

**CERTIFICATE OF ANALYSIS**

**CUSTOMER:** OMFE, S.A.  
**ITEM DESCRIPTION:** 2AOXAOX QG  
**CUSTOMER ITEM:** 30204141  
**LOT NUMBER:** R2103584  
**LOT QUANTITY APPROVED:** 1190000  
**PRINTING:** NOT APPLICABLE  
**INK COLOR:** NOT APPLICABLE

**COUNTRY:** Spain  
**SIZE:** 2  
**CUSTOMER ORDER:** 4900053436/2  
**NAME:** NÂ°2 AZUL 23  
**APPROVAL DATE:** 23/02/2022  
**MANUFACTURING DATE:** 29/01/2022  
**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
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*	6,38 - 6,36	(max-min)
	Body (mm)	Meets spec	TM*	6,10 - 6,08	(max-min)
Length	Cap (mm)	Meets spec	TM*	9,1 - 8,8	(max-min)
	Body (mm)	Meets spec	TM*	15,4 - 15,2	(max-min)
End thickness	Cap (micr)	Meets spec	QS*	147 - 131	(max-min)
	Body (micr)	Meets spec	QS*	138 - 105	(max-min)
Weight (mg)		Meets spec	TM*	63,8	(Average)
Moisture (%)		Meets spec	TM*	14,6	(Average)

**VISUAL ATTRIBUTES**

<b>VISUAL DEFECTS</b>	Critical	Major	Minor	TM*	Meets
AQL (%)	0,010	0,040	0,25		
<b>PRINTING DEFECTS</b>	Critical	Major	Minor	TM*	Meets (if applicable)
AQL (%)	0,010	0,040	1,0		

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

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### CAPSULE COLOR FORMULATION

The design weight of a size 2 capsules is 63,0 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 58,3 - 67,7 mg.

**CAP :**

CODE	TITLE	GM OF DYE PER 100 GM CAPSULE	
AOX	OP BLUE 23	INDIGO CARMINE	0.050
		TITANIUM DIOXIDE	2.000
		WATER (14,5%) TARGET MOISTURE	
		GELATIN	

**BODY :**

CODE	TITLE	GM OF DYE PER 100 GM CAPSULE	
AOX	OP BLUE 23	INDIGO CARMINE	0.050
		TITANIUM DIOXIDE	2.000
		WATER (14,5%) TARGET MOISTURE	
		GELATIN	

COLORANT	C.I. NUMBER	E.E.C. NUMBER
TITANIUM DIOXIDE	77891	E171
INDIGO CARMINE	73015	E132

### 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.04, R1-CEP-2002-110-Rev.00, R1-CEP-2000-050-Rev.02).

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.

ADRIANA OPREA  
QA/QC MANAGER


