Residual Solvent–Statement

Product group:	Lactose and Inhalation
Brand name:	Lactochem®, Lactohale®, Lactopress®, Lactose FC, Pharmatose®, Respitose®, and SuperTab®
Document No.:	PD-0110 Page 1 of 1

Dear Customer,

Herewith we certify the following:

For the manufacturing of our pharmaceutical grade lactose no other solvents than potable water and reverse osmosis water are used, and therefore the final product is only tested on presence of free water by the pharmacopoeia test 'Loss on Drying'.

Water is not an organic solvent and hence not mentioned in the solvent list in the ICH Q3C guideline (as amended). This guideline is referenced by the USP-NF (general chapter <467>) and in the European Pharmacopoeia (General Chapter 5.4).

Our pharmaceutical grade lactose thus complies with the current requirements for Residual Solvents in the Ph. Eur, USP-NF and ICH Q3C.

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.

Name : Lorina Bisharat
Job title : Regulatory Affairs Manager
Signature :

This document is controlled by a validated, electronic system and is valid without signature.
The above facsimile signature is only for display.

DFE Pharma GmbH & Co. KG
Klever Strasse 187, 47574 Goch, Germany. P.O. Box 20 21 20, 47568 Goch, Germany. T. +49 2823 9288 770. F. +49 2823 9288 7799

The document is an uncontrolled copy and is valid only at the time of distribution. Timestamp: 03-11-2026; 00:58 UTC

Release date: 19-03-2025