

**Name of the Product:** Hard Gelatin Capsule Shells**Brand Name:** ACGcaps GR**Application:** Oral**Segment:** Pharmaceuticals / Nutraceuticals**Specification No:**  
ACPL0001**Issue No:** 07**Revision No:** 02**Effective Date:**  
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## 2. PHYSICOCHEMICAL & MICROBIOLOGICAL SPECIFICATION

SR. NO	TEST	SPECIFICATIONS							
	<b>IDENTIFICATION</b>								
1	Description	Unlocked cylindrical capsules							
2	Capsule colour	As per approved colour shade							
3	Identification of Gelatin	Positive for gelatin							
4	Identification of Colourants	Conforms to composition							
5	Identification of Titanium dioxide	Conforms to composition							
6	Identification of Iron Oxides	Conforms to composition							
	<b>PERFORMANCE</b>								
1	Disintegration Time in water at 37 ± 2°C	Maximum 15 minutes (with guided disc)							
2	Loss on drying (at 105°C ± 1°C for minimum 4 hours or to constant weight)	13.0 - 16.0 %							
3	Average weight of capsule shells in mg (Weight of 100 capsules/100)	Size	000	00EL	00	0XEL	0EL+	0EL	0
		Target	163	130	119	109	108.3	104	96
		Tolerance	±7 %	±7 %	±7 %	±7 %	±7 %	±7 %	±7 %
		Range	151.6	120.9	110.7	101.4	100.7	96.7	89.3
			174.4	139.1	127.3	116.6	115.9	111.3	102.7
		Size	1EL	1	2EL	2	3	4	5
		Target	81	76	68.4	63	50	39	28
		Tolerance	±7 %	±7 %	±7 %	±7 %	±7 %	±7 %	±7 %
		Range	75.3	70.7	63.6	58.6	46.5	36.3	26.0
			86.7	81.3	73.2	67.4	53.5	41.7	30.0
	<b>PURITY</b>								
1	Odour	No foreign odour							
	<b>SAFETY</b>								
1	Sulphated ash#	Maximum 7%							
2	Arsenic	Maximum 1 ppm							
3	Lead	Maximum 1 ppm							
4	Lubricant content	Maximum 0.5%							
5	Sulphur Dioxide	Maximum 50 ppm							
6	Mercury	Maximum 0.1 ppm							
7	Cadmium	Maximum 0.5 ppm							
	<b>MICROBIAL LIMITS</b>								
1	Total aerobic microbial count	Maximum 500 cfu / g							
2	Yeast and Molds	Maximum 100 cfu / g							
3	Escherichia coli	Absent in 1g							



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SR. NO	TEST	SPECIFICATIONS
4	Salmonella	Absent in 10g
5	Pseudomonas aeruginosa	Absent in 1g
6	Staphylococcus aureus	Absent in 1g

#The limit for sulphated ash for the Hard Gelatin Capsule Shells without titanium dioxide and/or iron oxide(s) is 5% (w/w)



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**3. ACCEPTABLE QUALITY LEVEL AND AVERAGE OUTGOING QUALITY LIMIT**

**Capsule defects:**

Capsules are manufactured under controlled conditions through statistical process control to ensure conformance to specifications.

**Definition of capsule defects:**

Critical defect	Is a defect that affects the performance of a capsule as package for the final product or contributes to a major filling problem
Major defect	Is a defect that may cause a problem on a filling machine
Minor defect	Is a defect that has no effect on the performance of a capsule as a package. It is a slight blemish that makes the capsule visually imperfect.

**Categorization of capsule defects:**

Critical defects	Major defects	Minor defects
Hole	Loose piece	Minor splits
Uncut body	Closed capsules	Minor rough cuts
Uncut cap	Double caps	Minor collet pinches
Cracked / split (rapid dried)	Bad join	Minor punched dome
Short body	Major rough cuts	Bubbles
Double dip	Major collet pinches	Wrinkles
Telescoped	Major punched end / dome (dented)	Star ends
Mashed	Thin spots	Specks
Trims (loose ring inside)	Short cap	Dirt marks / dirty
Trims (loose ring outside)	Long cap	Strings (spiral cut)
String on end	Long body	Scrapes / scratches
	Grease / oil rings	Uneven cut

**Sampling plan:**

Capsule defects are evaluated based on sample size & acceptance number derived from the ISO 2859 Part I using single sampling plan.

