Compliance to Pharmacopoeia

Product group:	MCC, Starch, Lactose, Inhalation, Biopharma and Superdisintegrants
Brand name:	Lactochem®, Lactohale®, Lactopress®, Nutracel®, Pharmatose®, Respitose®, SuperTab®, Solani Amylum, Prejel PA5 PH, Pharmacel®, Pharmacel® sMCC 90, Primojel®, Primellose®, BioHale® Sucrose, BioHale® Trehalose Dihydrate
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Dear Customer,

DFE Pharma GmbH & Co. KG is the manufacturer of pharmaceutical excipients under the brand names mentioned above.

DFE Pharma specifies in its product specifications that the product complies with the current edition of the relevant pharmacopoeia(s), i.e., USP - NF, Ph.Eur., JP, ChP.
We herewith certify that our products conform to pharmacopeial monographs current at time of manufacture and will continue to comply with the requirements of the relevant pharmacopeia(s) in the future. Product specifications will specify the exact pharmacopeial compliance for each corresponding product.

The current underlying Pharmacopoeia editions are:

- Ph. Eur. Edition according to the following official publishing scheme: European Pharmacopoeia Online
- USP–NF according to the following official publishing scheme: https://www.uspnf.com/publication-comment-schedule
- JP 18th Edition (2021) including published supplements
- CP 2025 Edition (2025) including published supplements

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 : Lorina Bisharat
Job title : Regulatory Affairs Manager
Signature :

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The above facsimile signature is only for display.

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Release date: 21-10-2025