

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 am Inn, 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.

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