

CERTIFICATE OF QUALITY

Customer Name : PT. ACG Indonesia, JL. GADING KIRANA BARAT IX,

COA No : 40000958940

Name of Product : Hard Gelatin Capsule Shells

Product Code : PT76170

Customer Code :

Cap Color : MAROON

Body Color : MAROON

Batch : 4900006795

Batch Qty : 10,000,000

Spec Ref : ACPL0001

Mfg. Date : MAY 2026

Expiry Date : APR 2031

Size : 0



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
4) Identification of colourants	Conforms to composition	-	Complies*
5) Identification of Titanium dioxide	Conforms to composition	-	Complies*
2.PERFORMANCE			
1) Disintegration Time	Maximum - 15.0	min	4
2) Loss on Drying	13.0 - 16.0	%	15.0
3) Average Weight	89.3 - 102.7	mg	96.1
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 - 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

A member of ACG Worldwide

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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.

Watcharakiat K.

Approved By Watcharakiat Kuekoon
Designation Approver

Digitally Signed by:
ACG Capsules (Thailand) Company Limited
04/06/2026@03:01:39 UTC

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 per prescribed release specification.



PRODUCT INFORMATION

Name Of Product : Hard Gelatin Capsule Shells

Brand Name : ACGcaps GR

Product Code : PT76170

Customer Code :

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

CAP

Colorants	Brilliant Blue FCF	CI.NO-42090, E133,(EU) 231/2012	0.0180
	Quinoline Yellow	CI.NO-47005, E104,(EU) 231/2012	0.0750
	Sunset Yellow FCF	CI.NO-15985, E110,(EU) 231/2012	0.1920
	Amaranth	CI.NO-16185, E123,(EU) 231/2012	0.6600
Opacifier	Titanium Dioxide	77891,E171,USP+EP,21CFR,EU231/2012	1.4625

BODY

Colorants	Brilliant Blue FCF	CI.NO-42090, E133,(EU) 231/2012	0.0180
	Quinoline Yellow	CI.NO-47005, E104,(EU) 231/2012	0.0750
	Sunset Yellow FCF	CI.NO-15985, E110,(EU) 231/2012	0.1920
	Amaranth	CI.NO-16185, E123,(EU) 231/2012	0.6600
Opacifier	Titanium Dioxide	77891,E171,USP+EP,21CFR,EU231/2012	1.4625

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) is used as a manufacturing aid.

The product is manufactured in accordance with IPEC GMP. The visual quality and print quality of capsules wherever applicable conform to the AQL (Acceptable level of Quality) as defined in the specification.

BSE compliance :

ACG Capsules 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 & ammendment 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 For Filling	Closed Joined Length (mm)	Volume (ml)
Nominal	21.4	0.68
Tolerance	± 0.4	APPROX CAPACITY