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Qualicaps Quali-G™

Quali-G™ GELATIN CAPSULE

CERTIFICATE OF ANALYSIS

CUSTOMER: OSMOPHARM S.A.
ITEM DESCRIPTION: 3AAAAAA QG
CUSTOMER ITEM: CA037B30
LOT NUMBER: R2203682
LOT QUANTITY APPROVED: 3050000
PRINTING: NOT APPLICABLE
INK COLOR: NOT APPLICABLE

COUNTRY: Switzerland
SIZE: 3
CUSTOMER ORDER: AH0024
NAME: CAPSULE 3 CLEAR/CLEAR
APPROVAL DATE: 18/04/2023
MANUFACTURING DATE: 03/03/2023
EXPIRY DATE: 5 YEARS

FINISHED PRODUCT TESTS

PARAMETERS		LIMITS	REFERENCE	RESULT
MICROBIOLOGICAL AND CHEMICAL TEST				
Total Aerobic Microbial Count (TAMC)		10^3 CFU/G	EP/USP	≤ 10
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*	5,86 - 5,84 (max-min)
	Body (mm)	Meets spec	TM*	5,59 - 5,57 (max-min)
Length	Cap (mm)	Meets spec	TM*	8,08 - 7,84 (max-min)
	Body (mm)	Meets spec	TM*	13,74 - 13,45 (max-min)
End thickness	Cap (micr)	Meets spec	QS*	129 - 114 (max-min)
	Body (micr)	Meets spec	QS*	150 - 109 (max-min)
Weight (mg)		Meets spec	TM*	49,6 (Average)
Moisture (%)		Meets spec	TM*	15,2 (Average)

VISUAL ATTRIBUTES					
VISUAL DEFECTS	Critical	Major	Minor	TM*	Meets
AQL (%)	0,010	0,040	0,25		
PRINTING DEFECTS	Critical	Major	Minor	TM*	Meets (if applicable)
AQL (%)	0,010	0,040	1,0		

*TM = Qualicaps Technical Manual *QS = Qualicaps internal specification "Meets test" means conforms to specification

METAPHARMACEUTICAL
N DE LOTE:
0110925
05/09/2025

ISO 9001-14001 CERTIFIED

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INK COLOR:	NOT APPLICABLE	**EXPIRY DATE:**	5 YEARS

CAPSULE COLOR FORMULATION

The design weight of a size 3 capsules is 50,0 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 46,3 - 53,8 mg.

CAP :

CODE	TITLE	GM OF DYE PER 100 GM CAPSULE
AAA	CLEAR	WATER (14,5%) TARGET MOISTURE GELATIN

BODY :

CODE	TITLE	GM OF DYE PER 100 GM CAPSULE
AAA	CLEAR	WATER (14,5%) TARGET MOISTURE GELATIN

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

REGULATORY COMPLIANCE

RAW MATERIAL

GELATIN: Complies with the requirements of current EP, JP 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.04, R1-CEP-2002-110-Rev.00, R1-CEP-2000-050.Rev.02).
COLORANTS: Comply with Directive 2009/35, Commission Regulation 231/2012 and where applicable, with the requirements of the EP and USP/NF.
PRINTING INKS: Comply with pharmaceutical regulations.

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 Acid Solubility Test.

This is to certify that the information above has been approved by QA as conforming to Qualicaps Europe specifications, as described in the current technical manual and applicable regulatory requirements.

ADRIANA OPREA
QA/QC MANAGER

QUALICAPS ROMANIA S.R.L. CALITATE BUCUREȘTI - ROMÂNIA

DATE: *18/04/2023*

ISO 9001-14001 CERTIFIED