Capsuline® Since 2002

KalChem™ INTERNATIONAL Compounding Chemicals You Can Trust

CERTIFICATE OF ANALYSIS FOR EMPTY GELATIN CAPSULES

LOT: F2409001834 MANUFACTURE DATE:2024-10

CUSTOMER: CAPSULINE II, INC EXPIRATION DATE:2029-10

SIZE:00

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	116.0-130.0	122.4
Disintegration	(%)	USP	N.M.T. 15 Min	MEETS
MICROBIOLOGICAL LIMITS				
Total viable aerobic count: bacteria		USP	N.M.T. 1000 CFU/g	90
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® fulfill all the requirements established by the Kosher and Halal Standards.

Approval by: Lina Otero.

Quality Assurance Department

DATE: 2024-11-15

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

Capsuline®
Since 2002

CERTIFICATE FOR COLOR AND FLAVOR CAPSULES FORMULATION

EMPTY HARD GELATIN CAPSULES

CUSTOMER: CAPSULINE II, INC **LOT No.** F2409001834 **SIZE:** 00

COLOR AND FLAVOR FORMULATION % INGREDIENTS TO 100% GELATIN

CAP		BODY	
COLOR: NATURAL CODE: 1-0		COLOR: NATURAL CODE: 1-0	
DYE, PIGMENT OR FLAVOR	**%**	**DYE, PIGMENT OR FLAVOR**	**%**

"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.

Lina Otero.
Quality Assurance Department

DATE: 2024-11-15

Code: DCC-337 (Current April 22th, 2021)
Edition 2

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