



TECHNICAL DATA SHEET

004512-TDS-ENG-2023

CAPSULAS N° 0 BLANCO (Capsugel)		
DESCRIPTION DCI: ---		DESCRIPTION DOE: ---
CAS N°: ---	EC N°: ---	AEMPS CODE: ---
MOL. WEIGHT: ---	MOL. FORMULA: ---	ARTICLE CODE: 004512

ATTRIBUTES	SHOULD BE
Ingredients	
Titanium dioxide	Complies
Gelatin	Complies
Characters	
Identification of gelatin	Complies
Identification of TiO ₂	Complies
Sulfated ash	=< 7.0 %
Lubricant content	=< 0.5 %
Dioxido de sulfuro	=< 10.0 ppm
Tiempo desintegración (Ph.Eur)	< 10.00 min
Loss on drying	13.0 % - 16.0 %
Average weight	90.0 mg - 102.0 mg
Microbiological control	
Total Aerobic Microbial Count	< 1000 cfu / g
Escherichia coli	Absence / 1g
Salmonella	Absence / 10g
Staphylococcus aureus	Absence / 1g
Pseudomonas aeruginosa	Absence / 1g
Total yeasts/Moulds count	< 100 cfu / g
Heavy metals	
Arsenic	=< 1.0 ppm
Lead	=< 1.0 ppm
Cadmium	=< 0.5 ppm
Mercury	=< 0.1 ppm
Cobalt	=< 5.0 ppm
Vanadium	=< 10.0 ppm
Nickel	=< 20.0 ppm
Chromium	=< 2.0 ppm

COMPLIES WITH

Manufacturer Specifications

STORAGE

Store in a cool place. Keep the container closed, in a dry and well-ventilated place.

REMARKS

Due to the nature of raw materials, their sourcing, and technology improvements, the colorant composition data indicated are target values and actual values may vary to insure the consistency of lot color. Capsugel supports the expiry date if



TECHNICAL DATA SHEET

004512-TDS-ENG-2023

CAPSULAS N° 0 BLANCO (Capsugel)		
DESCRIPTION DCI: ---		DESCRIPTION DOE: ---
CAS N°: ---	EC N°: ---	AEMPS CODE: ---
MOL. WEIGHT: ---	MOL. FORMULA: ---	ARTICLE CODE: 004512

precautions for warehousing and transportation are observed (recommended: 15 °C - 25 °C and 35 % - 65 % relative humidity).

With reference to ICH Q3D and other applicable standards controlling levels of elemental impurities in drug products and food supplements. Capsugel empty capsule products are meeting below levels of applicable elements. Monitoring testing is in place under validated methods, as described in the current edition of Capsugel's applicable Technical Reference File. A documented risk assessment based on the ICH Q3D principles is available on www.mycapsugel.com.

In accordance with ICH Q3D residual solvent guideline, Class 3 solvents may be used according to good manufacturing practices such that their cumulative value does not exceed 5000 ppm or 0.5 %, under option 1 as defined in ICH Q3C, USP<467>, and EP General Text 5.4.

Related to the specific regulations aiming to secure the TSE / BSE safety, Lonza sources bovine gelatin fully complying with the International Guidance.