

Product name: Empty Gelatin CONI-SNAP Capsules

Stock code: various

BSE/TSE: 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 September 1st 2019, the capsules will be manufactured under any (or all) of the following Certificates of Suitability: R1-CEP 2000-029; R1-CEP-2010-043; R1-CEP 2000-045; R1-CEP 2001-424; R1-CEP 2001-211; R1-CEP 2000-344; R1-CEP 2005-217-Rev 01.

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

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

- United States Food and Drug Administration (FDA) – Proposed Rule on “Use of Materials Derived from Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants,” 72 Fed. Reg. 1582 (Jan. 12, 2007) (to be codified at 21 CFR Parts 211, 226, 300, 500, 530, 600, 895, and 1271).

- United States Food and Drug Administration (FDA) – Final Rule on “Use of Materials Derived From Cattle in Human Food and Cosmetics,” 81 Fed. Reg. 14718 (March 18, 2016), as amended and codified at 21 CFR §§ 189.5, 700.27; and Final Rule on “Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle,” 71 Fed. Reg. 59653 (Oct. 11, 2006), codified at 21 CFR §§ 189.5, 700.27.

- 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.

- Japanese Ministry of Health, Labor and Welfare - Notification No. 210 of the MHLW issued on May 20, 2003 and the latest version by Notification No. 1002-27 about the partial amendment of the criteria eliminating source country restrictions, applicable from November 25th 2014.

- 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), next to the removal of skulls and spinal cords, bovine bone gelatin suppliers certify vertebrae removal independent from the geographical origin and/or age of the animals.

- The manufacture continuously monitors all regulatory activities.

Vega/Vegetarian: Empty Gelatin capsules do not comply with a vegan or vegetarian diet.

GMO: Empty Gelatin capsules are GMO free.

Allergen: 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, however it is unlikely that any traces of these items are present in the starting materials or in the end product.

<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"/> 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"/> Sunflower Oil
<input checked="" type="checkbox"/> Sulfites >10ppm
<input checked="" type="checkbox"/> Artificial Colours (Can be present depending on the color formulation used. Please verify COFA)
<input type="checkbox"/> Beef/Chicken/Pork/Fish derivatives
<input checked="" type="checkbox"/> Preservatives
<input checked="" type="checkbox"/> Latex
<input checked="" type="checkbox"/> Phthalates

This statement is provided for **informational purposes** only, as instructed to Medisca by the manufacturer, and is not meant to be a guarantee of absence of the above stated allergens.

Salutations

The MEDISCA Team