cGMP – Statement Lactohale®, Respitose®

Product group: Inhalation
Brand name: Respitose®, Lactohale®
Document No.: PD-0120

Dear Customer,

We, DFE Pharma (legal name: DFE Pharma GmbH & Co.KG), are the manufacturer of the Pharmaceutical grade Lactose with the brand names Respitose® and Lactohale®.

Respitose® is produced at the production site FrieslandCampina DMV B.V. located in Veghel. Our product Lactohale® is produced at our Borculo location DFE Pharma B.V. and at our site located in Kapuni DFE Pharma (NZ) Ltd..
All production sites have implemented and comply with a quality system based on the Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients (IPEC) and the guidelines for Good Manufacturing Practice for Active Pharmaceutical Ingredients (ICH Q7).

DFE Pharma`s Quality Assurance program ensures that the latest requirements are consistently met. The FrieslandCampina DMV B.V. production site in Veghel was inspected by the FDA for Pharmaceutical grade Lactose in October 2002 and declared acceptable. The production site DFE Pharma B.V in Borculo was inspected by the FDA for Pharmaceutical grade Lactose in September 2001 and declared acceptable.

Our Quality Assurance department will be pleased to answer any further questions with respect to the above.

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 : Wilbert van de Rakt
Job title : Quality Director
Signature :

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

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