Cellulose, Microcrystalline

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1 Nonproprietary Names

BP: Microcrystalline Cellulose
JP: Microcrystalline Cellulose
PhEur: Cellulose, Microcrystalline
USP–NF: Microcrystalline Cellulose

2 Synonyms

Avicel PH; *Cellets*; *Celex*; cellulose gel; cellulosum microcristallinum; *Celphere*; *Ceolus KG*; crystalline cellulose; *Cyclocel*; E460; *Emcocel*; *Fibrocel*; *Grinsted MCC*; *MCC Sanaq*; *Microcel*; *Pharmacel*; *Tabulose*; *Vivapur*.

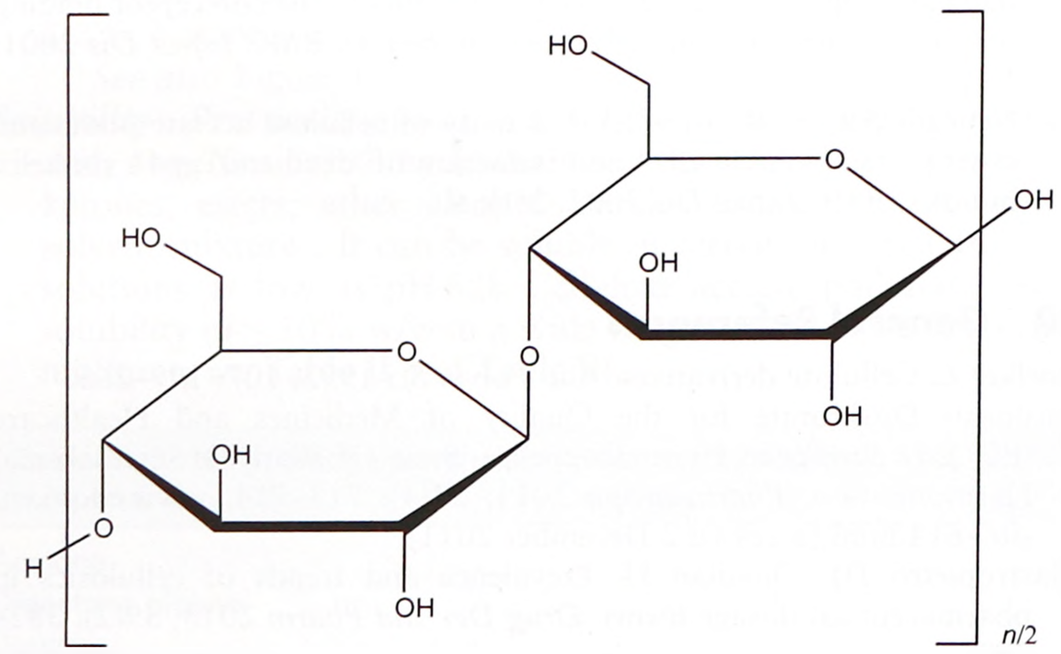
3 Chemical Name and CAS Registry Number

Cellulose [9004-34-6]

4 Empirical Formula and Molecular Weight

$(C_6H_{10}O_5)_n$ ≈36 000 where $n \approx 220$.

5 Structural Formula



6 Functional Category

Adsorbent; direct compression excipient; suspending agent; tablet and capsule diluent.

7 Applications in Pharmaceutical Formulation or Technology

Microcrystalline cellulose is widely used in pharmaceuticals, primarily as a binder/diluent in oral tablet and capsule formulations where it is used in dry-granulation, wet-granulation, and direct-compression processes.[1–6] In addition to its use as a binder/diluent, microcrystalline cellulose may also reduce friction during tablet ejection[7] and facilitate tablet disintegration.[8] Microcrystalline cellulose has been used with nanoparticles and nanogels for modified drug release.[9,10] Certain spherical-shaped grades may be used for drug layering.[11] *See* Table I for some of the uses and concentrations of microcrystalline cellulose.

8 Description

Microcrystalline cellulose is a purified, partially depolymerized cellulose that occurs as a white, odorless, tasteless powder composed of porous particles.

Table I: Uses of microcrystalline cellulose.

Use	Concentration (%)
Adsorbent	20–90
Antiadherent	5–20
Capsule binder/diluent	20–90
Tablet disintegrant	5–15
Tablet binder/diluent	20–90

9 Pharmacopeial Specifications

The pharmacopeial specifications for microcrystalline cellulose have undergone harmonization of many attributes for JP, PhEur, and USP–NF.

See Table II. *See also* Section 18.

Table II: Pharmacopeial specifications for microcrystalline cellulose.

Test	JP XVII	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+	+
Characters[a]	+	+	–
pH	5.0–7.5	5.0–7.5	5.0–7.5
Bulk density	+	–	+
Loss on drying	≤7.0%	≤7.0%	≤7.0%
Residue on ignition	≤0.1%	–	≤0.1%
Conductivity	+	+	+
Sulfated ash	–	≤0.1%	–
Ether-soluble substances	≤0.05%	≤0.05%	≤0.05%
Water-soluble substances	+	≤0.25%	≤0.25%
Heavy metals[a]	≤10 ppm	–	≤10 ppm
Microbial limits[a]			
Aerobic	≤10^3 cfu/g	≤10^3 cfu/g	≤10^3 cfu/g
Molds and yeasts	≤10^2 cfu/g	≤10^2 cfu/g	≤10^2 cfu/g
Solubility	–	+	–
Particle size distribution	–	+	+

(a) This test has not been fully harmonized at the time of publication.

SEM 1: Excipient: microcrystalline cellulose; manufacturer: JRS Pharma LP; lot no.: 98662; magnification: 100×.