

ACG Europe d.o.o.

A member of ACG Worldwide

Frankopanska 79, 42230, Ludbreg,

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ACG**CERTIFICATE OF QUALITY**

Customer Name : ACG Europe stock

COA No : 40000624613

Name of Product : Hard Gelatin Capsule Shells

Spec Ref : ACG LU001

Product Code : ACA1911

Customer Code :

Cap Color : CLEAR TRANSPARENT

Body Color : CLEAR TRANSPARENT

Batch : 4100038332

Batch Qty : 5.031.000

Size : 000

Mfg. Date : JUL 2024

Expiry Date : JUN 2029

PRINTING DETAILS

----- No Printing -----

TEST	SPECIFICATION	UNIT	RESULT
1.IDENTIFICATION			
1) Description	Unlocked cylindrical capsules	-	Complies
2) Capsule colour	As per approved colour shade	-	Complies
3) Identification of gelatin	Positive for gelatin	-	Complies
2.PERFORMANCE			
1) Disintegration Time	Maximum - 15,0	min	1
2) Loss on Drying	13,0 - 16,0	%	14.4
3) Average Weight	151,6 - 174,4	mg	164.1
3.PURITY			
1) Odour	No foreign odour	-	Complies
4.SAFETY			
1) Sulphated ash	Maximum 7%	-	Complies*
2) Arsenic	Maximum 1 ppm	-	Complies*
3) Lead	Maximum 1 ppm	-	Complies*
4) Lubricant content	Maximum 0.5%	-	Complies*
5) Sulphur Dioxide	Maximum 50 ppm	-	Complies*
6) Mercury	Maximum 0.1 ppm	-	Complies*
7) Cadmium	Maximum 0.5 ppm	-	Complies*
5.MICROBIAL LIMITS			
1) Total aerobic microbial count	0 - 1000	cfu/g	30
2) Yeast and Molds	0 - 100	cfu/g	10
3) Escherichia coli	Absent in 1g	-	Absent
4) Salmonella	Absent in 10g	-	Absent
5) Pseudomonas Aeruginosa	Absent in 1g	-	Absent
6) Staphylococcus aureus	Absent in 1g	-	Absent

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ACG**CERTIFICATE OF QUALITY****Customer Name : ACG Europe stock****COA No : 40000624613****Name of Product : Hard Gelatin Capsule Shells****Spec Ref : ACG LU001****Product Code : ACA1911****Customer Code :****Cap Color : CLEAR TRANSPARENT****Body Color : CLEAR TRANSPARENT****Batch : 4100038332****Batch Qty : 5.031.000****Size : 000****Mfg. Date : JUL 2024****Expiry Date : JUN 2029****PRINTING DETAILS**

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In Accordance with ICH Q3C Residual solvent guideline, Class 3 solvents may be used according to good manufacturing practices such that their cumulative value does not exceed 5000 ppm or 0.5% under option 1 as defined in ICH Q3C, USP-467 & Ph.Eur General text 5.4

Hard gelatin capsule shells are complying to less than 0.0002% (2ppm) Chromium as defined in monograph of vacant gelatin capsules as per Chinese Pharmacopoeia.

DISPOSITION: The above batch was tested using methods described in current edition of our capsules testing guide and conforms to the prescribed release specifications for Hard Gelatin Capsule Shells.

Approved By Rahul Dixit**Designation** Approver**Date** 22.07.2024

Signature Not Verified

Digitally Signed By:

ACG Europe d.o.o.
Mon 22-Jul-2024 06:23:18 UTC*This document is digitally signed.*

These capsules are produced under very carefully controlled GMP conditions. Controls are performed continuously during the process and assure that the capsules conform to the highest standards as defined in the ACG Europe d.o.o. specification.

PRODUCT INFORMATION

Name Of Product : Hard Gelatin Capsule Shells

Brand Name : ACGcaps GR

Product Code : ACA1911

Customer Code :

COMPOSITION

Component	Reference	Percentage (%)
Gelatin	USPNF+Ph.Eur	q.s for 100
Purified Water	Ph.Eur	14 - 15
No added Preservatives		

CAP

Colorants	No Colorants	0.0000
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BODY

Colorants	No Colorants	0.0000
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Limitations: The indicated composition data are target values based on lab scale development. The actual values may vary for matching the color.

The product is manufactured in accordance with cGMP in an ISO certified plant. The visual quality and print quality of capsules wherever applicable conform to the AQL (Acceptable level of Quality) as defined in our Technical Manual.

ACG Europe d.o.o. ensures that bovine gelatin, when used conforms to TSE/BSE regulations as applicable to the country of use :

- 1.Regulation (EC) No 999/2001 & ammendment thereof.
- 2.Regulation (EC) No 853/2004
- 3.USFDA Sept 1997, Guidance to Industry for the sourcing & processing of gelatin to reduce the potential risk posed by BSE in FDA regulated product
- 4.USFDA 21 CFR parts 189,589,700 pertaining to prohibited cattle materials in human food,drugs & cosmetic & animal feeds.
- 5.USFDA 9 CFR Part 94.23 pertaining to the importation of gelatin from bovines.
- 6.Commission directive 2003/63/EC and Ph. Eur. -1483 evidenced by the certificate of suitability.The gelatin corresponding to one or more of the COS is used.

Gelatin Supplier	COS No	Gelatin Supplier	COS No
PB Gelatins	CEP 2000-045	Gelita Group	R1-CEP 2001-424
Rousselot SAS	R1-CEP 2000-027	Rousselot SAS	R1-CEP 2002-098
Rousselot SAS	R1-CEP 2000-029	PB Gelatins	R1-CEP 2002-110
Gelita Group	R1-CEP 2000-050	Gelita Group	R1-CEP 2003-172
Rousselot SAS	R1-CEP 2000-067	India Gelatine & Chemicals Ltd	R1-CEP 2003-261
Nitta Gelatin India Ltd.	R1-CEP 2000-344	Gelco Gelatin	R1-CEP 2006-086
Sterling Biotech Ltd.	R1-CEP 2001-211	PB Gelatins	R1-CEP 2014-280

Storage Conditions	(a) Temperature between 15-25 °C and RH between 35-65%. (b) Do not store near a source of heat & avoid wide temperature fluctuation during storage
Handling Precautions	(a) Temperature between 15-25°C and RH between 35-65% during usage. (b) Use Only S.S Scoops & Spatulas. (c) Do not leave capsules in a filling machine hopper for prolonged period when not in use. (d) Keep mouth of the bag closed when not in use.
Shelf Life	5 Years from date of manufacturing when stored & handled as above

Recommendation

	Closed Joined Length (mm)	Volume (ml)
Nominal	25.9	1.37
Tolerance	± 0.4	APPROX CAPACITY