

## CAPSULAS 3 AZULES/BLANCAS

PRODUCT CODE: 002095		ANALYSIS Nº: C07/25	
MANUFACTURER BATCH:	R2501829	CERTIFICATE ID:	47.350
SUPPLIER BATCH:	----	MANUFACTURING DATE:	11/06/2025
METAPH BATCH:	0120725	EXPIRY DATE:	11/06/2030

ATTRIBUTES	SHOULD BE	IS
<b>Chemical tests</b>		
Sulfur dioxide	< 0.1 %	< 0.10 %
Disintegration test	< 15 min	Complies
Lubricants	< 0.5 %	< 0.50 %
Sulfated ash	< 9.0 %	< 9.0 %
Arsenic	< 1.0 ppm	< 1.0 ppm
<b>Microbiological control</b>		
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
Bile Tolerant Gram (-) Bacteria	Negative/1g	Negative/1g
<b>Dimensional and physical tests</b>		
Diameter cap	5.88 - 5.86 mm	Complies
Body diameter	5.59 - 5.58 mm	Complies
Cap length	8.0 - 7.6 mm	Complies
Length body	13.7 - 13.4 mm	Complies
	195 - 123 µm	Complies
	165 - 130 µm	Complies
Weight	46.3 - 53.8 mg	50.3 mg
Moisture	16.0 - 13.0 %	14.5 %
<b>Capsule colour formulation</b>		
Cap	Op Blue 27 (IQL)	Complies
	Indigo Carmin (CI #73015 - E132)	0.133 %
	Titanium dioxide (CI #77891 - E171)	1.000 %
Body	Opaque white (AJA)	Complies
	Titanium dioxide (CI #77891 - E171)	2.000 %

### COMPLIES WITH

Manufacturer specifications

### REMARKS

All data have been adapted from the authorized supplier's certificate of analysis.

The design weight of a size 3 of capsules is 50.0 mg, the cap represents 40% and the body 60% of the capsule weight. The average weight of 100 capsules can vary between 46.3 - 53.8 mg.

### Raw material

GELATIN (\*\*): Complies with the requirements of the current Editions of Eur. Ph. and USP/NF. It is of purely bovine origin; it complies with the current revision of the European guideline EMEA/410/01. Each supplier has a CEP 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 and R1-CEP-2001-211.Rev.01)

Analysis date: 09/07/2025

Signature: Cristina Borrell Olea (QA/QP)

Conclusion: Complies

Manufacturer: 40000533





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DYES: They comply with Directive 2009/35, Commission Regulation 231/2012 and, where applicable, with the requirements of the Eur. Ph. and USP/NF pharmacopoeias.

PRINTING INKS: They comply with pharmaceutical regulations.

### Capsules

It does not contain preservatives and has not been treated with ethylene oxide. They comply with the CPMP/ICH/283/95 guideline of the European Agency for the Evaluation of Medicinal Products (EMA) and with the European Pharmacopoeia for residual solvents.

DISINTEGRATION: Less than 15 minutes per test according to Eur. Ph.. They have a breakdown time of less than 5 minutes according to US Federal Specification 285a on the acid solubility test.

With this we certify that the above information has been approved by technical management in accordance with the specifications, as described by the applicable regulatory requirements.

### STORAGE

Analysis date: 09/07/2025

Manufacturer: 40000533

Signature: Cristina Borrell Olea (QA/QP)

Conclusion: Complies