METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

0315-TDS-ENG-2023

CAPSULAS Nº 2 BLANCO (Qualicaps)		
DESCRIPTION DCI: ---	DESCRIPTION DOE: ---	
CAS Nº: ---	EC Nº: ---	AEMPS CODE: ---
MOL. WEIGHT: ---	MOL. FORMULA: ---	ARTICLE CODE: 0315

ATTRIBUTES	SHOULD BE
Description	Complies
Odour	Complies
Identification	
Gelatin	Complies
Soluble dyes	Complies
Iron oxides	Complies
Titanium dioxide	Complies
S.L.S.	Complies
Chemical tests	
Sulfated ash	=< 9 %
Arsenic	< 1 ppm
Heavy metals	< 30 ppm
Sulfur dioxide	< 0.1 %
Disintegration test	< 15 min
Lubricants	< 0.5 %
Microbiological control	
TAMC	< 1000 CFU/g
TYMC	< 100 CFU/g
Salmonella	Negative/10g
Escherichia coli	Negative/1g
Staphylococcus aureus	Negative/1g
Pseudomonas aeruginosa	Negative/1g
Gram negative bacteria	Negative/1g
Dimensional and physical tests	
Diamter cap	6.35 - 6.37 mm
Body diameter	6.06 - 6.08 mm
Cap length	8.9 - 9.2 mm
Length body	15.2 - 15.5 mm
Thickness cap	93 - 190 µm
Body thickness	93 - 156 µm
Weight	62 mg
Moisture	15.4 %
Capsule colour formulation	
Cap	Opaque white (AJA)
	Titanium dioxide (CI #77891 - E171)
	Water
	Gelatin

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CAS Nº: ---	EC Nº: ---	AEMPS CODE: ---
MOL. WEIGHT: ---	MOL. FORMULA: ---	ARTICLE CODE: 0315

ATTRIBUTES	SHOULD BE
Body	Opaque white (AJA)
	Titanium dioxide (CI #77891 - E171)
	Water
	Gelatin

COMPLIES WITH

Manufacturer specifications

STORAGE

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

REMARKS

The design weight of a "size 2" capsule is 63 mg, the cap representing 40% and the body 60% of the capsule weight. The mean capsule weight of 100 capsules can vary within the range of 58-68 mg.

Raw material
GELATIN: Complies with the requirements of current EP and USP/NF editions.
It is of pure bovine origin, complies with revision in force of European Guideline EMEA/410/01. Each supplier has a Ph. Eur certificate of suitability for their product (R1-CEP-2000-027-Rev.02, R1-CEP-2000-029-Rev.05, R1-CEP-2000-045-Rev.03, R1-CEP-2002-110-Rev.00, R1-CEP-2001-211.Rev.01).

COLORANTS: Comply with Directive 2009/35, Commission Regulation 231/2012 and where applicable, with the requirements of the EP and USP/NF.

PRINTING INKS: Comply with pharmaceutical regulations.

Capsules
Do not contain preservatives and have not been treated with Ethylene Oxide. They comply with The European Agency for the Evaluation of Medicinal Products (EMEA) guideline CPMP/ICH/283/95 and the European Pharmacopoeia for residual solvents.

DISINTEGRATION: Less than 15 minutes by the Ph. Eur. test and have a rupture time of less than 5 minutes by the USA Federal Specification 285AAcid Solubility Test.

This is to certify that the information above has been approved by QA, as described in the applicable regulatory requirements.