

## CERTIFICATE OF ANALYSIS

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

|                                |                |                            |            |
|--------------------------------|----------------|----------------------------|------------|
| <b>CUSTOMER :</b>              | OMFE, S.A.     | <b>COUNTRY :</b>           | SPAIN      |
| <b>ITEM DESCRIPTION :</b>      | 2DRBAJA        | <b>SIZE :</b>              | 2          |
| <b>CUSTOMER ITEM :</b>         | E00900F        | <b>CUSTOMER ORDER :</b>    | 4900020213 |
| <b>LOT NUMBER :</b>            | E1503973       | <b>NAME :</b>              | .          |
| <b>LOT QUANTITY APPROVED :</b> | 2100000        | <b>APPROVAL DATE :</b>     | 22/06/2015 |
| <b>PRINTING :</b>              | NOT APPLICABLE | <b>MANUFACTURING DATE:</b> | 14/06/2015 |
| <b>INK COLOR :</b>             | NOT APPLICABLE | <b>EXPIRY DATE:</b>        | 5 YEARS    |

**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 the EC directives 2009/35 & 2015/463 and where applicable with the requirements of the EP and USP/NF.

**PRINTING INKS:** Comply with pharmaceutical regulations.

## FINISHED PRODUCT TESTS

**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.

| PARAMETERS | LIMITS | REFERENCE | RESULT |
|------------|--------|-----------|--------|
|------------|--------|-----------|--------|

### MICROBIOLOGICAL AND CHEMICAL TEST

|   |                            |              |              |
|---|----------------------------|--------------|--------------|
| 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   |

### DIMENSIONAL AND PHYSICAL TEST

|               |                   |                  |           |      |           |      |           |
|---------------|-------------------|------------------|-----------|------|-----------|------|-----------|
| DIAMETER      | CAP (mm) .....    | Meets spec ..... | TM* ..... | 6,37 | -         | 6,37 | (max-min) |
|               | BODY (mm) .....   | Meets spec ..... | TM* ..... | 6,08 | -         | 6,07 | (max-min) |
| LENGTH        | CAP (mm) .....    | Meets spec ..... | TM* ..... | 9,0  | -         | 8,8  | (max-min) |
|               | BODY (mm) .....   | Meets spec ..... | TM* ..... | 15,4 | -         | 15,1 | (max-min) |
| END THICKNESS | CAP (micr) .....  | Meets spec ..... | QS* ..... | 159  | -         | 98   | (max-min) |
|               | BODY (micr) ..... | Meets spec ..... | QS* ..... | 175  | -         | 84   | (max-min) |
| WEIGHT (MG)   | .....             | Meets spec ..... | TM* ..... | 62   | (Average) |      |           |
| MOISTURE (%)  | .....             | Meets spec ..... | TM* ..... | 15,1 | (Average) |      |           |

\*TM = Qualicaps Technical Manual

\*QS = Qualicaps internal specification

"Meets test" means conforms to specification



CUSTOMER OMFE, S.A.  
LOT NUMBER: E1503973

COUNTRY: SPAIN  
LOT QUANTITY APPROVED: 2100000

### CAPSULE COLOR FORMULATION SHEET

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  |       |
|------|-----------------|-------------------------------|-------|
| DRB  | OPAQUE YELLOW 5 | QUINOLINE YELLOW              | 1,490 |
|      |                 | TITANIUM DIOXIDE              | 2,300 |
|      |                 | Water (14,5%) target moisture |       |
|      |                 | Gelatin                       |       |

|                  |                        |        |                               |
|------------------|------------------------|--------|-------------------------------|
| In the cap (40%) | 25,2mg Corresponds to: | 0,375  | QUINOLINE YELLOW              |
|                  |                        | 0,579  | TITANIUM DIOXIDE              |
|                  |                        | 3,654  | Water (14,5%) target moisture |
|                  |                        | 20,590 | Gelatin                       |

#### BODY :

| CODE | TITLE        | GM OF DYE PER 100 GM CAPSULE  |       |
|------|--------------|-------------------------------|-------|
| AJA  | OPAQUE WHITE | TITANIUM DIOXIDE              | 2,000 |
|      |              | Water (14,5%) target moisture |       |
|      |              | Gelatin                       |       |

|                   |                        |        |                               |
|-------------------|------------------------|--------|-------------------------------|
| In the body (60%) | 37,8mg Corresponds to: | 0,756  | TITANIUM DIOXIDE              |
|                   |                        | 5,481  | Water (14,5%) target moisture |
|                   |                        | 31,563 | Gelatin                       |

| COLORANT         | C.I. NUMBER | E.E.C. NUMBER |
|------------------|-------------|---------------|
| QUINOLINE YELLOW | 47005       | E104          |
| TITANIUM DIOXIDE | 77891       | E171          |

### VISUAL AND PRINT QUALITY

All the capsules are controlled statistically to ensure conformance to specifications. These values are derived from the MIL.STD.105E. The quality specifications are as follow :

|                  |         |         |       |
|------------------|---------|---------|-------|
| VISUAL DEFECTS   | Major A | Major B | Minor |
| AQL (%)          | 0,010   | 0,040   | 0,25  |
| PRINTING DEFECTS | Major A | Major B | Minor |
| AQL (%)          | 0,010   | 0,040   | 1,0   |