Preparation of Documents

MEGGLE Products:
- Lactose Monohydrate: CapsuLac® 60, FlowLac® 90, FlowLac® 90 MS, FlowLac® 100, FlowLac® 100 MS, FlowLac® 100 SD, GranuLac® 70, GranuLac® 70 MS, GranuLac® 80, GranuLac® 140, GranuLac® 140 S, GranuLac® 200, GranuLac® 200 MS, GranuLac® 200 S, GranuLac® 230, InhaLac® 70, InhaLac® 120, InhaLac® 140, InhaLac® 145, InhaLac® 150, InhaLac® 160, InhaLac® 180, InhaLac® 230, InhaLac® 240, InhaLac® 251, InhaLac® 300, InhaLac® 400, InhaLac® 500, Lactose Monohydrate 200 Mesh IP, Lactose Monohydrate Impalpable, Lactose Monohydrate Low Endotoxin, PrismaLac® 40, SacheLac® 80, SorboLac® 400, SpheroLac® 100, Tablettose® 70, Tablettose® 80, Tablettose® 100, Tablettose® 100 MS
- Co-processed Excipients: Cellactose® 80, CombiLac®, MicroceLac® 100, MicroceLac® Plus, RetaLac®, StarLac®

All "Low Nitrite" Grades are included.

Specifications

The MEGGLE Lactose Monohydrate Products conform to the monograph "Lactose Monohydrate" in the Ph. Eur, USP-NF, JP and ChP. Testing is performed using the methods indicated in the respective product specification.

The components in MEGGLE Co-processed Excipients conform to the respective monographs.

The parameters mentioned in MEGGLE Specifications are taken from the respective pharmacopoeias and can be regarded as a "summary" of these requirements. MEGGLE Specifications for Co-processed Excipients are based on market requirements. Justification documents are available.

MEGGLE Specifications are generated within a validated ERP system. Check and approval of documents is conducted via electronic signature. Electronic signature meets the requirements of 21 CFR Part 11.

Certificates of Analysis

IPC testing and mixed sample testing is conducted according to defined sample codes. The results and their review are carried out by various different qualified employees. Product release is conducted within a validated ERP system. Only after positive release of the batch by the head of quality control departments or their deputies and is it technically possible to create certificates of analysis.

Due to the issuance within a validated electronic management system, these MEGGLE Certificates of Analysis are valid without signature.

Excipient Information Package and Standardised Information Documents

The Excipient Information Package (EIP) consists of the Product Regulatory Datasheet (Part I), Site Quality Overview (Part II), and Supply Chain and Security Overview (Part III).

The EIP is based on the IPEC Excipient Information Package User Guide and Template, 2020 of IPEC Federation. For definitions and glossary, please refer to this document.

Furthermore, MEGGLE is committed to give comprehensive regulatory and other information for MEGGLE Products to its customers. Monitoring of regulatory requirements and document control incl. resubmission is part of the MEGGLE QM system. It is assured that the current versions of documents and specific statements reflect the current regulatory status of the products.

The MEGGLE EIP's and Documents dealing with regulatory and other information are prepared in a validated Document Management System, are electronically approved and valid without signature.

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