

QUALI-G™ GELATIN CAPSULE

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 : OMF, S.A.

ITEM DESCRIPTION : OBYQBYQ

CUSTOMER ITEM : 30604242

LOT NUMBER : E1507519

LOT QUANTITY APPROVED : 2300000

PRINTING : NOT APPLICABLE

INK COLOR : NOT APPLICABLE

COUNTRY : SPAIN

SIZE : 0

CUSTOMER ORDER : 4900022235

NAME : 0 AZUL 83

APPROVAL DATE : 23/11/2015

MANUFACTURING DATE: 17/11/2015

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 & 2015/463 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.

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
Bile-Tolerant Gram-Negative Bacteria	Negative / 1 G	EP/USP	Meets test
Total Yeast & Mould Count (TYMC)	10 ² CFU/G	EP/USP	Meets Test **
Description / Odor	Meets test	EP	Meets Test **
Id. of Gelatine	Meets test	FP	Meets Test **
Id. of Soluble Dyes	Meets test	FP	Meets Test **
Id. of Iron Oxides	Meets test	FP	Meets Test **
Id. of Titanium Dioxide	Meets test	FP	Meets Test **
Id. of S.L.S.	Meets test	FP	Meets Test **
Sulphated Ashes	NMT3%(tr)-NMT 9%(op)	FP	< 9*
Arsenic	< 1 ppm	EP	< 1*
Heavy Metal	< 30 ppm	EP	< 30*
Sulphur Dioxide	< 0,1 %	FP	< 0,1*
Disintegration Test	< 15 min	EP	< 15*
Lubricants	< 0,5 %	FP	< 0,5*

DIMENSIONAL AND PHYSICAL TEST

DIAMETER	CAP (mm)	Meets spec	TM*	7,65	-	7,64	(max-min)
LENGTH	BODY (mm)	Meets spec	TM*	7,35	-	7,34	(max-min)
	CAP (mm)	Meets spec	TM*	11,2	-	10,8	(max-min)
END THICKNESS	BODY (mm)	Meets spec	TM*	18,8	-	18,6	(max-min)
	CAP (micr)	Meets spec	QS*	189	-	92	(max-min)
WEIGHT (MG)	BODY (micr)	Meets spec	QS*	159	-	95	(max-min)
MOISTURE (%)		Meets spec	TM*	101	(Average)		
		Meets spec	TM*	15,2	(Average)		

*QS = Qualicaps Technical Manual
*TM = Qualicaps Internal Specification

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

CAPSULE COLOR FORMULATION SHEET

The design weight of a size O capsule is 98 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 90-106 mg.

CAP:

CODE	TITLE	GM OF DYE PER 100 GM CAPSULE	BYQ
	OPAQUE BLUE 83	INDIGO CARMINE	0,170

In the cap (40%)

39.2

my Corresponds to:

INDIGO CARMINE	0,066
TITANIUM DIOXIDE	0,517
Water (14,5%) target moisture	5,684
Gelatin	32,931

BY

OPAQUE BLUE 83

INDIGO CARMINE	0,170
TITANIUM DIOXIDE	1,320
Water (14,5%) target moisture	
Gelatin	

(%09) *proq eht ui*

58,8

my Corresponds to:

INDIGO CARMINE	0,099
TITANIUM DIOXIDE	0,776
Water (14,5%) target moisture	8,526
Gelatin	49,397

Colorant	C.I. Number	E.E.C. Number
Titanium Dioxide	77891	E171
Indigo Carmine	73015	E132

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	0.10	Major B	0.040	Minor	0.25
AQL (%)						
PRINTING DEFECTS	Major A	0.10	Major B	0.040	Minor	1.0
AQL (%)						

