

**CERTIFICATE OF ANALYSIS**

**SMCC 50 - Silicified Microcrystalline Cellulose NF**

composed of

*(Microcrystalline Cellulose, NF, Ph. Eur., JP, and Colloidal Silicon Dioxide, NF, Silica, Colloidal Anhydrous, Ph. Eur., Light Anhydrous Silicic Acid, JP)*

| <b>Characteristics:</b>                             | <b>Specifications:</b>                                                                                     | <b>References:</b> |
|-----------------------------------------------------|------------------------------------------------------------------------------------------------------------|--------------------|
| Degree of polymerization                            | Not more than 350                                                                                          | NF, Ph. Eur., JP   |
| Particle size (air jet)                             | Not more than 1.0% retained on #60 mesh sieve (250 µm)<br>10.0 - 30.0% retained on #200 mesh sieve (75 µm) | Pharma Method      |
| Particle size by laser diffraction                  | d <sub>10</sub> 18 - 27 µm<br>d <sub>50</sub> 46 - 76 µm<br>d <sub>90</sub> 92 - 165 µm                    | Pharma Method      |
| Water-soluble substances                            | Not more than 0.24%                                                                                        | NF, Ph. Eur., JP   |
| Ether-soluble substances                            | Not more than 0.05%                                                                                        | NF, Ph. Eur., JP   |
| Heavy metals                                        | Not more than 0.001%                                                                                       | USP, Ph. Eur., JP  |
| Solubility in ammoniacal copper tetrammine solution | Completely dissolves                                                                                       | Ph. Eur.           |
| Escherichia coli                                    | Absent in 10 g                                                                                             | USP, Ph. Eur., JP  |
| Pseudomonas aeruginosa                              | Absent in 10 g                                                                                             | USP, Ph. Eur., JP  |
| Salmonella species                                  | Absent in 10 g                                                                                             | USP, Ph. Eur., JP  |
| Staphylococcus aureus                               | Absent in 10 g                                                                                             | USP, Ph. Eur., JP  |
| Identification V                                    | Stable suspension                                                                                          | JP                 |
| Residual solvents                                   | Meets the requirements                                                                                     | USP, Ph. Eur.      |
| Tapped density                                      | 0.37 - 0.50 g/mL                                                                                           | Pharma Method      |

\* Data based on manufacturer's document

*Jmk*

Quality Control

