Cellulose, Silicified Microcrystalline

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1 Nonproprietary Names

USP–NF: Silicified Microcrystalline Cellulose

2 Synonyms

ProSolv.

3 Chemical Name and CAS Registry Number

See Section 8.

4 Empirical Formula and Molecular Weight

See Section 8.

5 Structural Formula

See Section 8.

6 Functional Category

Tablet and capsule diluent.

7 Applications in Pharmaceutical Formulation or Technology

Silicified microcrystalline cellulose is used as a diluent in the formulation of capsules and tablets. It has improved compaction properties in both wet granulation and direct compression compared to conventional microcrystalline cellulose.[1–5] Silicified microcrystalline cellulose was specifically developed to address the loss of compactability that occurs with microcrystalline cellulose after wet granulation. Silicified microcrystalline cellulose also appears to have beneficial properties for use in the formulation of powder-filled capsules.[6,7]

8 Description

Silicified microcrystalline cellulose is a synergistic, co-processed mixture of two components: microcrystalline cellulose and colloidal silicon dioxide (for further information *see* Cellulose, Microcrystalline and Colloidal Silicon Dioxide). Silicified microcrystalline cellulose contains 2% w/w colloidal silicon dioxide.

9 Pharmacopeial Specifications

See Table I. *See also* Section 18.

10 Typical Properties

Acidity/alkalinity pH = 5.0–7.5 (12.5% w/v suspension)
Density 1.58 g/cm[5]
Density (bulk) 0.31 g/cm^3
Density (tapped) 0.39 g/cm[5]
Melting point The microcrystalline cellulose component chars at 260–270°C.
Moisture content Typically less than 6% w/w.
Particle size distribution Typical particle size is 20–200 µm. Different grades may have a different median particle size.
Solubility Practically insoluble in water, dilute acids, and most organic solvents. The microcrystalline cellulose component is slightly soluble in 5% w/w sodium hydroxide solution.
Spectroscopy

NIR spectrum *see* Figure 1.

11 Stability and Storage Conditions

Silicified microcrystalline cellulose is stable when stored in a well-closed container in a cool, dry place.

12 Incompatibilities

See Cellulose, Microcrystalline and Colloidal Silicon Dioxide.

13 Method of Manufacture

Silicified microcrystalline cellulose is manufactured by co-spray drying a suspension of microcrystalline cellulose particles and colloidal silicon dioxide such that the dried finished product contains 2% w/w colloidal silicon dioxide.

The colloidal silicon dioxide appears physically bound onto the surface and inside the silicified microcrystalline cellulose particles. Extensive studies using different spectroscopic methods have failed to show any form of covalent chemical interaction.[4,8,9]

14 Safety

See Cellulose, Microcrystalline and Colloidal Silicon Dioxide.

Table I: Pharmacopeial specifications for silicified microcrystalline cellulose.

Test	USP 40–NF 35 S1
Identification	+
Microbial contamination	
Aerobic bacteria	≤1000 cfu per g
Fungi	≤100 cfu per g
Conductivity	+
pH	5.0–7.5
Loss on drying	7.0%
Residue on ignition	1.8–2.2%
Bulk density	+
Degree of polymerization	≤350
Particle size and distribution	+
Water-soluble substances	≤12.5 mg
Ether-soluble substances	≤5.0 mg
Heavy metals	≤0.001%

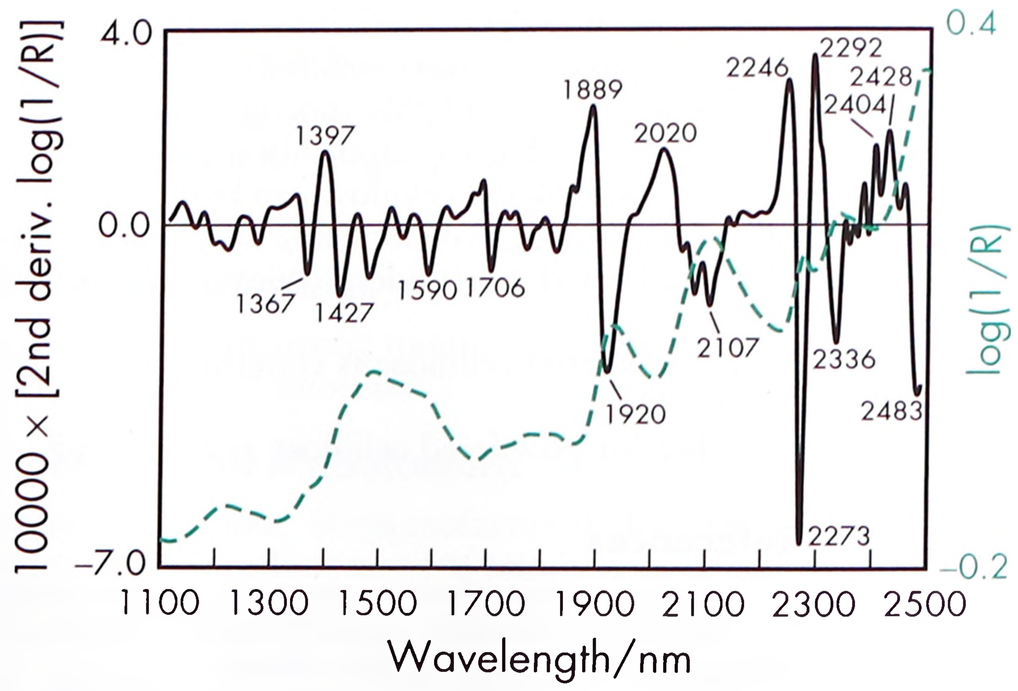

Figure 1: Near-infrared spectrum of silicified microcrystalline cellulose measured by reflectance.