

## CERTIFICATE OF ANALYSIS

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**1. PRODUCT DESCRIPTION:** Empty Cellulose Capsules

|                                |                              |  |            |
|--------------------------------|------------------------------|--|------------|
| Product Name:                  | Cellulose Capsules Shells    | Our Reference:                               | HV00CT B   |
| Packing Batch Number: HC221823 | Capsule Size: 00             | Capsules Batch Number:                       | 1100224140 |
| Manufacturing Date:            | Aug 2022                     | Expiration Date:                             | Jul 2027   |
| Cap Color Name:                | Clear TR                     | Body Color Name:                             | Clear TR   |
| Closed Joined length (mm):     | 23.5 (Tolerance: $\pm 0.4$ ) | Volume: 0.95 ml (Tolerance: Approx Capacity) |            |

| <b>2. Cap Composition:</b>   | (in %)  | <b>3. Body Composition:</b>  | (in %)  |
|------------------------------|---------|------------------------------|---------|
| Hydroxypropylmethylcellulose | qsp 100 | Hydroxypropylmethylcellulose | qsp 100 |
| Purified Water               | 4 -6    | Purified Water               | 4 -6    |
| Carrageenan                  | 2.0     | Carrageenan                  | 2.0     |
| Potassium Acetate            | 1.5     | Potassium Acetate            | 1.5     |

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)

| <b>4. Ingredient/Reference:</b> | <b>C.I No.</b> | <b>EEC No.</b> | <b>Function</b> | <b>Reference</b> |
|---------------------------------|----------------|----------------|-----------------|------------------|
| Hydroxypropylmethylcellulose    | -              | -              | Structure       | USP+Ph.Eur+IP    |
| Purified Water                  | -              | -              | -               | Ph.Eur+IP        |
| Carrageenan                     | -              | -              | -               | USPNF+Ph.Eur     |
| Potassium Acetate               | -              | -              | -               | USP+Ph.Eur       |

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.

| <b>5.Characteristics:</b>           | <b>Units</b> | <b>Specifications</b>   | <b>Results</b> |
|-------------------------------------|--------------|-------------------------|----------------|
| Identification of HPMC              | -            | 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 |
| Arsenic                             | ppm          | Less than 1             | Pass *         |
| Lead                                | ppm          | Less than 1             | Pass *         |
| Mercury                             | ppm          | Maximum 0.1ppm          | Pass *         |
| Cadmium                             | ppm          | Maximum 0.5ppm          | Pass *         |
| Lubricant content                   | %            | Less than 0.5           | Pass *         |
| Disintegration time                 | min/sec      | Less than 15:00         | 6:00           |
| Loss on drying                      | %            | 3.0 to 8.0              | 6.1            |
| Average weight                      | mg           | 114.3 – 139.7           | 123.5          |
| 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 regulation:**

Cellulose capsules shells are not concerned by the requirements of regarding TSE/BSE of regulation (EC) No. 999/2001 and amendments thereof, EMEA/410/01 & USFDA - 9CFR part 94.23. The cellulose Capsules shells do not pose any TSE/BSE risk.

The capsules are produced under very carefully controlled conditions. Controls are performed continuously throughout the process and guarantee that capsules conform to the highest quality standards.

**8. Kosher Certification:**

Empty Cellulose capsules are certified as Kosher by Kosher Inspection Services-India, Registration Number 246.

**9. Handling Precautions:**

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

**10. Manufacturing Processes:**

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

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**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: Rajendra Chaudhari**  
**13-Sep.-2022**

**Title: Sr. Executive Q.A.**