

Product name: Empty Gelatin Capsules

Source: Bovine gelatin

Stock code: 3270, 3271, 3272, 3273, 3274, 3157, 3158, 3159, 3160, 3161, 3162

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 selects pharmaceutical gelatin blends based on product quality requirement and regulatory compliances. All gelatins used conform to the applicable pharmacopoeia and food regulations. 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. The tissues used in the manufacture of gelatin are free from specified risk materials. In addition, manufacturer ensures that the bovine gelatin conforms to the following BSE regulations as applicable to the country of use.

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**. The gelatin corresponding to following COS is used: Gelatin Supplier COS No Rousselot R1-CEP 2000-067

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

GMO: Empty Gelatin capsules are GMO free and no GMO derived components involved.

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 and Flavours
<input checked="" type="checkbox"/> Chicken/Pork/Fish derivatives
<input checked="" type="checkbox"/> Preservatives

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.

The MEDISCA Team

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