

ACG Associated Capsules Pvt Ltd

A member of ACG Worldwide
 Gat No.-322, 323, Shindewadi, Post Shirwal
 Tal.Khandala, Dist.Satara-412801, Maharashtra, India.
 Phone : +91 2169-305100 / 305105
 Fax : +91 2169-305141

**CERTIFICATE OF QUALITY**

Customer Name : Sana Med Pharmaceutical Co. **COA No :** 40001399872
Name of Product : Hard Gelatin Capsule Shells **Spec Ref :** ACPL0001
Product Code : SAD9004 **Customer Code :**
Cap Color : PINK OPAQUE
Body Color : BROWN OPAQUE
Batch : 1120132607 **Batch Qty :** 8,925,000 **Size :** 2
Mfg. Date : JUL 2022 **Expiry Date :** JUN 2027

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*
6) Identification of Iron Oxides	Conforms to composition	-	Complies*
2.PERFORMANCE			
1) Disintegration Time	Maximum - 15.0	min	3
2) Loss on Drying	13.0 - 16.0	%	14.0
3) Average Weight	58.6 - 67.4	mg	63.4
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	35
2) Yeast and Molds	0 - 100	cfu/g	<10
3) E.coli	Absent in 1g	-	Absent
4) Salmonella	Absent in 10 g	-	Absent
5) Pseudomonas aeruginosa	Absent in 1g	-	Absent
6) S.aureus	Absent in 1g	-	Absent

* Compliance as per test parameter monitoring protocol.

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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 Shantinath Khot
Designation Approver
Date 25.07.2022

Validity unknown



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-ACPL specification.

PRODUCT INFORMATION

Name Of Product : Hard Gelatin Capsule Shells
Product Code : SAD9004 **Customer Code** :

COMPOSITION

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

CAP

Colorants	Reference	Percentage (%)
SUNSET YELLOW FCF	CI.NO-15985, E110,(EU) 231/2012	0.0120
BRILLIANT BLUE FCF	CI.NO-42090, E133,(EU) 231/2012	0.0007
ERYTHROSINE **	CI.NO-45430, E127 ,(EU) 231/2012	0.0050
Opacifier Titanium Dioxide USP+Ph.Eur+IP	CI.NO-77891,E171,(EU) 231/2012,21CFR	1.5600

BODY

Colorants	Reference	Percentage (%)
IRON OXIDE RED	CI.NO-77491, E172,(EU) 231/2012,21CFR	0.3698
IRON OXIDE YELLOW	CI.NO-77492, E172,(EU) 231/2012,21CFR	0.1389
Opacifier Titanium Dioxide USP+Ph.Eur+IP	CI.NO-77891,E171,(EU) 231/2012,21CFR	1.3195

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

** Light sensitive colorants, protect from light.

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 & 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

	Closed Joined Length (mm)	Volume (ml)
Nominal	17.8	0.37
Tolerance	± 0.4	APPROX CAPACITY