

# CERTIFICATE OF ANALYSIS

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1. PRODUCT DESCRIPTION: Empty Hard Gelatin Capsules			
Product Name:	Hard Gelatin Capsules Shells	Our Reference:	HT4CT B
Packing Batch Number: HC221841	Capsule Size: 4	Capsules Batch Number:	1100224872
Manufacturing Date:	Aug 2022	Expiration Date:	Jul 2 702
Cap Color Name:	Clear TR	Body Color Name:	Clear TR
Closed Joined length (mm):	14.4 (Tolerance: $\pm 0.4$ )	Volume: 0.21 ml (Tolerance: Approx Capacity)	

2. Cap Composition:	(in %)	3. Body Composition:	(in %)
Gelatin	qsp 100	Gelatin	qsp 100
Purified Water	14 -15	Purified Water	14 -15

Due to the nature of raw materials, their sourcing, and technology improvements, the colorant composition data indicated are target values and actual values may vary to insure the consistency of lot color. We supports the expiry date if precautions for warehousing and transportation are observed (Recommended: 15°C-30°C and 35%-65% relative humidity)

4. Ingredient/Reference:	C.I No.	EEC No.	Function	Reference
Gelatin	-	-	Structure	USP NF-Ph.Eur+IP+ACPL
Purified Water	-	-	-	Ph.Eur+IP

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

5.Characteristics:	Units	Specifications	Results
Identification of gelatin	-	Positive	Pass
Identification of TiO2	-	Conforms to Composition	Not Applicable
Identification of dyestuffs	-	Conforms to Composition	Not Applicable
Identification of iron oxides	-	Conforms to Composition	Not Applicable
Sulphated ash	%	Less than 5	Pass *
Arsenic	ppm	Less than 1	Pass *
Lead	ppm	Less than 1	Pass *
Mercury	ppm	Maximum 0.1ppm	Pass *
Cadmium	ppm	Maximum 0.5ppm	Pass *
Sulphur dioxide	ppm	Less than 50	Pass *
Lubricant content	%	Less than 0.5	Pass *
Disintegration time	min/sec	Less than 15:00	2:00
Loss on drying	%	13.0 to 16.0	15.0
Average weight	mg	36.3 – 41.7	39.1
Total Aerobic microbial count	cfu / g	Less than 500	Pass
Escherichia coli	-	Absent in 1 gram	Pass
Salmonella species	-	Absent in 10 gram	Pass
Pseudomonas aeruginosa	-	Absent in 1 gram	Pass
Staphylococcus aureus	-	Absent in 1 gram	Pass
Total combined Yeast and Mold count	cfu / g	Less than 100	Pass

\*Process monitoring Data

**6. Physical Characteristics**

This product conforms to established A.Q.L.'s for Physical Attributes.

Appearance - Clean empty capsules, meeting the specified requirements of color and size.

Odour - Free of disagreeable odour.

The reported disintegration time is subjective, and is provided to indicate Pass/ Fail status for 15 minutes.

**7. TSE/BSE Regulations:**

Blends of several pharmaceutical gelatin are used. When bovine gelatin is used, it is in full compliance with all pharmaceutical regulatory statutes.

Specifically capsules comply with the following where applicable:

Commission Directive 2003/63/EC, compliance is demonstrated by the "Certificate of Suitability".

Regulation (EC) No 853/2004 on specific hygiene rules for food of animal origin.

Regulation (EC) No 999/2001 & amendment thereof

United States FDA September 1997 Guidance for Industry.

United States FDA 9 CFR Part 94.23 pertaining to the importation of gelatin from bovines.

United States FDA - 21 CFR Parts 189, 589 and 700 related to use of materials Derived from Cattle in Human Food, Drug, Cosmetic & Animal Feeds.

Capsules were manufactured under any (or all) of the following Certificates of Suitability:

- |   |   |
|---|---|
| · GELCO GELATIN R1-CEP 2006-086             | · P.B. GELATIN LTD. R1-CEP 2002-110     |
| · GELITA GROUP R1-CEP 2000-050              | · ROUSSELOT SAS R1-CEP 2000-027         |
| · GELITA GROUP. R1-CEP 2003-172             | · ROUSSELOT SAS. R1-CEP 2000-029        |
| · NITTA GELATIN INDIA LTD. R1- CEP 2000-344 | · STERLING BIOTECH LTD. R1-CEP 2001-211 |

**8. Kosher Certification:**

Empty Hard Gelatin Capsules are certified as Kosher by Kosher Inspection Services-India, Registration Number 128.

**9. Handling Precautions:**

- During usage, Temperature between 20°C to 25 °C and RH between 45% to 55%.
- Use only Stainless Steel (Inox) Scoops and Spatulas
- Do not leave capsules in machine hopper for prolonged period when not in use
- Close bag when not in use.

**10. Manufacturing Processes:**

No addition of preservatives, No ethylene oxide treatment and No irradiation treatment.

**World Sales & Service:**

For further information on capsules, filling machines, dosing devices or assistance with research or other industrial use

Contact: Torpac Inc., 333 US 46, Fairfield, NJ 07004, USA. Tel.: 1-973-244-1125 Fax: 1-973-244-1365

[www.torpac.com](http://www.torpac.com), e-mail: [info37@torpac.com](mailto:info37@torpac.com)

This lot of capsules described is hereby certified to you.



**Name: Sunil Gaikwad**  
**29-Sep.-2022**

**Title: Executive Q.C.**