

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 :	7IETAJA	SIZE :	OE
CUSTOMER ITEM :	E00299F	CUSTOMER ORDER :	PEDIDO JP0624
LOTNUMBER :	E1005570	NAME :	
LOTQUANTITY APPROVED :	1125000	APPROVAL DATE :	4/01/2011
PRINTING :	NOT APPLICABLE	MANUFACTURING DATE:	19/12/2010
INK COLOR :	NOT APPLICABLE	EXPIRY DATE:	5 YEARS

GELATIN: Complies with the requirements of the EP (6th Ed.) and the USP32/NF27.

It is of pure bovine origin, complies with the European Guideline EMEA/410/01 rev. 02. Each supplier has a Ph. Eur certificate of suitability for their product (CEP-2000-027, CEP-2000-029, CEP-2002-110, CEP-2001-211) 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 and the French pharmacopoeia and the FDA.

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 (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*
	BODY (mm)	Meets spec	TM*
LENGTH	CAP (mm)	Meets spec	TM*
	BODY (mm)	Meets spec	TM*
END THICKNESS	CAP (micr)	Meets spec	TM*
	BODY (micr)	Meets spec	QS*
WEIGHT (MG)		Meets spec	QS*
		Meets spec	TM*
MOISTURE (%)		Meets spec	TM*
		Meets spec	TM*

*TM = Qualicaps Technical Manual

*QS = Qualicaps internal specification

"Meets test" means conforms to specification

CUSTOMER OMFE, S.A.
 LOT NUMBER: E1005570

COUNTRY: SPAIN
 LOT QUANTITY APPROVED: 1125000

CAPSULE COLOR FORMULATION SHEET

The design weight of a size OE capsules is 106 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 98-115 mg.

CAP:

<u>CODE</u>	<u>TITLE</u>	<u>GM OF DYE PER 100 GM CAPSULE</u>	
IET	OPAQUE GREEN 92	QUINOLINE YELLOW	0,640
		PATENT BLUE V	0,001
		TITANIUM DIOXIDE	1,800
		Water (14,5%) target moisture	
		Gelatin	

In the cap (40%)	42,4mg Corresponds to:	0,271	QUINOLINE YELLOW
		0,000	PATENT BLUE V
		0,763	TITANIUM DIOXIDE
		6,148	Water (14,5%) target moisture
		35,216	Gelatin

BODY:

<u>CODE</u>	<u>TITLE</u>	<u>GM OF DYE PER 100 GM CAPSULE</u>	
AJA	OPAQUE WHITE	TITANIUM DIOXIDE	2,000
		Water (14,5%) target moisture	
		Gelatin	

In the body (60%)	63,6mg Corresponds to:	1,272	TITANIUM DIOXIDE
		9,222	Water (14,5%) target moisture
		53,106	Gelatin

<u>COLORANT</u>	<u>C.I. NUMBER</u>	<u>E.E.C. NUMBER</u>
QUINOLINE YELLOW	47005	E104
PATENT BLUE V	42051	E131
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