

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 :	8GULBUV	SIZE :	OO
CUSTOMER ITEM :	E01996F	CUSTOMER ORDER :	4900019401
LOT NUMBER :	E1501063	NAME :	
LOT QUANTITY APPROVED :	1950000	APPROVAL DATE :	22/05/2015
PRINTING :	NOT APPLICABLE	MANUFACTURING DATE:	16/04/2015
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.

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 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

DIMENSIONAL AND PHYSICAL TEST

DIAMETER	CAP (mm)	Meets spec	TM*	8,57	-	8,55	(max-min)
	BODY (mm).....	Meets spec	TM*	8,23	-	8,18	(max-min)
LENGTH	CAP (mm)	Meets spec	TM*	11,9	-	11,5	(max-min)
	BODY (mm).....	Meets spec	TM*	20,4	-	20,1	(max-min)
END THICKNESS	CAP (micr).....	Meets spec	QS*	197	-	103	(max-min)
	BODY (micr).....	Meets spec	QS*	180	-	101	(max-min)
WEIGHT (MG)	Meets spec	TM*	120	(Average)		
MOISTURE (%)	Meets spec	TM*	15,0	(Average)		

*TM = Qualicaps Technical Manual

*QS = Qualicaps internal specification

"Meets test" means conforms to specification

CUSTOMER OMFE, S.A.
LOT NUMBER: E1501063

COUNTRY: SPAIN
LOT QUANTITY APPROVED: 1950000

CAPSULE COLOR FORMULATION SHEET

The design weight of a size OO capsules is 126 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 116-136 mg.

CAP :

CODE	TITLE	GM OF DYE PER 100 GM CAPSULE	
GUL	OPAQUE ORANGE 252	RED IRON OXIDE	0,130
		YELLOW IRON OXIDE	0,700
		TITANIUM DIOXIDE	1,000
		Water (14,5%) target moisture	
		Gelatin	

In the cap (40%)	50,4mg Corresponds to:	0,065	RED IRON OXIDE
		0,352	YELLOW IRON OXIDE
		0,504	TITANIUM DIOXIDE
		7,308	Water (14,5%) target moisture
		42,169	Gelatin

BODY :

CODE	TITLE	GM OF DYE PER 100 GM CAPSULE	
BUV	OPAQUE YELLOW 69	YELLOW IRON OXIDE	0,730
		TITANIUM DIOXIDE	2,100
		Water (14,5%) target moisture	
		Gelatin	

In the body (60%)	75,6mg Corresponds to:	0,551	YELLOW IRON OXIDE
		1,587	TITANIUM DIOXIDE
		10,962	Water (14,5%) target moisture
		62,498	Gelatin

COLORANT	C.I. NUMBER	E.E.C. NUMBER
RED IRON OXIDE	77491	E172
YELLOW IRON OXIDE	77492	E172
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