

CONSOLIDATION

Empty Hard Gelatine Capsules

- Empty (Lock Type) -

	GoCaps GmbH	C.I. Farmacapsulas S.A.
Article No.:	56-000007	F00076
Batch No.:	244-044	F2012001050
Production Date:	December 2020	
Expiry Date:	December 2025	
Halal-Status:	The product is Halal-certified.	
Kosher-Status:	The product is Kosher-certified.	
Manufacturer:	C.I. Farmacapsulas S.A.	
Country of origin:	Colombia	

Holder of valid EDQM Certificates of Suitability:

GELCO S.A., Barranquilla, Colombia, R1-CEP 2006-086-Rev 00

PROGEL S.A.S, Colombia, R1-CEP 2001-397 Rev 01

Please note:

Our supplier has adapted the values for the microbiological limits and lead within the compendial limits of the United States and European Pharmacopoeia. This is reflected in future certificates of analysis and specifications.

Edling, 01 February 2021

This document is valid without signature.

Moosreiner, Isabella



**CERTIFICATE OF ANALYSIS
EMPTY HARD GELATINE CAPSULES**

CUSTOMER: GoCaps GmbH

PURCHASE ORDER NUMBER: 132708

CHARGE No.: 244-044

ART No.: 56-000007

LOT: F2012001050

MANUFACTURING DATE: 2020-12

EXPIRATION DATE: 2025-12

SIZE: 4

COLOR/CODE: CAP/ NATURAL / 1-0

BODY/ NATURAL / 1-0

PHYSICAL	UNITS	METHOD REFERENCE	SPECIFICATIONS	RESULTS
Moisture	%	DCC-MA-P027	13.00-16.00	14.8
Average weight	mg	DCC-MI-P003 USP<2091>	35.00-41.00	37.3
Disintegration	min	DCC-MA-P063 USP<701>	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. 0,5	PASSES
Lead*	ppm	EXTERNAL	N.M.T. 0,5	PASSES
Mercury*	ppm	EXTERNAL	N.M.T. 0,1	PASSES
Cobalt*	ppm	EXTERNAL	N.M.T. 5,0	PASSES
Vanadium*	ppm	EXTERNAL	N.M.T. 10,0	PASSES
Nickel*	ppm	EXTERNAL	N.M.T. 20,0	PASSES
Total aerobic microbial count	cfu/g	DCC-MA-P031 USP<61>	N.M.T. 1000	30
Total combined Yeast and Molds count	cfu/g	DCC-MA-P040 USP<61>	N.M.T. 100	<10
Total Coliforms	---	DCC-MA-P036 USP<62>	Absence / 1 g	Absence
Escherichia Coli	---	DCC-MA-P036 USP<62>	Absence / 1 g	Absence
Salmonella	---	DCC-MA-P039 USP<62>	Absence / 10 g	Absence
Staphylococcus Aureus	---	DCC-MA-P037 USP<62>	Absence / 1 g	Absence
Pseudomona Aeruginosa	---	DCC-MA-P033 USP<62>	Absence / 1 g	Absence

* Reduced frequency testing

N.M.T.= No more than

Storage conditions: Temperature: 15°C - 25°C Relative Humidity: 35% - 65%

Some changes in color are due to natural colorants or can occur/are within the specification.

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 III 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 pharmaceutical gelatine derived 100% 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.

Manufactured by FARMACAPSULAS.


QUALITY ASSURANCE

DATE: 2021/01/27

Code: DCC-021F (Valid since July 1st, 2020)

Version 4

Manufacturer Address Calle 79B 78C-21 Barranquilla - Colombia
Telephone: (57-5) 330-4100 Fax: (57-5) 330-4105



a Lyfe Group Co.

CAPSULE COLOUR FORMULATION CERTIFICATE
CERTIFICADO DE FORMULACION DE COLOR DE LAS CAPSULAS

EMPTY HARD GELATIN CAPSULES
CAPSULAS DURAS DE GELATINA VACIAS

CLIENTE:
CUSTOMER: GoCaps GmbH

LOT No.: _____ SIZE: _____ DATE: _____
LOTE No.: F2012001050 TAMAÑO: 4 FECHA: 2020-12

COLOUR FORMULATION
FORMULACION DE COLOR
% INGREDIENTS TO 100% GELATIN
% DE INGREDIENTES SOBRE 100% DE GELATINA

CAP (TAPA)		BODY (CUERPO)	
COLOUR: <u>NATURAL</u>	CODE: <u>1-0</u>	COLOUR: <u>NATURAL</u>	CODE: <u>1-0</u>
COLOR:	CODIGO:	COLOR:	CODIGO:
DYE OR PIGMENT COLORANTE O PIGMENTO	%	DYE OR PIGMENT COLORANTE O PIGMENTO	%
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"PRESERVATIVE FREE"
"LIBRE DE PRESERVATIVOS"

This document certifies that all empty capsules manufactured by FARMACAPSULAS® are made from type B Pharmaceutical gelatin.
Gelatin used in the manufacturing of capsules meet specifications as described in the current United States Pharmacopoeia.
Colorant and ingredients used in capsules are officially approved for use as dye in Foods, Drugs and Cosmetics and/or Drugs and Cosmetics, in the country of destination.
Capsules manufactured meet Canadian, U.S.A. and European Food Drug and Cosmetics regulations.
The above specifications apply to all capsules having the same size and code numbers, unless otherwise stipulated.

Este documento certifica que todas las cápsulas fabricadas por FARMACAPSULAS® son hechas de gelatina farmacéutica tipo B.
La gelatina utilizada en la fabricación de cápsulas, cumple con las especificaciones descritas en la actual Farmacopea de los Estados Unidos.
Los colorantes e ingredientes utilizados en la fabricación de cápsulas son oficialmente certificados y aprobados como colorantes para comestibles, drogas y cosméticos y/o drogas y cosméticos en el país de destino.
Las cápsulas fabricadas cumplen con las especificaciones Canadienses, Americanas y Europeas para comestibles, drogas y cosméticos.
Lo mencionado se aplica para todas las cápsulas que corresponden al mismo color, tamaño y número de código, a menos que se estipule lo contrario.


Quality Assurance Department (Departamento de Aseguramiento de Calidad)

*These samples do not have a stability test / Estas muestras no cuentan con prueba de estabilidad.