

INFORMATION

Quality / Regulatory Affairs



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GMP GDP EXCiPACT

MEGGLE Products:

Lactose Monohydrate: InhaLac® 400, InhaLac® 500

For product manufacturing at

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

as the subcontracted production site as well as for release and distribution by

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

of the above mentioned MEGGLE Products:

GMP according to the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients and USP General Information Chapter <1078> is implemented.

GDP principles, based on the IPEC Good Distribution Practices Guide for Pharmaceutical Excipients, are implemented.

MEGGLE GmbH & Co. KG is GMP and GDP certified according to EXCiPACT standard for the manufacturing, testing, storage and distribution of lactose and co-processed excipients used as pharmaceutical excipient or claimed for pharmaceutical use.

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