

CAPSULAS Nº 2 BLANCO (QUALICAPS)			
PRODUCT CODE: 0315		CAS Nº: ---	ANALYSIS Nº: C03/25
MANUFACTURER BATCH:	R2500897	CERTIFICATE ID:	46.239
SUPPLIER BATCH:	----	MANUFACTURING DATE:	30/03/2025
METAPH BATCH:	0230425	EXPIRY DATE:	30/03/2030

ATTRIBUTES	SHOULD BE	IS
Identification		
Gelatin	Complies	Complies
Chemical tests		
Disintegration test	< 15 min	< 15 min
Ethylene oxide	Absence	Absence
Microbiological control		
TAMC	< 1000 CFU/g	< 10 CFU/g
Salmonella	Negative/10g	Negative/10g
Escherichia coli	Negative/1g	Negative/1g
Staphylococcus aureus	Negative/1g	Negative/1g
Pseudomonas aeruginosa	Negative/1g	Negative/1g
Dimensional and physical tests		
Diameter cap	6.36 - 6.38 mm	Complies
Body diameter	6.09 - 6.11 mm	Complies
Cap length	8.8 - 9.1 mm	Complies
Length body	15.1 - 15.4 mm	Complies
Thickness cap	128 - 167 µm	Complies
Body thickness	117 - 160 µm	Complies
Weight	58.3 - 67.7 mg	63.2 mg
Moisture	13.0 - 16.0 %	14.9 %
Capsule colour formulation		
Cap	Opaque white (AJA) Titanium dioxide (CI #77891 - E171) Water (14.5%) Gelatin	Complies 2.000 Complies Complies
Body	Opaque white (AJA) Titanium dioxide (CI #77891 - E171) Water (14.5%) Gelatin	Complies 2.000 Complies Complies

COMPLIES WITH

Manufacturer specifications

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.

Analysis date: 30/04/2025

Manufacturer: 40000533

Signature: Albert Sánchez López (QP)

Conclusion: Complies





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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 (EMA) 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.

STORAGE

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

Analysis date: 30/04/2025

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Conclusion: Complies

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