Availability of Certificate of Suitability (CEPs)

Product group: MCC, Starch, Lactose, Inhalation, Biopharma and Superdisintegrants

All products manufactured by:

DFE Pharma GmbH & Co. KG

Dear Customer,

DFE Pharma GmbH & Co. KG does not have a Certificate of Suitability (CEP) for its excipients.

The monographs of the Ph. Eur. describe our excipients (e.g. anhydrous lactose, lactose monohydrate, croscarmellose sodium, microcrystalline cellulose, sodium starch glycolate, starch pregelatinized, sucrose, trehalose dihydrate) in enough detail.

For a successful submission of a Medicinal Product in the European Union no reference to a Certificate of Suitability is necessary.

Details on the BSE/TSE status of pharmaceutical excipients supplied by DFE Pharma GmbH & Co. KG are provided in specific statements issued by DFE Pharma GmbH & Co. KG.

This statement substitutes all previous versions issued for the brand names mentioned above.
We trust this information, which is made up to the best of our knowledge, will be helpful to you.

Name : Armand M. Janssen
Job title : QA Regulatory Affairs Officer
Signature :

This document is controlled by a validated, electronic system and is valid without signature.
The above facsimile signature is only for display.

DFE Pharma GmbH & Co. KG
Klever Strasse 187, 47574 Goch, Germany, P.O. Box 20 21 20, 47568 Goch, Germany, T. +49 2823 9288 770, F. +49 2823 9288 7799

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