

CERTIFICATE OF ANALYSIS FOR EMPTY GELATIN CAPSULES

LOT: F2512000941	MANUFACTURE DATE: 2026-01
CUSTOMER: <u>CAPSULINE II, INC</u>	EXPIRATION DATE: 2031-01
SIZE: 1	
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	15.02
Average Capsule Weight	(mg)	Internal	71.0-81.0	76.53
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® fulfill all the requirements established by the Kosher and Halal Standards.

Approval by:

Jina Otero

Quality Assurance Department

DATE: 2026-01-30

Code: DCC-336 (Current March 15th, 2024)

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Edition 3