Data Integrity Statement

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

Document No.: PD-0611

Dear Customer,

DFE Pharma is consistently working on the development of higher quality standards to serve our customer needs. We understand the sensitivity of Data Integrity and take responsibility as part of our pursuit of excipient excellence.

DFE Pharma performs cGMP activities within the ERP system "SAP" and the controlled documentation software "MasterControl". These systems are restricted to the usage of authorized persons with restricted rights. Documentation practices and data handling processes (paper and electronic) are defined and followed by applicable positions.
The validation of these systems is performed including 21 CFR part 11 and contains relevant documentation such as Risk Assessment, User Requirement Specification and Configuration Specification.
Changes affecting these systems are assessed and evaluated via DFE Pharma`s change control process.
Regression tests are performed on regularly basis within the SAP`s life cycle to ensure valid state and compliance to cGMP. There are processes defined, if unexpected critical incidents occur.
cGMP relevant activities are traceable via audit trail and data is stored for 10 years. The systems are backuped on regularly basis.

We believe that measurements as described above ensure that data is secured regarding intentional or unintentional manipulation or loss.

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.

With kindest regards,

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.

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