Manufacturing Licenses (EU)

Product group: Lactose and Inhalation

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

Document No.: PD-0592

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

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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