

## PRODUCT DECLARATION

**Product name:** Empty Gelatin CONI-SNAP Capsules

**Stock code:** various

**Starting material:** Not applicable

**Manufactured via:** Not applicable

**INGREDIENTS:** Refer to Medisca Certificate of Analysis

**BSE/TSE:** As per the manufacturer, CAPSULE CONI-SNAP – gelatin capsules use a blend of several pharmaceutical gelatins and/or porcine origin, in full compliance with all pharmaceutical regulatory statutes. Specifically, CAPSULE CONI-SNAP – bovine gelatin capsules fully comply with the following, where applicable. Considering the below conditions, as well as the present scientific knowledge about Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE), the US and European experts from respectively the US Food and Drug Administration and the European Food Safety Authority have declared bovine gelatin and bovine collagen peptides safe end-products regarding BSE/TSE risk.

The manufacturer of the Empty Gelatin Capsules - Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev.3), which is published by the European Commission following Commission Directive 2003/63/EC, (amending Directive 2001/83/EC on the Community code relating to medicinal products for human use), Annex I, Part I, paragraph 3.2.2.4. Control of excipients.

- These Directives require that applicants for Marketing Authorization must demonstrate that medicinal products are manufactured in accordance with the latest version of this Note for Guidance and compliance is demonstrated by the “**Certificate of Suitability**” issued to the manufacturer of the bovine gelatin by the European Directorate for the Quality of Medicines (EDQM). As such, **from May 1<sup>st</sup>, 2024**, the capsules will be manufactured under any (or all) of the following Certificates of Suitability: R1-CEP 2000-029-Rev 06; R1-CEP-2010-043-Rev 00; CEP 2000-045-Rev 06; R1-CEP 2001-424-Rev 03; R1-CEP 2001-211-Rev 01; R1-CEP 2000-344-Rev 03; R1-CEP 2005-217-Rev 02; R1-CEP 2008-048-Rev 00.

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

- Regulation (EC) No 999/2001, laying down rules for the prevention, control, and eradication of certain transmissible spongiform encephalopathies.

- United States Food and Drug Administration (FDA) –21 CFR Part 189 – “Substances Prohibited from Use in Human Food: Prohibited Cattle Materials”.

- United States Department of Agriculture (USDA) – 9 CFR 94.23 Importation of Gelatin Derived from Bovines.

- Japanese Ministry of Health, Labor Welfare (MHLW) - “Food Sanitation Law”, Chapter 2, Article 7 and Article 10 “Specifications and Standards for Food or additives” revised and announced by MHLW Notice No.0327-2 of March 27, 2015.

- 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.

- For what concerns specified risk materials (SRMs), the bovine gelatin applied does not contain skulls and spinal cord, but may contain vertebrae of animals younger than 30 months old independently of their geographical origin.

- The manufacturer continuously monitors all regulatory activities.

**GMO:** Empty capsules do not contain and are not produced from or by genetically modified organisms (GMO) within the meaning of the Directive 2001/18/EC and subsequent amendments and 7 CFR 66 National Bioengineered Food Disclosure Standard of the USA. Consequently, they are not impacted by Regulation (EC) N° 1829/2003 on genetically modified food and feed, Regulation (EC) N° 1830/2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products from GMOs, amending Directive 2001/18/EC, or the labeling requirements of 7 CFR 66 National Bioengineered Food Disclosure Standard.

**VEGAN:** Empty Gelatin capsules do not comply with a vegan or vegetarian diet.

**ALLERGEN:** Please note that there may be several steps before the raw material is produced and access to data on manufacturing raw materials is not easily obtained for the starting materials and intermediates used in the production process. The following items are not used in the manufacturing process of the product, and although manufacturer does not specifically assay for the presence of the items below, it is unlikely that any traces of these items are present in the starting materials or in the final product.

**The product is unlikely to contain the following -**

**PRODUCT DECLARATION**

<input checked="" type="checkbox"/> Cereals containing gluten and products thereof
<input checked="" type="checkbox"/> Corn and products thereof
<input checked="" type="checkbox"/> Celery and products thereof
<input checked="" type="checkbox"/> Soybeans and products thereof
<input checked="" type="checkbox"/> Yeast
<input checked="" type="checkbox"/> Fish and crustacean shellfish and products thereof
<input checked="" type="checkbox"/> Eggs and products thereof
<input checked="" type="checkbox"/> Dairy Products (Milk, Lactose, Caseinates, Whey)
<input checked="" type="checkbox"/> Peanuts and products thereof
<input checked="" type="checkbox"/> Tree nuts (oils) or derivatives
<input checked="" type="checkbox"/> Mustard and products thereof
<input checked="" type="checkbox"/> Sesame Oil
<input checked="" type="checkbox"/> Preservatives
<input checked="" type="checkbox"/> Sulfites >10ppm
<input checked="" type="checkbox"/> Artificial Colors and Flavors (Can be present depending on the color formulation used. Please verify CofA)
<input type="checkbox"/> Beef/Chicken/Pork derivatives (Gelatin source is bovine)

This allergen statement is for the use of the product in pharmaceutical compounding and is provided for informational purposes only. It is based on information received from the manufacturer concerning the product contents and manufacturing process, and Medisca makes no representations, and takes no responsibility for the content thereof. No analytical testing has been performed by Medisca or by the manufacturer for these allergens, and representations concerning their presence in trace amounts are based on theoretical considerations. Accordingly, this statement should not be taken as a guarantee of the absence of the above-stated allergens.

This statement replaces all previous versions for the above-mentioned product.

We trust this information, which is made to the best of our knowledge in conformance with the foregoing, will be helpful to you.

With kind regards,

**The MEDISCA Team**