


QUALI-G™
GELATIN CAPSULE

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

CUSTOMER :	OMFE, S.A.	COUNTRY :	SPAIN
ITEM DESCRIPTION :	4DRBDRB	SIZE :	4
CUSTOMER ITEM :	30401212	CUSTOMER ORDER :	4900023038
LOT NUMBER :	E1600508	NAME :	4 AMARILLO 5
LOT QUANTITY APPROVED :	2100000	APPROVAL DATE :	12/05/2016
PRINTING :	NOT APPLICABLE	MANUFACTURING DATE:	6/05/2016
INK COLOR :	NOT APPLICABLE	EXPIRY DATE:	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.

PARAMETERS	LIMITS	REFERENCE	RESULT
MICROBIOLOGICAL AND CHEMICAL TEST			
Total Aerobic Microbial Count (TAMC)	10 ³ 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 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	FP	Meets Test **
Id. of Iron Oxides	Meets test	FP	Meets Test **
Id. of Titanium Dioxide	Meets test	FP	Meets Test **
Id. of S.L.S.	Meets test	EP	Meets Test **
Sulphated Ashes	NMT3%(tr)-NMT 9%(op)	FP	< 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*	5,34	-	5,33	(max-min)
	BODY (mm)	Meets spec	TM*	5,06	-	5,05	(max-min)
LENGTH	CAP (mm)	Meets spec	TM*	7,4	-	7,2	(max-min)
	BODY (mm)	Meets spec	TM*	12,5	-	12,3	(max-min)
END THICKNESS	CAP (micr)	Meets spec	QS*	160	-	97	(max-min)
	BODY (micr)	Meets spec	QS*	132	-	86	(max-min)
WEIGHT (MG)		Meets spec	TM*	39	(Average)		
MOISTURE (%)		Meets spec	TM*	14,7	(Average)		

*TM = Qualicaps Technical Manual
 *QS = Qualicaps internal specification

"Meets test" means conforms to specification
 **Data from process monitoring

CUSTOMER: OMFE, S.A.

COUNTRY: SPAIN

LOT NUMBER: E1600508

LOT QUANTITY APPROVED: 2100000

CAPSULE COLOR FORMULATION SHEET

The design weight of a size 4 capsules is 40 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- 43 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%)	16,0 mg Corresponds to:	0,238	QUINOLINE YELLOW
		0,368	TITANIUM DIOXIDE
		2,320	Water (14,5%) target moisture
		13,073	Gelatin

BODY :

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 body (60%)	24,0 mg Corresponds to:	0,357	QUINOLINE YELLOW
		0,552	TITANIUM DIOXIDE
		3,480	Water (14,5%) target moisture
		19,610	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

