MEDISCA®
YOUR TRUSTED PARTNER IN COMPOUNDING

August 15th, 2019

BSE/TSE Certificate

Dear valued customer,

As per the manufacturer, ***CAPSULE CONI-SNAP*** – gelatin capsules uses 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:

- 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:
    - Rousselot R1-CEP 2000-029-Rev 05
    - Rousselot R1-CEP-2010-043-Rev 00
    - Tessenderlo Group R1-CEP 2000-045-Rev 04
    - Gelita Group R1-CEP 2001-424-Rev 03
    - Sterling Gelatin R1-CEP 2001-211-Rev 01
    - Nitta Gelatin R1-CEP 2000-344-Rev 02
    - Nitta Gelatin 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).

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- 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, Lonza's bovine bone gelatin suppliers certify vertebrae removal independent from the geographical origin and/or age of the animals.
- Capsugel continuously monitors all regulatory activities; please let us know if there are further questions or clarification needed.

Salutations
The MEDISCA Team

Melvin Lam Sze Ko
Quality Assurance Specialist