

CERTIFICATE OF ANALYSIS

Lot: 620113

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 :	E01983F	CUSTOMER ORDER :	PEDIDO JP0021
LOT NUMBER :	E1200874	NAME :	Nº4 AMARILLO 5
LOT QUANTITY APPROVED :	1145000	APPROVAL DATE :	23/02/2012
PRINTING :	NOT APPLICABLE	MANUFACTURING DATE:	17/02/2012
INK COLOR :	NOT APPLICABLE	EXPIRY DATE:	5 YEARS

GELATIN: Complies with the requirements of current EP and USP 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.01, R1-CEP-2000-029-Rev.03, 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.

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	<10 (Average)*
Description / Odor	Meets test	EP/FP	Meets Test *
Id. of Gelatine	Meets test	EP/FP	Meets Test *
Id. of Soluble Dyes	Meets test	EP/FP	Meets Test *
Id. of Iron Oxides.....	Meets test	EP/FP	Meets Test *
Id. of Titanium Dioxide.....	Meets test	EP/FP	Meets Test *
Id. of S.L.S.....	Meets test	EP/QS	Meets Test *
Sulphated Ashes (%).....	NMT3%(tr)-NMT 9%(op)....	EP/FP	< 9*
Arsenic (ppm)	< 1 ppm	EP/FP	<1*
Heavy Metal (ppm)	< 30 ppm	EP/FP	<30*
Sulphur Dioxide (%).....	<0,1 %	EP/FP	<0,1*
Disintegration Test	<15 min	EP/FP	<15*
Lubricants (%)	< 0,5 %	EP/FP	<0,5*

DIMENSIONAL AND PHYSICAL TEST

DIAMETER	CAP (mm)	Meets spec	TM*	5,34	-	5,31	(max-min)
	BODY (mm)	Meets spec	TM*	5,07	-	5,05	(max-min)
LENGTH	CAP (mm)	Meets spec	TM*	7,5	-	7,1	(max-min)
	BODY (mm)	Meets spec	TM*	12,6	-	12,3	(max-min)
END THICKNESS	CAP (micr)	Meets spec	QS*	162	-	115	(max-min)
	BODY (micr)	Meets spec	QS*	123	-	83	(max-min)
WEIGHT (MG)		Meets spec	TM*	38			(Average)
MOISTURE (%)		Meets spec	TM*	14,5			(Average)

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

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

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%)	16,0mg 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%)	24,0mg 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

