



## 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 |  |
| Diameter 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)<br>Indigo Carmin (CI #73015 - E132)<br>Quinoline Yellow (CI #47005 - E104)<br>Titanium dioxide (CI #77891 - E171) |
| Body                           | Opaque white (AJA)<br>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" capsule is 40.0 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 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-



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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 (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.