

## 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

<b>CUSTOMER :</b>	STOCK	<b>COUNTRY :</b>	FRANCE
<b>ITEM DESCRIPTION :</b>	1AJAAJA	<b>SIZE :</b>	1
<b>CUSTOMER ITEM :</b>	R66008F	<b>CUSTOMER ORDER :</b>	
<b>LOT NUMBER :</b>	R1101071	<b>NAME :</b>	1AJAAJA
<b>LOT QUANTITY APPROVED :</b>	5015000	<b>APPROVAL DATE :</b>	1/02/2012
<b>PRINTING :</b>	NOT APPLICABLE	<b>MANUFACTURING DATE:</b>	17/01/2012
<b>INK COLOR :</b>	NOT APPLICABLE	<b>EXPIRY DATE:</b>	3 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.

**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 <sup>3</sup> 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

<b>DIAMETER</b>	CAP (mm) .....	Meets spec .....	TM* .....	6,94	-	6,93	(max-min)
	BODY (mm).....	Meets spec .....	TM* .....	6,67	-	6,65	(max-min)
<b>LENGTH</b>	CAP (mm) .....	Meets spec .....	TM* .....	9,9	-	9,6	(max-min)
	BODY (mm).....	Meets spec .....	TM* .....	16,8	-	16,6	(max-min)
<b>END THICKNESS</b>	CAP (micr) .....	Meets spec .....	QS* .....	190	-	144	(max-min)
	BODY (micr).....	Meets spec .....	QS* .....	173	-	128	(max-min)
<b>WEIGHT (MG)</b>	.....	Meets spec .....	TM* .....	76			(Average)
<b>MOISTURE (%)</b>	.....	Meets spec .....	TM* .....	14,9			(Average)

\*TM = Qualicaps Technical Manual

\*QS = Qualicaps internal specification

"Meets test" means conforms to specification



CUSTOMER STOCK  
LOT NUMBER: R1101071

COUNTRY: FRANCE  
LOT QUANTITY APPROVED: 5015000

### CAPSULE COLOR FORMULATION SHEET

The design weight of a size 1 capsules is 76 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 70- 82 mg.

#### CAP :

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

In the cap (40%)	30,4mg Corresponds to:	0,608	TITANIUM DIOXIDE
		4,408	Water (14,5%) target moisture
		25,384	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%)	45,6mg Corresponds to:	0,912	TITANIUM DIOXIDE
		6,612	Water (14,5%) target moisture
		38,076	Gelatin

COLORANT	C.I. NUMBER	E.E.C. NUMBER
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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