

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 :	1DRBDRB	SIZE :	1
CUSTOMER ITEM :	E00694F	CUSTOMER ORDER :	4900002300
LOT NUMBER :	E1207839	NAME :	.
LOT QUANTITY APPROVED :	1215000	APPROVAL DATE :	30/10/2012
PRINTING :	NOT APPLICABLE	MANUFACTURING DATE:	24/10/2012
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.04, R1-CEP-2002-110-Rev.00, R1-CEP-2001-211-Rev.01) and has confirmed that it is manufactured from raw material not imported from UK, Ireland and Portugal.

COLORANTS: Comply with the EC directives 2009/35 & 2008/128 and where applicable with the requirements of the European Pharmacopoeia and the FDA.

INTING 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 (EMEA) 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*	6,94	-	6,91	(max-min)
	BODY (mm)	Meets spec	TM*	6,63	-	6,61	(max-min)
LENGTH	CAP (mm)	Meets spec	TM*	9,8	-	9,5	(max-min)
	BODY (mm)	Meets spec	TM*	16,8	-	16,7	(max-min)
END THICKNESS	CAP (micr)	Meets spec	QS*	181	-	116	(max-min)
	BODY (micr)	Meets spec	QS*	178	-	125	(max-min)
WEIGHT (MG)	Meets spec	TM*	77	(Average)		
MOISTURE (%)	Meets spec	TM*	15,4	(Average)		

*TM = Qualicaps Technical Manual

*QS = Qualicaps internal specification

"Meets test" means conforms to specification

CUSTOMER OMFE, S.A.
LOT NUMBER: E1207839

COUNTRY: SPAIN
LOT QUANTITY APPROVED: 1215000

CAPSULE COLOR FORMULATION SHEET

The design weight of a size 1 capsules is 76 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 70- 82 mg.

CAP:

<u>CODE</u>	<u>TITLE</u>	<u>GM OF DYE PER 100 GM CAPSULE</u>	
DRB	OPAQUE YELLOW 5	QUINOLINE YELLOW	1,490
		TITANIUM DIOXIDE	2,300
		Water (14,5%) target moisture	
		Gelatin	

In the cap (40%)	30,4mg Corresponds to:	0,452	QUINOLINE YELLOW
		0,699	TITANIUM DIOXIDE
		4,408	Water (14,5%) target moisture
		24,839	Gelatin

BODY:

<u>CODE</u>	<u>TITLE</u>	<u>GM OF DYE PER 100 GM CAPSULE</u>	
DRB	OPAQUE YELLOW 5	QUINOLINE YELLOW	1,490
		TITANIUM DIOXIDE	2,300
		Water (14,5%) target moisture	
		Gelatin	

In the body (60%)	45,6mg Corresponds to:	0,679	QUINOLINE YELLOW
		1,048	TITANIUM DIOXIDE
		6,612	Water (14,5%) target moisture
		37,259	Gelatin

<u>COLORANT</u>	<u>C.I. NUMBER</u>	<u>E.E.C. NUMBER</u>
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