

CERTIFICATE OF ANALYSIS

This is to certify that the information below has been approved by QA as conforming to Qualicaps Romania, S.R.L. specifications, as described in the current technical manual and applicable regulatory requirements

CUSTOMER :	OMFE, S.A.	COUNTRY :	SPAIN
ITEM DESCRIPTION :	4DRAAJA	SIZE :	4
CUSTOMER ITEM :	R00738F	CUSTOMER ORDER :	4900002606
LOT NUMBER :	R1201407	NAME :	4DRAAJA
LOT QUANTITY APPROVED :	1162000	APPROVAL DATE :	2/10/2012
PRINTING :	NOT APPLICABLE	MANUFACTURING DATE:	25/09/2012
INK COLOR :	NOT APPLICABLE	EXPIRY DATE:	3 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.

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
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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*	5,38	-	5,36	(max-min)
	BODY (mm)	Meets spec	TM*	5,08	-	5,06	(max-min)
LENGTH	CAP (mm)	Meets spec	TM*	7,4	-	7,0	(max-min)
	BODY (mm)	Meets spec	TM*	12,3	-	12,1	(max-min)
END THICKNESS	CAP (micr)	Meets spec	QS*	149	-	113	(max-min)
	BODY (micr)	Meets spec	QS*	140	-	100	(max-min)
WEIGHT (MG)		Meets spec	TM*	39	(Average)		
MOISTURE (%)		Meets spec	TM*	14,4	(Average)		

*TM = Qualicaps Technical Manual

*QS = Qualicaps internal specification

"Meets test" means conforms to specification

CUSTOMER OMFE, S.A.
LOT NUMBER: R1201407

COUNTRY: SPAIN
LOT QUANTITY APPROVED: 1162000

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 :

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

In the cap (40%)	16,0mg Corresponds to:	0,005	INDIGO CARMINE
		0,001	QUINOLINE YELLOW
		0,272	TITANIUM DIOXIDE
		2,320	Water (14,5%) target moisture
		13,400	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%)	24,0mg Corresponds to:	0,480	TITANIUM DIOXIDE
		3,480	Water (14,5%) target moisture
		20,040	Gelatin

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



QA/QC DIRECTOR
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