The AQLs indicated could be verified on a composite random sample drawn from  $\sqrt{k+1}$  cartons in the shipment, where k = number of cartons in the shipment.

Corresponding AQL and AOQL values are also provided therein.



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**Acceptable quality level and average outgoing quality limit:**

Corresponding sampling plans to be used during incoming inspection are as follows:

Categorization of defects	Lot size 500,000 & above				
	Sample size*	Acceptance number	Rejection number	AQL %	AOQL %
<b>CAPSULE DEFECTS</b>					
Critical	1250	0	1	0.01	0.029
Major	1250	1	2	0.04	0.067
Minor	1250	7	8	0.25	0.360

\* To be selected from  $(\sqrt{k}+1)$  cartons where k = number of cartons in the lot.

**Method of inspection of capsule defects:**

Take capsule samples as per sampling plan & spread it on inspection table. Inspect it in upper and lower light of inspection table for 3 - 4 minutes. Check capsules from every side.





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**Print defects:**

**Definition of print defects:**

Critical defect	Missing print or complete absence of the logo. Non-Oriented print leading to illegibility of print matter
Major defect	Defect resulting in illegibility of print or non-identification of printed logo.
Minor defect	Printing defects, which do not affect the legibility or identification of the printed logo but detract from the visual appearance of the capsules.

**Categorization of print defects:**

Critical defects	Major defects	Minor defects
Unprinted Non-oriented with illegible message	Illegible print	Multiple print Broken letters (cut print) Smudged print Off-register Ink spots / ink lines Light / dark print Non-oriented Skewed print

**Sampling plan:**

Printing defects are evaluated based on sample size & acceptance number derived from the ISO 2859 Part I using single sampling plan.

The AQLs indicated could be verified on a composite random sample drawn from  $\sqrt{k}+1$  cartons in the shipment, where k = number of cartons in the shipment.

Corresponding AQL and AOQL values are also provided therein.





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**Acceptable quality level and average outgoing quality limit:**

Corresponding sampling plans to be used during incoming inspection are as follows:

Categorization of defects	Lot size 500,000 & above				
	Sample size*	Acceptance number	Rejection number	AQL %	AOQL %
<b>PRINT DEFECTS</b>					
Critical	1250	0	1	0.01	0.029
Major	1250	2	3	0.065	0.110
Minor	1250	21	22	1.0	1.2

\* To be selected from  $(\sqrt{k}+1)$  cartons where k = number of cartons in the lot.

**Method of inspection of print defects:**

Take capsule samples as per sampling plan & spread it on inspection table. Inspect it in upper and lower light of inspection table for 3 - 4 minutes. Check capsules from every side.

Note: Categorization and description of capsule and print defects can be referred in our testing guide available on our website : <http://apps.acg-world.com>



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### 4. DIMENSION SUMMARY

CAPSULE SIZE	000	00EL	00	0XEL	0EL+	0EL	0
<b>1. CAPACITY</b>							
Body Volume (ml)	1.37	1.02	0.95	0.82	0.78	0.78	0.68
Capsule capacity (mg) for powder density							
0.6 g / cc	822	612	570	492	468	468	408
0.8 g / cc	1096	816	760	656	624	624	544
1.0 g / cc	1370	1020	950	820	780	780	680
1.2 g / cc	1644	1224	1140	984	936	936	816
<b>2. WEIGHT</b>							
Average weight in mg	163	130	119	109	108.3	104	96
Tolerance	±7 %	±7 %	±7 %	±7 %	±7 %	±7 %	±7 %
<b>3. LENGTH</b>							
Cap Nominal (mm)	13	13	11.8	11.8	12	11.7	10.7
Tolerance (mm) *	± 0.40	± 0.40	± 0.40	± 0.40	± 0.40	± 0.40	± 0.40
Body Nominal (mm)	22.2	22.2	20.2	21.8	21	20.3	18.5
Tolerance (mm) *	± 0.40	± 0.40	± 0.40	± 0.40	± 0.40	± 0.40	± 0.40
<b>4. OVERALL CLOSED LENGTH</b>							
Nominal Joined Length (mm)	25.9	25.5	23.5	24.8	24.2	23.2	21.4
Tolerance (mm) *	± 0.40	± 0.40	± 0.40	± 0.40	± 0.40	± 0.40	± 0.40
<b>5. NORMAL OUTSIDE DIAMETER</b>							
Cap Nominal (mm)	9.96	8.55	8.55	7.66	7.66	7.66	7.66
Tolerance (mm) *	± 0.03	± 0.03	± 0.03	± 0.03	± 0.03	± 0.03	± 0.03
Body Nominal (mm)	9.61	8.22	8.22	7.34	7.34	7.34	7.34
Tolerance (mm) *	± 0.03	± 0.03	± 0.03	± 0.03	± 0.03	± 0.03	± 0.03

