



To whom it may concern

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Quality Unit / Regulatory Affairs

Date of issue: 01.07.2020
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Doc.-No. EIP-1033 -B
Revision 6

Content of Lactose

MEGGLE Products:

- Lactose Monohydrate (USP-NF / Ph. Eur. / JP): Lactose monohydrate Low Endotoxin
- Inhaler Grade Lactose Monohydrate (USP-NF / Ph. Eur. / JP): InhaLac[®] 70, InhaLac[®] 120, InhaLac[®] 140, InhaLac[®] 150, InhaLac[®] 160, InhaLac[®] 230, InhaLac[®] 250, InhaLac[®] 251, InhaLac[®] 400, InhaLac[®] 500

The products conform to the monograph "Lactose Monohydrate" in the USP-NF, Ph. Eur. and JP. The monograph has undergone pharmacopoeial harmonization.

The content of lactose is minimum 99%. This is based on the following specification parameters:

Specification parameter	Value	Method
Optical rotation	+54.4° – +55.9 (calculated on the anhydrous basis)	USP-NF (781S) <i>Specific rotation</i>
Loss on drying	NMT 0.5%	USP-NF (731)
Residue on ignition	NMT 0.1%	USP-NF (281)

Best regards

MEGGLE GmbH & Co. KG


Dr. Stefan Dreiheller