CGMP - Statement

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

All products manufactured by DFE Pharma GmbH & Co. KG

Dear Customer,

Herewith we certify DFE Pharma GmbH & Co. KG has implemented a quality system in compliance with:
- ISO 9001:2015
- The Joint Good Manufacturing Practices Guide For Pharmaceutical Excipients (IPEC Federation)

Additionally, the quality system is based on the Guidelines for Good Manufacturing Practice for Active Pharmaceutical Ingredients (ICH Q7). None of these regulations require a Site Master File nor is this document required by any supervising body according to any national requirements in which DFE Pharma manufacture.

This quality system applies to all production sites of

- DFE Pharma:
  - Foxhol and Borculo, The Netherlands;
  - Nörten-Hardenberg and Schöneck, Germany;
  - Kapuni, New Zealand;
  - Cuddalore and Nagpur, India;
- FrieslandCampina DMV B.V., Veghel, The Netherlands;
- FrieslandCampina Ingredients B.V., Borculo, The Netherlands;
- Fonterra Limited, Kapuni, New Zealand;
- Laboratorium Ofichem BV, Ter Apel, The Netherlands;
- Agglomix BV, Tilburg, The Netherlands.

All mentioned sites are ISO 9001:2015 certified.
Manufacturing of excipients is generally not supervised by regulatory bodies who issue GMP certificates (exception: the Indian Regulatory body issues a WHO GMP certificate).
DFE Pharma's Quality Assurance program ensures that the implemented quality system is maintained on the GMP-level for Pharmaceutical Excipients. All regulatory changes are evaluated and implemented when deemed necessary.

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

With kindest regards,

Name : MAJ Nijman
Job title : Global 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.

DFE Pharma GmbH & Co. KG
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