

# CERTIFICATE OF ANALYSIS FOR EMPTY GELATIN CAPSULES

|                                    |                 |                          |  |
|------------------------------------|-----------------|--------------------------|--|
| LOT: F2509000636                   |                 | MANUFACTURE DATE:2025-09 |  |
| CUSTOMER: <u>CAPSULINE II, INC</u> |                 | EXPIRATION DATE:2030-09  |  |
| SIZE: 1                            |                 |                          |  |
| COLOR / CODE:                      | CAP: BLUE 4-409 | BODY: WHITE 20-1         |  |

| PHYSICAL CHARACTERISTIC              | MEASURE UNIT | METHOD   | LIMITS            | REAL VALUE |
|--------------------------------------|--------------|----------|-------------------|------------|
| Loss on drying                       | (%)          | USP      | 13.0-16.0         | 14.52      |
| Average Capsule Weight               | (mg)         | Internal | 71.0-81.0         | 77.00      |
| Disintegration                       | (%)          | USP      | N.M.T. 15 Min     | MEETS      |
| MICROBIOLOGICAL LIMITS               |              |          |                   |            |
| Total viable aerobic count: bacteria |              | USP      | N.M.T. 1000 CFU/g | 60         |
| 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    |

\* Reduced frequency testing

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<sup>®</sup> fulfill all the requirements established by the Kosher and Halal Standards.

Approval by:

L. Leon

Quality Assurance Department

DATE: 2025-10-24

Code: DCC-336 (Current March 15<sup>th</sup>, 2024)

Edition 3

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



## CERTIFICATE FOR COLOR AND FLAVOR CAPSULES

### EMPTY HARD GELATIN CAPSULES

CUSTOMER: CAPSULINE II, INC

LOT No. F2509000636

SIZE: 1

#### COLOR AND FLAVOR FORMULATION % INGREDIENTS TO 100% GELATIN

##### CAP

##### BODY

| COLOR: BLUE            | CODE: 4-409 | COLOR: WHITE           | CODE: 20-1 |
|------------------------|-------------|------------------------|------------|
| DYE, PIGMENT OR FLAVOR | %           | DYE, PIGMENT OR FLAVOR | %          |
| FD&C BLUE #1           | 0,352800    | TITANIUM DIOXIDE E171  | 2,640000   |
| FD&C RED #3            | 0,031580    |                        |            |
| FD&C YELLOW #5         | 0,001340    |                        |            |
| TITANIUM DIOXIDE E171  | 0,900000    |                        |            |
|                        |             |                        |            |
|                        |             |                        |            |

#### "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.

L. Leon

Quality Assurance

DATE: 2025-10-24

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

Edition 2

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