

Qualicaps Europe, S.A.U.

C/ de la Granja, 49 28108 Alcobendas (Madrid)

TEL: +34 .916.630.800 FAX: +34.916.630.30

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.

ITEM DESCRIPTION: 7IETAJA CUSTOMER ITEM:

E00299F

LOT NUMBER:

E1302667

LOT QUANTITY APPROVED: 1050000 PRINTING:

NOT APPLICABLE

INK COLOR:

NOT APPLICABLE

COUNTRY: SPAIN

SIZE:

CUSTOMER ORDER:

NAME: .

EXPIRY DATE:

APPROVAL DATE:

14/05/2013

4900008926

OF

MANUFACTURING DATE: 7/05/2013

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 & 231/2012 and where applicable with the requirements of the EP and USP/NF.

PRINTING INKS: Comply with pharmaceutical regulations.

FINISHED PRODUCT TESTS

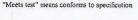
CAPSULES: Do not contain preservatives and have not been treated with Ethylene Oxide. They comply with The European Agency for the Evaluation of Medicinal Products (EMEA) guideline CPMP/ICH/283/95 and the European Pharmacopoeia for residual solvents. DISINTEGRATION: Less than 15 minutes by the Ph. Eur. test and have a rupture time of less than 5 minutes by the USA Federal Specification 285A

PARAMETERS	LIMITS	REFERENCE	RESULT
	MICROBIOLOGICAL	AND CHEMICAL TEST	
Total Aerobic Microbial Count (Salmonella	TAMC) ₁₀ ° CFU/G Negative / 10 G	EP/USP	

Total Aerobic Microbial Count (TAM)	C) 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

DIAMETER	CAP (mm)	Meets spec	TM*	7,67	-	7,66	(max-min)
			TM*				(max-min)
LENGTH			TM*				(max-min)
			TM*				(max-min)
END THICKNESS			QS*				(max-min)
			QS*				(max-min)
WEIGHT (MG)			TM*				
MOISTURE (%)	*****************************	Meets spec	TM*	15,1	(Ave	rage)	

^{*}TM = Qualicaps Technical Manual *QS = Qualicaps internal specification





CUSTOMER

OMFE, S.A.

LOT NUMBER: E1302667

COUNTRY:

SPAIN

LOT QUANTITY APPROVED: 1050000

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.

CODE TITLE **GM OF DYE PER 100 GM CAPSULE**

IET

OPAQUE GREEN 92

QUINOLINE YELLOW

0,640

PATENT BLUE V

0,001

TITANIUM DIOXIDE

1,800

Water (14,5%) target moisture

In the cap (40%)

42,4mg Corresponds to:

0,271

QUINOLINE YELLOW

0,000 0,763 PATENT BLUE V TITANIUM DIOXIDE

6,148

Water (14,5%) target moisture

35,216 Gelatin

BODY :

CODE TITLE **GM OF DYE PER 100 GM CAPSULE**

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

COLORANT

QUINOLINE YELLOW PATENT BLUE V TITANIUM DIOXIDE

C.I. NUMBER

42051

77891

E.E.C. NUMBER

47005

E104 E131 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 0,010

Major B

Minor

AQL (%) PRINTING DEFECTS

Major A 0,010

0,040 Major B 0,25 Minor

AQL (%)

0,040

1,0

QUALITY ASSURANCE MANAGEMENT **ENRIQUE REQUEJO**

The Best Page

of 2

DATE:

14/05/2013

