Residual Solvents Statement

Product group: MCC

Brand name: Pharmacel® 101, 102, 112 & 200
Pharmacel® sMCC 50 & 90

Document No.: PD-0540

Dear Customer,

Herewith we certify the following:
For the manufacturing of our microcrystalline cellulose products (Pharmacel® 101, 102, 112, 200, sMCC50 and sMCC 90) no other solvents than water are used.
This is certified with reference to the solvents listed in the "Q3C ICH guidelines on residual solvents (EMA/CHMP/ICH/82260/2006)" and USP general chapter <467>: no class 1, 2, 3 solvents are used in the raw materials, manufacturing process and product. General test 5.4 of the European Pharmacopoeia is also applicable. In addition, we do not use other organic solvents that are not listed in the ICH Q3C or the USP<467> either.
Since only water is used during the raw material and end product production, the final product is only tested on presence of free water by the pharmacopoeia test 'Loss on Drying'.
Our pharmaceutical grade microcrystalline cellulose complies with the current Ph. Eur. Requirements for Residual Solvents and USP requirements for Organic Volatile Impurities / Residual Solvents.

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 : MAJ Nijman
Job title : Global Quality Director
Signature :

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

The document is an uncontrolled copy and is valid only at the time of distribution. Timestamp: 15-11-2026; 16:13 UTC
Kiever Strasse 187, 47574 Goch, Germany, P.O. Box 20 21 20, 47568 Goch, Germany, T. +49 2823 9288 770, F. +49 2823 9288 7799
Release date: 24-10-2026