



GELATIN CAPSULE

CERTIFICATE OF ANALYSIS

CUSTOMER: OMFE S.A.
ITEM DESCRIPTION: 4DRAAJA QG
CUSTOMER ITEM: 30403101
LOT NUMBER: E2304548
LOT QUANTITY APPROVED: 2400000
PRINTING: NOT APPLICABLE
INK COLOR: NOT APPLICABLE

COUNTRY: Spain
SIZE: 4
CUSTOMER ORDER: 4900058512
NAME: 4 VERDE 1/BLANCO
APPROVAL DATE: 13/09/2023
MANUFACTURING DATE: 01/09/2023
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	≤ 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*	5,36 - 5,32	(max-min)
	Body (mm)	Meets spec	TM*	5,09 - 5,07	(max-min)
Length	Cap (mm)	Meets spec	TM*	7,40 - 7,25	(max-min)
	Body (mm)	Meets spec	TM*	12,48 - 12,23	(max-min)
End thickness	Cap (micr)	Meets spec	QS*	160 - 122	(max-min)
	Body (micr)	Meets spec	QS*	144 - 83	(max-min)
Weight (mg)		Meets spec	TM*	41,1	(Average)
Moisture (%)		Meets spec	TM*	14,9	(Average)

VISUAL ATTRIBUTES

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

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

METAPHARMACEUTICAL

N DE LOTE:

0210923

Signature 26/09/2023

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CAPSULE COLOR FORMULATION

The design weight of a size 4 capsules is 40,0 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 37,0 - 43,0 mg.

CAP :

CODE	TITLE	GM OF DYE PER 100 GM CAPSULE	
DRA	OP GREEN 1	INDIGO CARMINE	0.034
		QUINOLINE YELLOW	0.012
		TITANIUM DIOXIDE	1.700
		WATER (14,5%) TARGET MOISTURE	
		GELATIN	

BODY :

CODE	TITLE	GM OF DYE PER 100 GM CAPSULE	
AJA	OPAQUE WHITE	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
QUINOLINE YELLOW	47005	E104

REGULATORY COMPLIANCE

RAW MATERIAL

GELATIN: Complies with the requirements of current EP, JP 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.

FEDERICO GARCIA
QUALITY ASSURANCE MANAGEMENT

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DATE: 13/09/2023

