichia Coli		DCC - MA - P036	Negative / 10 g	Negative
Salmonella		DCC - MA - P039	Negative / 10 g	Negative
Staphylococcus Aureus		DCC - MA - P037	Negative / 10 g	Negative
Pseudomona Aeruginosa		DCC - MA - P033	Negative / 10 g	Negative
Yeast and Molds, in cfu/g		DCC - MA - P040	N.M.T. 100	Conform

Manufactured by FARMACAPSULAS<sup>®</sup>.

NOTE : The VISUAL QUALITY is superior to the established figures in the sampling plans of the Norm ISO 2859 - 1 "Procedure of sampling to inspect for attributes", using simple sampling with level II of General Inspection and Acceptable Quality Level (AQL) of 0,010 for Critical defects, 0,040 for Major defects and 0,250 for Minor defects. They also fulfill the specifications established in the Technical Information Manual in force.

This document certifies that the hard capsules of vegetable origin (K-CAPS)<sup>®</sup> are made from cellulose ethers, which are polymers derived from cellulose.

FDA Drug Master File Number 16376. Kosher certified.

N.M.T. = No more than.

\* Reduced Frequency Testing

P/P Daniela Mendoza M.  
QUALITY ASSURANCE

DATE: 2016/11/01

Code: DCC-032G (Valid since September 24<sup>th</sup>, 2013)