

Viral Safety

Ph. Eur. General Text 5.1.7

MEGGLE USA Products:

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

The MEGGLE USA Products are lactose as animal derived ingredient. They are produced from milk gained from the animal species *Bos Taurus*. Milk from other species is not used. Purchased raw material, used in the manufacture of the products is whey.

The necessity of virus validation studies is defined in Note for Guidance CPMP/BWP/268/95 and includes the following products, derived from

- in vitro cell lines of human and animal origin,
- vivo culture of cell lines or from organs or tissues of human or animal origin,
- blood or urine or other biological fluids of human or animal origin.

In chapter 2 of the Note for Guidance some cases of sources of viral contamination are mentioned. None of the contamination sources are applicable to milk as source material for lactose. The sourcing of the milk is constantly, officially supervised according to the FDA Pasteurized Milk Ordinance in the current version.

For the manufacture of lactose no virus validation studies have been performed, because:

- The source material milk is not considered to be an (important) source of viruses, and is fit for human consumption (see above);
- Virus validation studies could compromise the safety of our manufacturing equipment;
- The products are prepared from milk, which has been heat-treated by a treatment involving a high temperature for a short time (at least 161 °F (72 °C) for 15 seconds) ensuring that the products show a negative reaction to an alkaline phosphatase test immediately after such treatment. Furthermore, a second heat treatment of at least 206 °F (97 °C) for at least 30 minutes is carried out and the products are dried.

These treatments are recognized to provide sufficient guaranties with regard to the destruction of e.g. the foot and-mouth disease virus in milk and milk products for human consumption.

The heat treatment conditions and the measurements to prevent recontamination of the product (closed production line, hygiene rules, etc.) ensure that for the production of the products there should be no viral risk.