



QUALI-G™
GELATIN CAPSULE

CERTIFICATE OF ANALYSIS

CUSTOMER: OMFE, S.A.
ITEM DESCRIPTION: 2AOXAOX QG
CUSTOMER ITEM: 30204141
LOT NUMBER: E1806730
LOT QUANTITY APPROVED: 1225000
PRINTING: NOT APPLICABLE
INK COLOR: NOT APPLICABLE

COUNTRY: Spain
SIZE: 2
CUSTOMER ORDER: 4900038652
NAME: 2 AZUL 23
APPROVAL DATE: 04/02/2019
MANUFACTURING DATE: 28/01/2019
EXPIRY DATE: 5 YEARS

FINISHED PRODUCT TESTS

PARAMETERS	LIMITS	REFERENCE	RESULT
MICROBIOLOGICAL AND CHEMICAL TEST			
Total Aerobic Microbial Count (TAMC)	10 ³ CFU/G	EP/USP	27 (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 ² 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 **

DIMENSIONAL AND PHYSICAL TEST						
Diameter	Cap (mm)	Meets spec	TM*	6,37	-	6,35 (max-min)
	Body (mm)	Meets spec	TM*	6,09	-	6,07 (max-min)
Length	Cap (mm)	Meets spec	TM*	9,1	-	8,8 (max-min)
	Body (mm)	Meets spec	TM*	15,1	-	15,0 (max-min)
End thickness	Cap (micr)	Meets spec	QS*	172	-	110 (max-min)
	Body (micr)	Meets spec	QS*	146	-	97 (max-min)
Weight (mg)		Meets spec	TM*	64		(Average)
Moisture (%)		Meets spec	TM*	15.0		(Average)

VISUAL ATTRIBUTES

VISUAL DEFECTS	Major A	Major B	Minor	TM*	Meets
AQL (%)	0,010	0,040	0,25		
PRINTING DEFECTS	Major A	Major B	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

**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
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.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.

FEDERICO GARCIA
QUALITY ASSURANCE MANAGEMENT

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DATE: 04/02/2019

