



**ALLERGEN FREE  
FOR EMPTY HARD BOVINE HIDE GELATIN CAPSULES**

This document certifies that the empty hard gelatin capsules manufactured by C.I. FARMACAPSULAS S.A.S. are produced using the ingredients of bovine hide gelatin and water.

In the production process there are not raw materials, including additives, used that are listed as substances or products causing allergies or intolerances in Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011. Nor does the product contain sulphur dioxide or sulphites at concentrations of more than 10 mg/kg.

All sizes of gelatin capsules are free of the following allergens and their derivatives:

- Wheat
- Pollen
- Starch
- Peanuts or peanut products (butter, oil, flour)
- Tree nuts (almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios or walnuts).
- Plant derivatives, including nuts and seeds (except for highly purified cellulose).
- Eggs or eggs products (whites, yolks, meringue, mayonnaise, etc.)
- Sugar including Glucose and Fructose
- Fish (cod, flounder, salmon, trout, tuna, etc.)
- Shellfish (crustaceans and mollusks)
- Celery (root, leaves, stem, not seeds)
- Dairy or dairy derivatives
- Sesame seeds
- Mustard seeds
- Honey and bee products
- Barley or barley derivatives
- Corn or corn derivatives
- Lupin
- Gluten
- Cereals that contain gluten included, but not limited:

3236 SW 30TH AVENUE, DANIA BEACH, FLORIDA, 33312, USA.  
TELEPHONE / TELEFONO (954) 975-6618 FAX (954) 979-1370

CALLE 79B 78C-21 BARRANQUILLA – COLOMBIA  
TELEPHONE / TELEFONO (57-5) 330-4100 FAX (57-5) 330-4105



- Corn or corn derivatives
  - Oatmeal or oatmeal derivatives
  - Rice or rice derivatives
  - Rye or rye derivatives
  - Spelt or spelt derivatives
  - Wheat or wheat derivatives, including triticale
- 
- Soybeans or soy products (soy derived vegetable protein, tofu, etc.)
  - Preservatives and antioxidants
  - Umbelliferae (carrot or parsley family)
  - Flavors / enhancers
  - Nitrites / nitrates.

Our capsules are certified as Kosher and Halal; and the raw materials used to produce them meet all the requirements of current United States Pharmacopoeia (USP).

The above specifications apply to all gelatin capsules manufactured by C.I. FARMACAPSULAS S.A.S., except otherwise stipulated.

Issued: **January 1<sup>st</sup>, 2022**

Name/Position: **Leonardo De la Hoz P. / Quality Assurance Manager**

Signature:

Certificate code: G001-07

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## CERTIFICATE OF ANALYSIS FOR EMPTY GELATIN CAPSULES

LOT: TBD

SIZE: 000

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	14.1
Average Capsule Weight	(mg)	Internal	153.0-173.0	166.8
Disintegration	(%)	USP	N.M.T. 15 Min	MEETS
MICROBIOLOGICAL LIMITS				
Total viable aerobic count: bacteria		USP	N.M.T. 1000 cfu/g	40
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: 2022-02-16



**CERTIFICATE FOR COLOR AND FLAVOR CAPSULES FORMULATION**

**EMPTY HARD GELATIN CAPSULES**



COLOUR AND FLAVOR FORMULATION % INGREDIENTS TO 100% GELATIN			
CAP		BODY	
COLOR:	NATURAL	CODE:	1-0
COLOR:	NATURAL	CODE:	1-0
<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 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: 2022-02-16

Code: DCC-337B (Current April 22<sup>th</sup>, 2021)  
 Edition 1



בס"ד  
Founded in 1940 by

Rabbi David S. Novoseller, זצ"ל,  
Rabbi Moshe Schnall, זצ"ל,  
Rabbi Dr. Shalom Novoseller, זצ"ל.

מנהל ראשי ומנהל כשרות  
Rabbi Amiel B. Novoseller  
amiel@kokosher.org  
הרב עמיאל בירד נאומאסעלער  
מזרינג שלום זי"ם זצוק  
זר שמי להמחש"א וללה  
מזרינג ר' דוד שלמה זצוק וצוקללה  
אברקק פלשטין פאר אלע מילאדעלפא

רב המכשיר  
Rabbi Moshe E. Novoseller  
הרב משה זנד מדיני מדינת ישראל  
מזרינג ר' דוד שלמה זצוק וצוקללה  
אברקק פלשטין פאר אלע מילאדעלפא  
נבד הודא ר' לוי יצחק  
ברדישובער רבי  
נבד הודא ר' משה מדיני וצוקללה  
מזרינג

מאקאריווער רבי  
נבד הודא ר' יואל וצוקללה  
המשל  
קריליווער רבי  
נבד הודא ר' יהושע וצוקללה  
ר' יצחק  
בפלזער רבי

LOC Page 1 of 1

Wednesday, November 17, 2021  
Kislev/13/5782

י"ג/כסלו/תשפ"ב  
Member/affiliate of IFT and NPA

For more information about  
Ko Kosher Service



www.kokosher.com  
email: info@kokosher.org  
Phone # 800-626-1100  
Postal Mailing:  
1504 Von Steuben Drive  
West Chester PA 19380  
USA

This *תעודת כשרות* is valid as  
indicated and is the  
property of  
Adas Harabonim of  
Philadelphia

# Ko KOSHER SERVICE

Certificate of Kashruth תעודת כשר 2022

תחת ועד הכשרות לעדת הרבנים דפילאדעלפא ארה"ב לשנת תשפ"ב  
ער יום ז שבת תשפ"ג התעודה חוקפה עד 31 דצמבר 2022 למספרם.

## C.I. FARMACAPSULAS S.A.S.

Calle 79B No. 78C-21  
Barranquilla Colombia  
Tel: (57-5) 330-4100 Fax: (57-5) 330-4105  
Website: www.farmacapsulas.com



This letter of certification issued on י"ג כסלו תשפ"ב has been explicitly approved to produce and or  
distribute kosher certified products under the **Ko** and is  
valid through December 31, 2022:

The following products are Kosher & PAREVE unless otherwise noted.

**Empty Kosher Gelatin Capsules**  
**all sizes & variations**  
**"000", "00", "00E", "0E", "0", "1", "2", "3", "4"**

*Reverend Moshe E. Novoseller*  
רב המכשיר  
*Reverend Amiel B. Novoseller*

*Alexandra Rono H.*  
Signature of C.I. FARMACAPSULAS S.A.S. representative