

CERTIFICATE OF ANALYSIS EMPTY HARD CAPSULES OF VEGETABLE ORIGIN

CUSTOMER: GOCAPS GMBH			
LOT No.: K2207002035	PRODUCT CODE: K00012	SIZE: 00	
PURCHASE ORDER NUMBER: 2000178	CHARGE No.: 1-000235	ART No.: 56-000106	
CAPSULE COLOR / CODE: CAP - NATURAL 1-0K / BODY - NATURAL 1-0K			
PRINT: N/A	TEXT: N/A	INK COLOR: N/A	

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 vegetable sources. Our capsules are certified as Kosher and Halal, and meet all requirements of current European Pharmacopoeia (EP) and United States Pharmacopoeia (USP). Hypromellose used in the manufacturing of capsules meet specifications as described in the current United States Pharmacopoeia. Cellulose ethers are considered as Generally Recognized As Safe (GRAS) by the FDA.

(% Ingredients to % Cellulose)

Cap	%	Body	%
<p><i>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.</i></p> <p><i>Some changes in color are due to natural colorants or can occur/are within the specification. The above specifications apply to all capsules having the same size and code numbers, unless otherwise stipulated.</i></p>			

Date of Manufacture: 2022-08

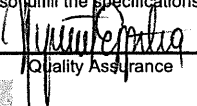
Expiration Date: 2027-08

CRITERIA	METHOD / REFERENCE	SPECIFICATIONS	RESULTS
PHYSICAL			
Average Capsule Weight	DCC-MI-P003/ USP<2091>	132.00-146.00 mg	136.4
Loss on drying	DCC-MA-P027	4.00-8.00 %	5.7
Disintegration	DCC-MA-P063/ USP<701>	N.M.T. 15 min	PASSES
Residue on Ignition *	USP	N.M.T. 1.5% Transparent Capsules	PASSES
		N.M.T. 6.0% Colored Capsules	
Identification of HPMC	DCC-MA-P073 / USP	Meets USP Requirements	PASSES
ANALYTICAL			
Arsenic *	EXTERNAL	N.M.T. 0.8 ppm	PASSES
Chromium *	EXTERNAL	N.M.T. 2 ppm	PASSES
Cadmium *	EXTERNAL	N.M.T. 0.5 ppm	PASSES
Lead *	EXTERNAL	N.M.T. 0.5 ppm	PASSES
Mercury *	EXTERNAL	N.M.T. 0.1 ppm	PASSES
Cobalt *	EXTERNAL	N.M.T. 5.0 ppm	PASSES
Vanadium *	EXTERNAL	N.M.T. 10.0 ppm	PASSES
Nickel *	EXTERNAL	N.M.T. 20.0 ppm	PASSES
Total Aerobic Microbial Count	DCC-MA-P031 / USP <61>	N.M.T. 1000 cfu/g	10
Total Yeasts and Molds Count	DCC-MA-P040 / USP <61>	N.M.T. 100 cfu/g	<10
Total Coliforms	DCC-MA-P036 / USP <62>	Absence / 1 g	Absence
Salmonella	DCC-MA-P039 / USP <62>	Absence / 10 g	Absence
Escherichia Coli	DCC-MA-P036 / USP <62>	Absence / 1g	Absence
Staphylococcus aureus	DCC-MA-P037 / USP <62>	Absence / 1g	Absence
Pseudomonas aeruginosa	DCC-MA-P033 / USP <62>	Absence / 1g	Absence

*Reduced Frequency Testing

Storage Conditions: Temperature: 15°C - 30°C / Relative Humidity: 35 % - 70 % RH 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 III 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.


 Quality Assurance

Date: 2022/08/23



Code: DCC-032G (Valid since November 1st, 2021)
Edition 7