

INFORMATION

Quality / Regulatory Affairs



EIP-0050

Revision 10

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Country of Origin, Production Site, Release Site

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® 145, InhaLac® 150, InhaLac® 160, InhaLac® 180, InhaLac® 230, 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, RetaLac®, StarLac®

The country of origin of the above mentioned MEGGLE Products is Germany.

Production site of the above mentioned products except the below mentioned products:

MEGGLE GmbH & Co. KG, Megglestr. 6-12, 83512 Wasserburg, Germany

Subcontracted production site of InhaLac® 400, InhaLac® 500:

Micronisierungs-Kontor Oberrot GmbH, Industriestr. 17, 74420 Oberrot, Germany

Subcontracted production site of RetaLac®:

IPC Process Center GmbH & Co. KG Grunaer Weg 26 01277 Dresden, Germany

Release site of the above mentioned MEGGLE Products:

MEGGLE GmbH & Co. KG, Megglestr. 6-12, 83512 Wasserburg, Germany

Regarding the subcontracted production sites:

The responsibility for the quality of the material is taken by MEGGLE.

Quality Agreements with the subcontracted production sites are in place.

The distribution offices of MEGGLE are the partners of any quality issues or complaints.

The product related statements are issued by MEGGLE in behalf of the manufacturer.

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