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. The capsules described below conform to the specifications as defined in the current edition of the Capsugel “Technical Reference File” for empty hard gelatin capsules.

### PRODUCT DESCRIPTION
Empty Hard Gelatin Capsules (Bovine and/or Porcine Origin)

- **Customer:** GALA TRADE REPRESENTATIONS LTD.
- **Lot Number:** 34362001
- **Product Name:** HGC SIZE 0 - IVORY 38.063
- **Customer Reference:** GTR/367/2015
- **Product Code:** 003306.53
- **Manufacturing Date:** 01-Sep-2015
- **Expiration Date:** Sep 2020
- **Type:** CONI-SNAP

### BODY
- **Code:** 38.063
- **Name:** IVORY OP. C063

### CAP
- **Code:** 38.063
- **Name:** IVORY OP. C063

### BODY Composition
- **Titanium dioxide**
  - Code: 38.063
  - Code: 38.063
  - Name: IVORY OP. C063
  - Name: IVORY OP. C063

### Cap Composition
- **Titanium dioxide**
  - Code: 38.063
  - Code: 38.063
  - Name: IVORY OP. C063
  - Name: IVORY OP. C063

Due to the nature of raw materials, their sourcing, and technology improvements, the color composition data indicated are target values and actual values may vary to insure the consistency of lot color. Capsugel supports the expiry date if recommendations for warehousing and transportation are observed (recommended: 15°C - 25°C and 35% - 65% relative humidity).

### Ingredient / Reference

<table>
<thead>
<tr>
<th>Ingredient / Reference</th>
<th>E Nr</th>
<th>C.I. Nr</th>
<th>Function</th>
<th>Regulatory References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yellow iron oxide</td>
<td>E172</td>
<td>77492</td>
<td>Colorant</td>
<td>(EU) 231/2012, 21 CFR, JPE, USP/NF</td>
</tr>
<tr>
<td>GELATIN</td>
<td></td>
<td></td>
<td>Structure</td>
<td>EP, JP, USP/NF</td>
</tr>
</tbody>
</table>

### ANALYTICAL DATA

#### Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Test Method</th>
<th>Units</th>
<th>Specifications</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification of gelatin</td>
<td>CP010</td>
<td>Positive</td>
<td></td>
<td>pass *</td>
</tr>
<tr>
<td>Identification of TiO2</td>
<td>CP011</td>
<td>Conforms to composition</td>
<td>pass *</td>
<td></td>
</tr>
<tr>
<td>Identification of iron oxides</td>
<td>CP013</td>
<td>%</td>
<td>Less than 7</td>
<td>pass *</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>CP015</td>
<td>ppm</td>
<td>Less than 7</td>
<td>pass *</td>
</tr>
<tr>
<td>Arsenic</td>
<td>CP017A</td>
<td>ppm</td>
<td>Less than 1</td>
<td>pass *</td>
</tr>
<tr>
<td>Cadmium</td>
<td>CP017B</td>
<td>ppm</td>
<td>Less than 0.5</td>
<td>pass *</td>
</tr>
<tr>
<td>Lead</td>
<td>CP017C</td>
<td>ppm</td>
<td>Less than 1</td>
<td>pass *</td>
</tr>
<tr>
<td>Mercury</td>
<td>CP017D</td>
<td>ppm</td>
<td>Less than 0.1</td>
<td></td>
</tr>
<tr>
<td>Lubricant content</td>
<td>CP019</td>
<td>%</td>
<td>Less than 0.5</td>
<td>0.06 *</td>
</tr>
<tr>
<td>Sulphur dioxide</td>
<td>CP020</td>
<td>ppm</td>
<td>Less than 50</td>
<td>0 *</td>
</tr>
<tr>
<td>Disintegration time</td>
<td>CP001</td>
<td>min/sec</td>
<td>Less than 15:00</td>
<td>3.13 *</td>
</tr>
<tr>
<td>Loss on drying</td>
<td>CP014</td>
<td>%</td>
<td>13.0 to 16.0</td>
<td>14.3</td>
</tr>
<tr>
<td>Average weight</td>
<td>CP003</td>
<td>mg</td>
<td>90 to 102</td>
<td>94.5</td>
</tr>
<tr>
<td>Total Aerobic Microbial Count</td>
<td>CP031</td>
<td>cfu / g</td>
<td>Less than 1000</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>CP033</td>
<td>Absence in 1 gram</td>
<td>pass *</td>
<td></td>
</tr>
<tr>
<td>Salmonella</td>
<td>CP034</td>
<td>Absence in 10 gram</td>
<td>pass *</td>
<td></td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>CP035</td>
<td>Absence in 1 gram</td>
<td>pass *</td>
<td></td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>CP036</td>
<td>Absence in 1 gram</td>
<td>pass *</td>
<td></td>
</tr>
<tr>
<td>Total Yeasts/Moulds Count</td>
<td>CP032</td>
<td>cfu / g</td>
<td>Less than 100</td>
<td>&lt; 10 *</td>
</tr>
</tbody>
</table>

* Reduced frequency testing

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GALA TRADE REPRESENTATIONS LTD.
Mr. Vassil Kanev

TO THE ATTENTION OF:

CERTIFICATE OF ANALYSIS

Page: 1 of 2
Capsugel hard gelatin capsules are meeting not more than 2 ppm Chromium as defined in the Chinese pharmacopoeia for Vacant Gelatin Capsules. 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 5000ppm or 0.3%, under option 1 as defined in ICH Q3C, USP<467>, and EP General Text 5.4.

**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.
Odor - Free of disagreeable odor.
The reported disintegration time is subjective, and is provided to indicate Pass/Fail status for 15 minutes.
Tests for color, solubility and acidity conform to Japanese Pharmacopoeia requirements.

**TSE/BSE Regulations**

Capsugel can use blends of several pharmaceutical gelatins. When bovine gelatin is used by Capsugel, it is in full compliance with all pharmaceutical regulatory statutes.
Specifically, Capsugel fully complies with the following where applicable:
- Regulation (EC) No 999/2001 as regards specified risk material.
- United States FDA - 21 CFR Parts 211, 226, 300, 500, 530, 600, 895, and 1271 related to Use of Materials Derived from Cattle in Medical Products.
- United States FDA - 21 CFR Parts 189 and 700 related to Use of Materials Derived From Cattle in Human Food and Cosmetics.
- The raw material is derived from healthy animals slaughtered in a slaughterhouse, which have been inspected by an official veterinarian and have been deemed fit for human consumption.
Capsugel currently manufactures capsules under any (or all) of the following Certificates of Suitability:
- Rousselot R1 CEP 2000-027
- Rousselot R1 CEP 2000-029
- Rousselot R1 CEP 2001-332
- PB Gelatins R1 CEP 2000-045
- PB Gelatins R1 CEP 2002-110
- Gelita group R1 CEP 2001-424
- Gelita group R1 CEP 2003-172
- Sterling Gelatin R1-CEP 2001-211
- Nitta Gelatin R1-CEP 2000-344
- Nitta Gelatin R1 CEP 2005-217
- Nitta Gelatin R1 CEP 2004-247
- Nitta Gelatin R1 CEP 2004-320

Manufacturing Processes:
- No Addition of Preservatives
- No Ethylene Oxide Treatment
- No Irradiation Treatment