

**CERTIFICATE OF ANALYSIS FOR EMPTY GELATIN CAPSULES**

LOT: SAMPLE	MANUFACTURE DATE: 2022-01	
CODE: <u>F05484</u>	EXPIRATION DATE: 2027-01	
SIZE: 3		
COLOR / CODE:	CAP: NATURAL 1-0	BODY: NATURAL 1-0

PHYSICAL CHARACTERISTIC	MEASURE UNIT	METHOD	LIMITS	REAL VALUE
Loss on drying	(%)	USP	13.0-16.0	14.7
Average Capsule Weight	(mg)	Internal	45.0-51.0	48.8
Disintegration	(%)	USP	N.M.T. 15 Min	MEETS

**MICROBIOLOGICAL LIMITS**

Total viable aerobic count: bacteria	USP	N.M.T. 1000 cfu/g	<10
Total Combined Yeast and Molds Count	USP	N.M.T. 100 cfu/g	<10
Escherichia Coli	USP	Absence / 1g	Absence
Salmonella	USP	Absence / 10g	Absence
Staphylococcus Aureus	USP	Absence / 1g	Absence
Pseudomona Aeruginosa	USP	Absence / 1g	Absence

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

N.M.T.: No more than

**NOTE:**

The VISUAL QUALITY is superior to the established figures in the sampling plans of the ANSI/ASQ Z1.4-2013 - "Procedure of Sampling to inspect for attributes", using simple sampling with level of General Inspection III 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.

Empty hard gelatin capsules manufactured by C.I. FARMACAPSULAS S.A.S. for Capsuline® fulfill all the requirements established by the Kosher and Halal Standards.



Quality Assurance Department

DATE: 2022-06-02



**CERTIFICATE FOR COLOR AND FLAVOR CAPSULES FORMULATION**

**EMPTY HARD GELATIN CAPSULES**

<b>CODE:</b>	F05484-1000	<b>LOT No.</b>	F2205001103	<b>SIZE:</b>	3
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<b>COLOUR AND FLAVOR FORMULATION % INGREDIENTS TO 100% GELATIN</b>			
<b>CAP</b>		<b>BODY</b>	
<b>COLOR:</b>	NATURAL	<b>CODE:</b>	1-0
<b>DYE, PIGMENT OR FLAVOR</b>	<b>%</b>	<b>DYE, PIGMENT OR FLAVOR</b>	<b>%</b>
SYNTHETICAL CHICKEN FLAVOR	1,200000	SYNTHETICAL CHICKEN FLAVOR	1,200000

**"PRESERVATIVE FREE"**

To whom it may concern:

This is to certify that all empty capsules manufactured by C.I. FARMACAPSULAS S.A.S. are made from type B Pharmaceutical gelatin.

All gelatin used in the manufacture of C.I. FARMACAPSULAS S.A.S. capsules meets specifications as described in the current United States Pharmacopeia.

All colour and ingredients used in C.I. FARMACAPSULAS S.A.S. capsules are officially approved, for use as dye in Foods, Drugs and Cosmetics and/or Drugs and Cosmetics, in the country of destination.

The flavor used in the formulation of the gelatin solution are classified as food grade.

All capsules manufactured by C.I. FARMACAPSULAS S.A.S. conform to all Canadian, U.S.A. and European Food Drug and Cosmetic regulations.

The above applies to all capsules having the same colors, size and code numbers, unless otherwise stipulated.

Quality Assurance Department

**DATE:** 2022-06-02

Code: DCC-337B (Current April 22<sup>th</sup>, 2021)

Edition 1

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