



To whom it may concern

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Revision 1

Content of Lactose

MEGGLE Product:

Anhydrous Lactose (USP-NF / Ph. Eur. / JP): DuraLac® H

The product conforms to the monograph "(Anhydrous) Lactose" 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 USA inc.



Dr. Gabriele Müller