\*On average of 20

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CAPSULE SIZE	1EL	1	2EL	2	3	4	5
<b>1. CAPACITY</b>							
Body Volume (ml)	0.54	0.50	0.41	0.37	0.30	0.21	0.10
Capsule capacity (mg) for powder density							
0.6 g / cc	324	300	246	222	180	126	60
0.8 g / cc	432	400	328	296	240	168	80
1.0 g / cc	540	500	410	370	300	210	100
1.2 g / cc	648	600	492	444	360	252	120
<b>2. WEIGHT</b>							
Average weight in mg	81	76	68.4	63	50	39	28
Tolerance	±7 %	±7 %	±7 %	±7 %	±7 %	±7 %	±7 %
<b>3. LENGTH</b>							
Cap Nominal (mm)	10.5	9.8	9.7	9	8.1	7.2	6.2
Tolerance (mm) *	± 0.40	± 0.40	± 0.40	± 0.40	± 0.40	± 0.40	± 0.40
Body Nominal (mm)	17.7	16.6	16.7	15.2	13.6	12.2	9.3
Tolerance (mm) *	± 0.40	± 0.40	± 0.40	± 0.40	± 0.40	± 0.40	± 0.40
<b>4. OVERALL CLOSED LENGTH</b>							
Nominal Joined Length (mm)	20.4	19.3	19.3	17.8	15.8	14.4	11.4
Tolerance (mm) *	± 0.40	± 0.40	± 0.40	± 0.40	± 0.40	± 0.40	± 0.40
<b>5. NORMAL OUTSIDE DIAMETER</b>							
Cap Nominal (mm)	6.93	6.93	6.37	6.37	5.85	5.33	4.91
Tolerance (mm) *	± 0.03	± 0.03	± 0.03	± 0.03	± 0.03	± 0.03	± 0.03
Body Nominal (mm)	6.63	6.63	6.08	6.08	5.57	5.06	4.65
Tolerance (mm) *	± 0.03	± 0.03	± 0.03	± 0.03	± 0.03	± 0.03	± 0.03

\*On average of 20

**Note 1:** Empty Capsules can be filled with powders, granules, pellets, tablets, semisolid materials, pastes etc. The useful capacity value is the available volume of the capsule body.

**Note 2:** The average empty capsule weight is estimated by a representative sample of 100 capsules. Significant variation in average weight will occur if moisture content changes. Moisture content of capsules is assumed to be 14% and tolerances are given at 99.7% confidence level.

**Note 3:** Capsules cap/body length is controlled during manufacture and each lot is audited for conformance to specification.

**Note 4:** Closed joined length not recommended for capsules closed offline by hand. This is a recommendation for machine setting for appropriate locking.

**Note 5:** The body diameters are indicative only. Body diameters are adjusted to achieve correct fit, oriented towards better machinability. Outside diameters should not be measured by Vernier caliper

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15.09.2021**Page No:** 10 of 10**5. SPECIFICATION ACCEPTANCE**

Specification ACPL0001: Hard Gelatin Capsule Shells (ACGcaps GR) of ACG Associated Capsules Pvt. Ltd. as above is acceptable to us

Name of Organization		
Address	Postal	
	Email	
Name of Person		
Designation		
Signature		
Date		
Company seal		