



**QUALI-G™**  
**GELATIN CAPSULE**

## CERTIFICATE OF ANALYSIS

**CUSTOMER:** OMFE, S.A.  
**ITEM DESCRIPTION:** 2AJAAJA QG  
**CUSTOMER ITEM:** 30200101  
**LOT NUMBER:** E1705653N1  
**LOT QUANTITY APPROVED:** 1048000  
**PRINTING:** NOT APPLICABLE  
**INK COLOR:** NOT APPLICABLE

**COUNTRY:** Spain  
**SIZE:** 2  
**CUSTOMER ORDER:** 4900038960  
**NAME:** 2 BLANCO  
**APPROVAL DATE:** 11/03/2019  
**MANUFACTURING DATE:** 16/11/2017  
**EXPIRY DATE:** 5 YEARS

## FINISHED PRODUCT TESTS

| PARAMETERS                               | LIMITS                | REFERENCE  | RESULT         |
|------------------------------------------|-----------------------|------------|----------------|
| <b>MICROBIOLOGICAL AND CHEMICAL TEST</b> |                       |            |                |
| Total Aerobic Microbial Count (TAMC)     | 10 <sup>3</sup> CFU/G | EP/USP     | 10 (Average)   |
| Salmonella                               | Negative / 10 G       | EP/USP     | Meets test     |
| E. Coli                                  | Negative / 1 G        | EP/USP     | Meets test     |
| S. Aureus                                | Negative / 1 G        | EP/USP     | Meets test     |
| Ps. Aeruginosa                           | Negative / 1 G        | EP/USP     | Meets test     |
| Bile-Tolerant Gram-Negative Bacteria     | Negative / 1 G        | EP/USP     | Meets Test **  |
| Total Yeast & Mould Count (TYMC)         | 10 <sup>2</sup> CFU/G | EP/USP     | Meets Test **  |
| Description / Odor                       | Meets test            | EP         | Meets Test **  |
| Id. of Gelatine                          | Meets test            | FP         | Meets Test **  |
| Id. of Soluble Dyes                      | Meets test            | EP         | Meets Test **  |
| Id. of Iron Oxides                       | Meets test            | EP         | Meets Test **  |
| Id. of Titanium Dioxide                  | Meets test            | EP         | Meets Test **  |
| Id. of S.L.S.                            | Meets test            | EP         | Meets Test **  |
| Sulphated Ashes                          | NMT3%(tr)-NMT 9%(op)  | EP         | < 9 **         |
| Arsenic                                  | < 1 ppm               | EP         | < 1 **         |
| Heavy Metal                              | < 30 ppm              | EP         | < 30 **        |
| Sulphur Dioxide                          | <0,1 %                | FP         | < 0,1 **       |
| Disintegration Test                      | <15 min               | EP         | < 15 **        |
| Lubricants                               | < 0,5 %               | FP         | < 0,5 **       |
| <b>DIMENSIONAL AND PHYSICAL TEST</b>     |                       |            |                |
| Diameter                                 | Cap (mm)              | Meets spec | TM*            |
|                                          | Body (mm)             | Meets spec | TM*            |
| Length                                   | Cap (mm)              | Meets spec | TM*            |
|                                          | Body (mm)             | Meets spec | TM*            |
| End thickness                            | Cap (micr)            | Meets spec | QS*            |
|                                          | Body (micr)           | Meets spec | QS*            |
| Weight (mg)                              | Meets spec            | TM*        | 62 (Average)   |
| Moisture (%)                             | Meets spec            | TM*        | 15,4 (Average) |

## VISUAL ATTRIBUTES

|                  |         |         |       |     |                       |
|------------------|---------|---------|-------|-----|-----------------------|
| VISUAL DEFECTS   | Major A | Major B | Minor | TM* | Meets                 |
| AQL (%)          | 0,010   | 0,040   | 0,25  | TM* |                       |
| PRINTING DEFECTS | Major A | Major B | Minor | TM* | Meets (if applicable) |
| AQL (%)          | 0,010   | 0,040   | 1,0   | TM* |                       |

\*TM = Qualicaps Technical Manual \*QS = Qualicaps internal specification "Meets test" means conforms to specification  
\*\*Data from process monitoring

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### CAPSULE COLOR FORMULATION

The design weight of a size 2 capsules is 63 mg, the cap representing 40% and the body 60% of the capsule weight. The mean capsule weight of 100 capsules can vary within the range of 58- 68 mg.

#### CAP :

| CODE | TITLE        | GM OF DYE PER 100 GM CAPSULE                                       |
|------|--------------|--------------------------------------------------------------------|
| AJA  | OPAQUE WHITE | TITANIUM DIOXIDE 2.000<br>WATER (14,5%) TARGET MOISTURE<br>GELATIN |

#### BODY :

| CODE | TITLE        | GM OF DYE PER 100 GM CAPSULE                                       |
|------|--------------|--------------------------------------------------------------------|
| AJA  | OPAQUE WHITE | TITANIUM DIOXIDE 2.000<br>WATER (14,5%) TARGET MOISTURE<br>GELATIN |

| COLORANT         | C.I. NUMBER | E.E.C. NUMBER |
|------------------|-------------|---------------|
| TITANIUM DIOXIDE | 77891       | E171          |

### REGULATORY COMPLIANCE

#### RAW MATERIAL

GELATIN: Complies with the requirements of current EP and USP/NF editions.

It is of pure bovine origin, complies with revision in force of European Guideline EMEA/410/01. Each supplier has a Ph. Eur certificate of suitability 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, R1-CEP-2001-211.Rev.01).

COLORANTS: Comply with Directive 2009/35, Commission Regulation 231/2012 and where applicable, with the requirements of the EP and USP/NF.

PRINTING INKS: Comply with pharmaceutical regulations.

#### CAPSULES :

Do not contain preservatives and have not been treated with Ethylene Oxide. They comply with The European Agency for the Evaluation of Medicinal Products (EMA) guideline CPMP/ICH/283/95 and the European Pharmacopoeia for residual solvents.

DISINTEGRATION: Less than 15 minutes by the Ph. Eur. test and have a rupture time of less than 5 minutes by the USA Federal Specification 285A Acid Solubility Test.

This is to certify that the information above has been approved by QA as conforming to Qualicaps Europe specifications, as described in the current technical manual and applicable regulatory requirements.

P.A.  
