

August 15th, 2019

BSE/TSE Certificate

Dear valued customer,

The manufacturer ensures that bovine gelatin, used for manufacturing of “Hard Gelatin Capsule Shells” conforms to TSE/BSE regulations as applicable to the country of use:

1. Regulation (EC) No 999/2001 & amendment thereof
2. Regulation (EC) No 853/2004
3. USFDA Sept 1997, Guidance to Industry for the sourcing & 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 & cosmetic & animal feeds.
5. USFDA 9 CFR Part 94.23 Importation of gelatin from bovines
6. Commission directive 2003/63/EC and Ph. Eur -1483 evidenced by the certificate of suitability. The gelatin corresponding to one or more of the following CEP is used.

Salutations

The MEDISCA Team



Melvin Lam Sze Ko
Quality Assurance Specialist