METAPHARMACEUTICAL

TECHNICAL DATA SHEET

0315-TDS-ENG-2026

CAPSULAS 2 BLANCAS		
DESCRIPTION DCI: ---	DESCRIPTION DOE: ---	
CAS Nº: ---	EC Nº: ---	AEMPS CODE: ---
MOL. WEIGHT: ---	MOL. FORMULA: ---	ARTICLE CODE: 0315

ATTRIBUTES	SHOULD BE
Identification	
Gelatin	Complies
Chemical tests	
Disintegration test	< 15 min
Ethylene oxide	Absence
Microbiological control	
TAMC	< 1000 CFU/g
Salmonella	Negative/10g
Escherichia coli	Negative/1g
Staphylococcus aureus	Negative/1g
Pseudomonas aeruginosa	Negative/1g
Dimensional and physical tests	
Diamter cap	6.34 - 6.36 mm
Body diameter	6.06 - 6.08 mm
Cap length	8.7 - 9.0 mm
Length body	15.1 - 15.5 mm
Thickness cap	102 - 153 µm
Body thickness	98 - 166 µm
Weight	58.3 - 67.7 mg
Moisture	13.0 - 16.0 %
Capsule colour formulation	
Cap	Opaque white (AJA)
	Titanium dioxide (CI #77891 - E171)
	Water (14.5%)
	Gelatin
Body	Opaque white (AJA)
	Titanium dioxide (CI #77891 - E171)
	Water (14.5%)
	Gelatin

COMPLIES WITH

Manufacturer specifications

STORAGE

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

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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.

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