



CAPSULAS 4 BLANCAS/VERDES

PRODUCT CODE: 0338	CAS Nº: ---	ANALYSIS Nº: C01/25
MANUFACTURER BATCH: R2402444	CERTIFICATE ID: 45.370	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 31/07/2024	
METAPH BATCH: 0010325	EXPIRY DATE: 31/07/2029	

ATTRIBUTES	SHOULD BE	IS
Chemical tests		
Disintegration test	< 15 min	
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	5.38 - 5.35 mm	Complies
Body diameter	5.11 - 5.07 mm	Complies
Cap length	7.5 - 7.2 mm	Complies
Length body	12.7 - 12.3 mm	Complies
	141 - 100 µm	Complies
	190 - 99 µm	Complies
Weight	43.0 - 37.0 mg	40.3 mg (*)
Moisture	16.0 - 13.0 %	14.6 %
Capsule colour formulation		
Cap	Op Green (DRA)	Complies
	Indigo Carmin (CI #73015 - E132)	0.034 %
	Quinoline Yellow (CI #47005 - E104)	0.012 %
	Titanium dioxide (CI #77891 - E171)	1.700 %
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 4 of capsules is 40.0 mg, the cap represents 40% and the body 60% of the capsule weight. The average weight of 100 capsules can vary between 37.0 - 43.0 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)

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

Analysis date: 10/03/2025

Manufacturer: 40000533

Signature: Albert Sánchez López (QP)

Conclusion: Complies



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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

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

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