METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

0338-TDS-ENG-2025

CAPSULAS 4 BLANCAS/VERDES		
DESCRIPTION DCI: ---	DESCRIPTION DOE: ---	
CAS Nº: ---	EC Nº: ---	AEMPS CODE: ---
MOL. WEIGHT: ---	MOL. FORMULA: ---	ARTICLE CODE: 0338

ATTRIBUTES	SHOULD BE
Chemical tests	
Sulfur dioxide	< 0.1 %
Disintegration test	< 15 min
Lubricants	< 0.5 %
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	5.38 - 5.35 mm
Body diameter	5.11 - 5.07 mm
Cap length	7.5 - 7.2 mm
Length body	12.7 - 12.3 mm
	141 - 100 µm
	190 - 99 µm
Weight	43.0 - 37.0 mg
Moisture	16.0 - 13.0 %
Capsule colour formulation	
Cap	Op Green (DRA)
	Indigo Carmin (CI #73015 - E132)
	Quinoline Yellow (CI #47005 - E104)
	Titanium dioxide (CI #77891 - E171)
Body	Opaque white (AJA)
	Titanium dioxide (CI #77891 - E171)

COMPLIES WITH

Manufacturer specifications

STORAGE

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

REMARKS

The design weight of a size 4 of capsules is 63.5 mg, the cap represents 40% and the body 60% of the capsule weight. The average weight of 100 capsules can vary between 58.6 - 67.4 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-

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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 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.

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.