

INFORMATION

Quality Management



EIP-0056-USA

Revision 6

Date of issue: 28.10.2024

1/1

Mutagenic Impurities

ICH Guideline M7 (R2)

MEGGLE USA Products:

- Lactose Monohydrate: GranuLac® 70 US, GranuLac® 140 US, GranuLac® 200 US
- Anhydrous Lactose: DuraLac® H

The mentioned MEGGLE USA Products are used as excipients for which – according chapter 2 – the guideline is not applicable.

Substances which can induce damage to the genetic material in the cells through interactions with the DNA sequence and structure are not used in the manufacturing process of the products.

The products are well known, has a long history of safe use as excipients. Furthermore, they are in compliance with US and EU legislation for food.

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