METAPHARMACEUTICAL IND SL
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CAPSULAS 3 INCOLORAS

PRODUCT CODE: 002561	CAS Nº: ---		ANALYSIS Nº: C09/25
MANUFACTURER BATCH:	R2203682	CERTIFICATE ID:	48.106
SUPPLIER BATCH:	----	MANUFACTURING DATE:	03/03/2023
METAPH BATCH:	0110925	EXPIRY DATE:	03/03/2028

ATTRIBUTES	SHOULD BE	IS
Chemical tests		
Disintegration test	< 15 min	< 5 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		
Diamter cap	5.86 - 5.84 mm	Complies
Body diameter	5.59 - 5.57 mm	Complies
Cap length	8.08 - 7.84 mm	Complies
Length body	13.74 - 13.45 mm	Complies
	129 - 114 µm	Complies
	150 - 109 µm	Complies
Weight	53.0 - 46.3 mg	49.6 mg
Moisture	16.0 - 13.0 %	15.2 %
Capsule colour formulation		
Cap	Water (14.5%) Target Moisture Gelatin	Complies
Body	Water (14.5%) Target Moisture Gelatin	Complies

COMPLIES WITH

Manufacturer Specifications

REMARKS

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

The design weight of a "size 3" capsule is 50.0 mg, with the cap accounting for 40% and the body for 60% of the capsule's weight. The average capsule weight calculated from 100 capsules may vary within the range of 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)

COLORANTS: 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 (EMEA) 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.

Analysis date: 09/09/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies

Manufacturer: 40000533

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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.

Analysis date: 09/09/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies

Manufacturer: 40000533