

CONSOLIDATION
Empty Hard Gelatine Capsule
- Empty (Lock Type) -

	Goerlich Pharma	Farmacapsulas
<u>Article No.:</u>	56-000010	F00055
<u>Batch No.:</u>	198-129	F1401000798
<u>Production Date:</u>	January 2014	
<u>Expiry Date:</u>	January 2019	

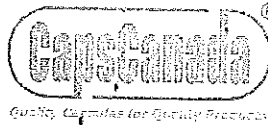
Holder of valid EDQM Certificates of Suitability:

GELCO S.A., Barranquilla, Colombia, R0-CEP 2006-086-Rev 00
PROGEL S.A., Colombia, R1-CEP 2001-397 Rev 00

Edling, 19 March 2014

This document is valid without signature.

Katharina Gietl



**CERTIFICATE OF ANALYSIS
EMPTY HARD GELATINE CAPSULES**

CUSTOMER: GoCaps GmbH

PURCHASE ORDER NUMBER: 47250

CHARGE No.: 198-129

ART No.: 56-000010

LOT :F1401000798

MANUFACTURING DATE : 2014-01

EXPIRATION DATE : 2019-01

SIZE : 1

COLOR / CODE :

CAP / NATURAL 1-0

BODY / NATURAL 1-0

PHYSICAL	UNIT OF MEASURE	METHOD	SPECIFICATIONS	RESULTS
Moisture	%	DCC - MA - P027	13,00 - 16,00	14,4
Average weight	mg	DCC - MI - P003	71,00-81,00	76,1
Cap length	mm	DCC - MI - P006	9,50-10,20	9,65-10,07
Body length	mm	DCC - MI - P006	16,05-16,75	16,25-16,62
Disintegration	min	DCC - MA - P063	*N.M.T. 15'	PASSES
ANALYTICAL				
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	10
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	NEGATIVE

Manufactured by FARMACAPSULAS®.

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 Level of Quality (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.

TSE/BSE Compliance: The capsules were produced with gelatine made from bovine hides originated from Colombia. Colombia is an officially free from Bovine Spongiform Encephalopathy country. This disease has never been recorded in the colombian territory.

FDA Drug Master File Number 12859. Kosher Certified.

N.M.T. = No more than

* Reduced Frequency Testing.


QUALITY ASSURANCE

DATE: 2014-02-17

Code: DCC-021F (Valid since September 25th, 2013)