Technical Unavoidable Particles

Product group:	Lactose, Inhalation, MCC
Brand name:	Pharmacel® Lactochem®, Lactopress®, Lactohale®, Respitose®, SuperTab®, Pharmatose®
Document No.:	PD-0788

Dear Customer,

Our pharmaceutical grade Lactose and Microcrystalline Celluloses are produced by different production processes. The product is either milled, sieved, granulated, spray dried, or roller dried. During the drying process normal fluctuations in retention time in the dryer can cause the product to be scorched and to develop a dark coloring.
This occurs incidentally and is inherent to the production process. In this case these dark particles cannot be specified as foreign material. Due to the process, it is not possible to avoid scorched particles. For these technical unavoidable particles (TUP) DFE Pharma implemented a system procedure, which is based on the "IPEC Technical Unavoidable Particle Profile (TUPP) Guide". This system procedure can be viewed during an on-site audit.

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 : M. Meijer
Job title : QA Manager
Signature :

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Release date: 04-05-2023