

Product group: Lactose and Inhalation

Brand name: Lactochem®, Lactohale®,
Lactopress®, Lactose FC,
Pharmatose®, Respitose®,
SuperTab®

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Dear Customer,

Virus validation studies are only necessary in those cases where a substantial amount of viruses may be present in a product.

This might be the case in the following cases:

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

These cases are defined by CPMP/BWP/268/95 (Validation of virus removal and inactivation procedures).

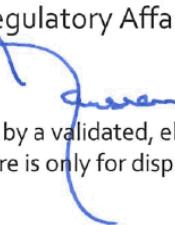
In chapter 2 of this guideline some cases of sources of viral contamination are mentioned. None of the contamination sources applies to milk (the source material for lactose). Furthermore, the milk used for the manufacture of lactose complies with the current health regulations in the EU. This means that the milk is derived from healthy cows and that it is fit for human consumption.

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,
- Virus validation studies could compromise the safety of our manufacturing equipment,
- All milk undergoes pasteurization. In case of the manufacture of lactose in addition to this the product is kept :
 - at least 95°C for on average 30 minutes in Europe
 - at least 90°C for at least 15 minutes in New Zealand
- It is a well known fact that a double pasteurization (15 s at 72°C) kills all Foot and Mouth disease virus. Many studies have been performed on this subject.

This statement substitutes all previous versions issued for the brand names mentioned above. We trust this information, which is made up to the best of our knowledge, will be helpful to you.

With kindest regards,

Name : Armand M. Janssen
Job title : QA Regulatory Affairs Officer
Signature : 

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