

August 22<sup>nd</sup>, 2019

**BSE/TSE Certificate**

Dear valued customer,

As per the manufacturer and to the best of our knowledge, clear and colored gelatin capsules are manufactured with select pharmaceutical bovine gelatin blends based on product quality requirement and regulatory compliances. The bovine gelatin conforms to the following BSE regulations as applicable to the country of use. Bovine gelatin, when used, is derived from bones and hides of healthy animals that have been certified as fit for human consumption by a veterinary official at slaughtering.

- 1.Regulation (EC) No 999/2001
- 2.Regulation (EC) No 853/2004
- 3.USFDA Sept 1997, Guidance to industry for the sourcing and processing of gelatin to reduce the potential risk posed by BSE in FDA regulated Products.
- 4.USFDA 21 CFR Parts 189, 589, 700 pertaining to prohibited cattle materials in human food, drugs cosmetics & animal feeds.
- 5.USFDA 9 CFR Part 94.18 pertaining to the restriction on importation of edible products from ruminants due to BSE.
- 6.USFDA 9 CFR Part 94.19 on gelatin from ruminants that have not been in any region where BSE exists.
- 7.Commission directive 2003/63/EC and Ph.Eur-1483 evidenced by the certificate of suitability.

Salutations

**The MEDISCA Team**



Melvin Lam Sze Ko

Quality Assurance Specialist