

Manufacturing Licenses (EU)

Product group: Lactose and Inhalation

Brand name: Lactochem®, Lactohale®,

Lactopress®, Lactose FC, Pharmatose®, Respitose®,

SuperTab®

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Dear Customer,

Pharmaceutical grade lactose produced in the European Union is manufactured under the requirements of the European Food Hygiene Regulations (Regulations (EC) 852/2004 and 853/2004). This includes continuous supervision by the competent authorities. All facilities approved under the Regulation (EC) 853/2004 have been assigned an approval number.

The approval numbers for the European production sites for pharmaceutical grade lactose are as follows:

Production site	Approval Number
FrieslandCampina DMV B.V.	NL Z0032
N.C.B. laan 80	
5462 GE Veghel	
The Netherlands	
DFE Pharma B.V.	NL Z0984
Needseweg 23	
7271 AB Borculo	
The Netherlands	
FrieslandCampina Ingredients B.V.	NL Z0199
Needseweg 23	
7271 AB Borculo	
The Netherlands	
DFE Pharma GmbH & Co. KG	DE NI200 EG
Lauenförder Strasse 5	
37176 Nörten Hardenberg	
Germany	

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

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