

ACG Associated Capsules Private Limited**A member of ACG Worldwide**

Ashagadh, Dahanu Road,

District: Thane-401602, Maharashtra, India

Phone : +91 2528 260130 / 260132

Email : sales.acpl@acg-world.com

**CERTIFICATE OF QUALITY****Customer Name :** PT. ACG Indonesia, JL. GADING KIRANA BARAT IX,**COA No :** 40000585683**Name of Product :** Hard Gelatin Capsule Shells**Spec Ref :** ACPL0001**Product Code :** PT76152**Customer Code :****Cap Color :** CLEAR TRANSPARENT**Body Color :** CLEAR TRANSPARENT**Batch :** 1100248376**Batch Qty :** 1,950,000**Size :** 0**Mfg. Date :** MAY 2024**Expiry Date :** APR 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	4
2) Loss on Drying	13.0 - 16.0	%	15.3
3) Average Weight	89.3 - 102.7	mg	96.8
3.PURITY			
1) Odour	No foreign odour	-	Complies
4.SAFETY			
1) Sulphated ash	Maximum 5%	-	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 - 500	cfu/g	10
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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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 Sonali Pilke**Designation** Approver**Date** 14.05.2024

Signature Not Verified

Digitally Signed By:
DS ACG ASSOCIATED CAPSULES PRIVATE
LIMITED 1
Tue 14-May-2024 12:47:05 IST

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 Capsules specification.

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**PRODUCT INFORMATION****Name Of Product** : Hard Gelatin Capsule Shells**Brand Name** : ACGcaps GR**Product Code** : PT76152**Customer Code** :

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

CAP**Colorants** No Colorants

0.0000

BODY**Colorants** No Colorants

0.0000

Limitations: The indicated composition data are target values based on lab scale development. The actual values may vary for matching the color.

Sodium lauryl sulphate (USP+Ph.Eur+IP) is used as a manufacturing aid.

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.

BSE compliance :

ACG-ACPL selects pharmaceutical gelatin blends based on product quality requirement and regulatory compliances. All gelatins used conform to the applicable pharmacopoeia and food regulations. Bovine gelatin, when used, is derived from bones and hides of healthy animals that have been certified as fit for human consumption by a veterinary official at slaughtering. The tissues used in the manufacture of gelatin are free from specified risk materials. In addition, ACG-ACPL ensures that the bovine gelatin conforms to the following BSE regulations as applicable to the country of use.

1.Regulation (EC) No 999/2001 & amendment thereof

2.Regulation (EC) No 853/2004

3.USFDA Sept 1997, Guidance to Industry for the sourcing and processing of gelatin to reduce the potential risk posed by BSE in FDA regulated Products.

4.USFDA 21 CFR parts 189,589,700 pertaining to prohibited cattle materials in human food, drugs cosmetics & animal feeds.

5.USFDA 9 CFR Part 94.23 pertaining to the importation of gelatin from bovines.

Storage Conditions (a) Temperature between 15-30 °C and RH between 40-65%.

(b) Do not store near a source of heat & avoid wide temperature fluctuation during storage

Handling Precautions (a) Temperature between 20-25°C and RH between 45-55% 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	21.4	0.68
Tolerance	± 0.4	APPROX CAPACITY