

## CERTIFICATE OF ANALYSIS FOR EMPTY HARD CAPSULES OF VEGETABLE ORIGIN

LOT: K2406001990	MANUFACTURE DATE: 2024-07
CUSTOMER: CAPSULINE II, INC	EXPIRATION DATE: 2029-07
SIZE: 4	
COLOR / CODE: CAP: NATURAL 1-0K	BODY: NATURAL 1-0K

PHYSICAL CHARACTERISTIC	MEASURE UNIT	METHOD	LIMITS	REAL VALUE
Loss on drying	(%)	USP	3.0-8.0	3.5
Average Capsule Weight	(mg)	Internal	37.0-43.0	39.4
Disintegration	(min)	USP	N.M.T. 15 Minutes	Passes
MICROBIOLOGICAL LIMITS				
Total viable aerobic count:		USP	N.M.T. 1000 cfu/g	<10
Total Combined Yeasts and Molds Count		USP	N.M.T. 100 cfu/g	<10
Escherichia Coli		USP	Absence / 1 g	Absence
Salmonella		USP	Absence / 10 g	Absence
Staphylococcus aureus*		USP	Absence in 1 g	Absence
Pseudomona Aeruginosa*		USP	Absence in 1 g	Absence

\* Reduced Frequency Testing

Storage conditions: Temperature 15°C-30°C Relative Humidity 35% - 70%

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 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 capsules of vegetables origin manufactured by C.I. FARMACAPSULAS S.A.S. for Capsuline® fulfill all the requirements established by the Kosher and Halal Standards.

Approval by:

  
Quality Assurance Department

DATE: 2024-08-20

Code: DCC-340 (Current March 15<sup>th</sup> 2024)

Edition 4



**CERTIFICATE FOR COLOR AND FLAVOR CAPSULES FORMULATION**

**EMPTY HARD CAPSULES OF VEGETABLE ORIGIN**

CUSTOMER: CAPSULINE II, INC		LOT No. K2406001990		SIZE: 4	
<b>COLOR AND FLAVOR FORMULATION % INGREDIENTS TO 100% HYPROMELLOSE</b>					
CAP			BODY		
COLOR: NATURAL	CODE: 1-0K	COLOR: NATURAL	CODE: 1-0K	COLOR: NATURAL	CODE: 1-0K
<b>DYE, PIGMENT OR FLAVOR</b>	<b>%</b>	<b>DYE, PIGMENT OR FLAVOR</b>	<b>%</b>	<b>DYE, PIGMENT OR FLAVOR</b>	<b>%</b>

**"PRESERVATIVE FREE"**

To whom it may concern:

This is to certify that the hard capsules of vegetable origin (K-CAPS®) manufactured by C.I. FARMACAPSULAS S.A.S. are made from cellulose ethers, which are polymers derived from cellulose.

All raw material used meets all requirements of current United States Pharmacopeia (USP) and European Pharmacopeia (EP) Cellulose ethers are considered as Generally Recognized As Safe (GRAS) by the FDA.

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 by C.I. FARMACAPSULAS S.A.S. 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.

Empty hard capsules of vegetables origin 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: 2024-08-20

Code: DCC-341 (Current May 17<sup>th</sup> 2021)  
Edition 2

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