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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 :	8BWTDR	SIZE :	00
CUSTOMER ITEM :	E00481F	CUSTOMER ORDER :	4900016924
LOT NUMBER :	E1405350	NAME :	
LOT QUANTITY APPROVED :	1200000	APPROVAL DATE :	14/10/2014
PRINTING :	NOT APPLICABLE	MANUFACTURING DATE:	2/10/2014
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 & 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 (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*	8,56	-	8,55	(max-min)
	BODY (mm)	Meets spec	TM*	8,25	-	8,24	(max-min)
LENGTH	CAP (mm)	Meets spec	TM*	12,0	-	11,7	(max-min)
	BODY (mm)	Meets spec	TM*	20,7	-	20,4	(max-min)
END THICKNESS	CAP (micr)	Meets spec	QS*	197	-	103	(max-min)
	BODY (micr)	Meets spec	QS*	164	-	94	(max-min)
WEIGHT (MG)		Meets spec	TM*	128	(Average)		
MOISTURE (%)		Meets spec	TM*	15,1	(Average)		

*TM = Qualicaps Technical Manual

*QS = Qualicaps internal specification

"Meets test" means conforms to specification



CUSTOMER OMFE, S.A.
LOT NUMBER: E1405350

COUNTRY: SPAIN
LOT QUANTITY APPROVED: 1200000

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	
BWT	OPAQUE GREEN 147	INDIGO CARMINE	0,200
		QUINOLINE YELLOW	0,233
		TITANIUM DIOXIDE	0,660
		Water (14,5%) target moisture	
		Gelatin	

In the cap (40%)	50,4mg Corresponds to:	0,100	INDIGO CARMINE
		0,117	QUINOLINE YELLOW
		0,332	TITANIUM DIOXIDE
		7,308	Water (14,5%) target moisture
		42,541	Gelatin

BODY:

CODE	TITLE	GM OF DYE PER 100 GM CAPSULE	
DRA	OPAQUE GREEN 1	INDIGO CARMINE	0,034
		QUINOLINE YELLOW	0,012
		TITANIUM DIOXIDE	1,700
		Water (14,5%) target moisture	
		Gelatin	

In the body (60%)	75,6mg Corresponds to:	0,025	INDIGO CARMINE
		0,009	QUINOLINE YELLOW
		1,285	TITANIUM DIOXIDE
		10,962	Water (14,5%) target moisture
		63,318	Gelatin

COLORANT	C.I. NUMBER	E.E.C. NUMBER
INDIGO CARMINE	73015	E132
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