TSE/BSE-Certificate

104852 Potassium hydrogen carbonate suitable for use as excipient EMPROVE® exp Ph Eur,BP,USP,FCC,E 501

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.

Potassium hydrogen carbonate is synthetically produced.

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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