EDAMIN®

The Pfizer supplier of Edamin®[4] (lactalbumin hydrolyzate) has certified that the animal sourced components are of porcine and bovine origin. The porcine enzyme used in the manufacture of Edamin® is sourced from the United States and Canada. The milk extract lactalbumin for the manufacture of Edamin® are sourced from healthy bovine animals in Australia and New Zealand. Additionally, a milk derived lactose carrier for the production of the dried enzymes is obtained from the United States. In addition to non-ruminant source material and low risk bovine milk, The supplier has indicated that specific processing steps are undertaken to prevent, minimize or eliminate microbial contamination.

CATALASE

The Pfizer supplier of catalase[5] received a Certificate of Suitability for Catalase from the European Directorate for the Quality of Medicines (EDQM) on 11 June 2001. The Certificate number is RO-CEP 2001-168-Rev 01.

Catalase contains an animal based component of bovine origin. The component is bovine liver and it is sourced from the United States. When tissues are removed, material of a low risk group does not come in contact with material from a high risk group. The animals are declared fit for human consumption.

SOY FLOUR HYDROLYZATE

Soy flour Hydrolyzate contains animal based components of porcine origin. The supplier of soy flour hydrolyzate[6] has certified that the porcine raw material used in the manufactured of soy flour hydrolyzate are sourced from Canada and the United States. The supplier has described additional measures that are being taken to minimize the risk for transmission of TSE, as follows: Specific high temperature processing steps are undertaken to prevent, minimize or eliminate microbial contamination. All processes are traceable and take place in an FDA regulated food plant.

In addition to the use of only low to minimal risk animal-derived materials in the synthesis of Methylprednisolone Acetate, Pfizer also uses only non-animal source cleaning agents for manufacturing equipment. Pfizer also has procedures and systems in place for the potential event of undesired material entering the plant, for the assurance of traceability for raw materials, intermediates, and final API's, for the auditing of raw material suppliers, and for internal auditing with regard to TSE risk.

[1] Geo. Pfau's Sons Company, inc., 800 Wall Street, P.O. Box 7, Jeffersonville, Indiana 47131
[2] The Neatsfoot Oil Refineries Corporation, East Ontario and Bath Street, Philadelphia, PA 10134
[3] BD Biosciences, 39 Loveton Circle, Mail Code 904, Sparks, MD 21152.
[4] Quest International, 5115 Sedge Blvd., Hoffman Estates, IL 60192
[5] Sigma-Aldrich, 3050 Spruce Street, St. Louis, Missouri, 63103, USA
[6] DMV International Nutritionals, 1712, Deltown Plaza, Fraser, New York, 13753

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Methylprednisolone Acetate
Certification of Materials from Animal Sources

An evaluation of all of the raw materials used in the production of Methylprednisolone Acetate was done by Pfizer in order to identify those raw materials sourced from animals. The materials lard oil, nutrient broth, Edamin® (lactalbumin hydrolyzate), soy flour hydrolyzate, and catalase used in the fermentation and bioconversion processes were identified as the only raw materials manufactured from animals.

LARD OIL

The Pfizer suppliers of lard oil[1,2], have certified that the porcine used in the manufacture of lard oil are sourced from the United States. In addition to non-ruminant source material, the suppliers have described additional measures that are being undertaken to prevent, minimize or eliminate microbial contamination.

NUTRIENT BROTH

Pfizer supplier of nutrient broth[3] received a TSE Certificate of Suitability for nutrient broth from the European Directorate for the Quality of Medicines (EDQM) on 1 October 2001. The certificate number is RO-CEP-2000-248-00.

Nutrient broth contains animal sourced components of bovine and porcine origin. The bovine sourced components are obtained from the United States, Canada and Australia, and the porcine sourced components are obtained from the United States.

Detail of the animal based nutrient broth components is as follows:

Beef Extract
Skeletal Muscle and Hearts from bovine.

Peptone (Gelatin hydrolyzate with porcine Pancreas and bovine bile)
Gelatin (alkaline treated): Sourced from bovine bone which is free from skulls, and spinal cords but not free from vertebrae), connective tissues , and skin.
Pancreas: Porcine pancreas tissue

Bile: bovine bile

The supplier of nutrient broth has described additional measures that are being taken to minimize the risk for transmission of TSE. They are as follows: 1) When tissues are removed, material of a low risk group does not come in contact with material from a high risk group. 2)Body fluids are collected with minimal damage to tissues. 3) Tissues are removed at USDA, AG Canada, or AQUIS regulated slaughter houses. 4) The animals are declared fit for human consumption. 5) Specific processing steps are undertaken to prevent, minimize or eliminate microbial contamination.

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