

Handbook of Pharmaceutical Excipients

FIFTH EDITION

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Cellulose, Silicified Microcrystalline

1 Nonproprietary Names

None adopted.

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 filler 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 compaction that occurs with microcrystalline cellulose after wet granulation.

8 Description

Silicified microcrystalline cellulose is a synergistic, intimate physical 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

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10 Typical properties

Acidity/alkalinity: pH = 5.0–7.5 (10% w/v suspension)

Density: 1.58 g/cm⁽⁵⁾

Density (bulk): 0.31 g/cm³

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 normal mean 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.

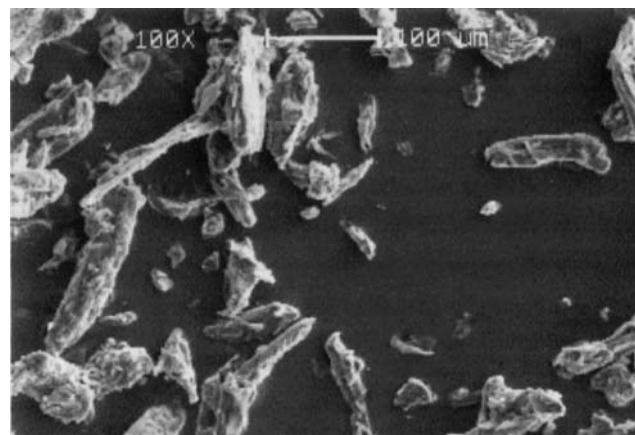
SEM: 1

Excipient: Silicified microcrystalline cellulose

Manufacturer: JRS Pharma LP

Lot No.: CSD5866

Magnification: 100×



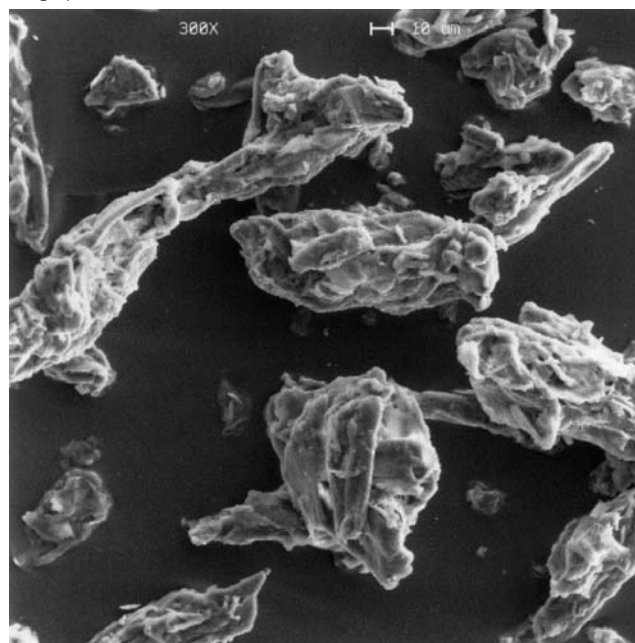
SEM: 2

Excipient: Silicified microcrystalline cellulose

Manufacturer: JRS Pharma LP

Lot No.: CSD5866

Magnification: 300×



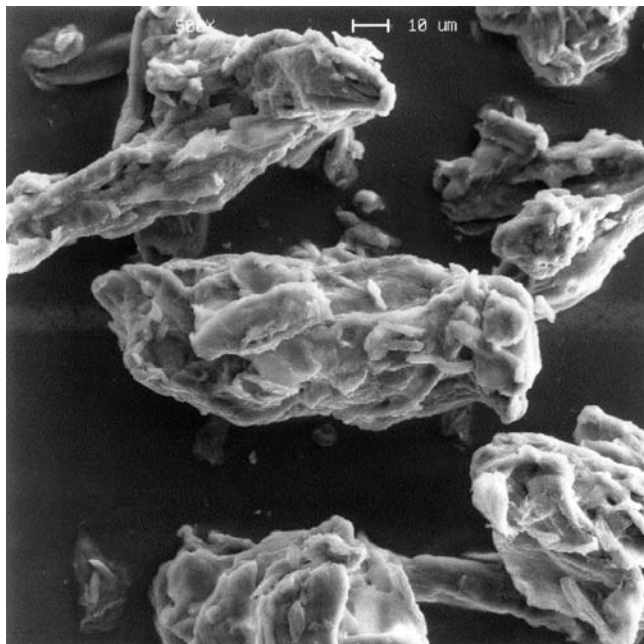
SEM: 3

Excipient: Silicified microcrystalline cellulose

Manufacturer: JRS Pharma LP

Lot No.: CSD5866

Magnification: 500×

**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-drying a suspension of microcrystalline cellulose particles and colloidal silicon dioxide so 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 chemical interaction.^(4,6,7)

14 Safety

See Cellulose, Microcrystalline and Colloidal Silicon Dioxide.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Handling of silicified microcrystalline cellulose can generate nuisance dusts and the use of a respirator or dust mask may be necessary.

Microcrystalline cellulose may be irritant to the eyes. Gloves, eye protection, and a dust mask are recommended. In the UK the long-term occupational exposure limits (8-hour

TWA) have been set at 10 mg/m³ for total inhalable dust and 4 mg/m³ for respirable dust; short-term limit for total inhalable dust has been set at 20 mg/m³.⁽⁸⁾

Since the colloidal silicon dioxide is physically bound to the microcrystalline cellulose the general recommendations of gloves, eye protection, and a dust mask should be followed when handling silicified microcrystalline cellulose.

16 Regulatory Status

Silicified microcrystalline cellulose is a physical mixture of two materials both of which are generally regarded as nontoxic:

Microcrystalline cellulose: GRAS listed. Included in the FDA Inactive Ingredients Guide (inhalations, oral capsules, powders, suspensions, syrups, and tablets). Included in nonparenteral medicines licensed in Europe and the US. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

Colloidal silicon dioxide: GRAS listed. Included in the FDA Inactive Ingredients Guide (oral capsules and tablets). Included in nonparenteral medicines licensed in Europe and the US. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

17 Related Substances

Cellulose, microcrystalline; colloidal silicon dioxide.

18 Comments

Silicified microcrystalline cellulose has greater tensile strength and requires lower compression pressures than regular grades of microcrystalline cellulose. Furthermore, silicified microcrystalline cellulose maintains its compactability when wet granulated; the compacts exhibit greater stiffness and they require considerably more energy for tensile failure to occur.^(4,9)

19 Specific References

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