

INFORMATION

Quality / Regulatory Affairs



EIP-0063

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Preparation of Documents

MEGGLE Products:

- Lactose Monohydrate: CapsuLac[®] 60, FlowLac[®] 90, FlowLac[®] 90 MS, FlowLac[®] 100, FlowLac[®] 90 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[®] 150, InhaLac[®] 160, InhaLac[®] 180, 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, StarLac[®], Tablettose[®] 70, Tablettose[®] 80, Tablettose[®] 100, Tablettose[®] 100 MS

- Co-processed Excipients: Cellactose[®] 80, CombiLac[®], MicroceLac[®] 100, RetaLac[®], StarLac[®]

MEGGLE Specifications for MEGGLE Products are generated within a validated document management system.

Check and approval of documents is conducted via electronic signature. Electronic signature meets the requirements of 21 CFR Part 11.

Product release is conducted and the issue of MEGGLE Certificates of Analysis are generated within a validated ERP system.

This MEGGLE Information was electronically released and is valid without signature.