



TSE/BSE-Certificate

500115 Choline hydrogen tartrate suitable for use as excipient EMPROVE® exp DAB 10,FCC

The note for guidance EMA/410/01 Rev. 3 of the EC considers the requirements of raw materials used for human and veterinary medicinal products. The document introduces risk assessment into the regulatory compliance process for products derived from TSE/BSE-relevant animal species.

We certify that this product is manufactured without the use of raw materials of animal or human origin.

Choline hydrogen tartrate is produced using raw materials of vegetable origin.

During processing the product does not come in contact with animal material.

Therefore, the product does not fall under the scope of the above-mentioned guideline and is not concerned by the TSE/BSE issue.

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