# Cellulose, Powdered

## 1 Nonproprietary Names

BP: Powdered Cellulose

JP: Powdered Cellulose

PhEur: Cellulose, Powdered

USP–NF: Powdered Cellulose

## 2 Synonyms

Alpha-cellulose; *Arbocel*; cellulosi pulvis; E460; Elcema; *JustFiber*; *KC Flock*; *Sanacel*; *Sanacel Pharma*; *Sancel-W*; *Sanacel Wheat*; *Solka-Floc*.

## 3 Chemical Name and CAS Registry Number

Cellulose [9004-34-6]

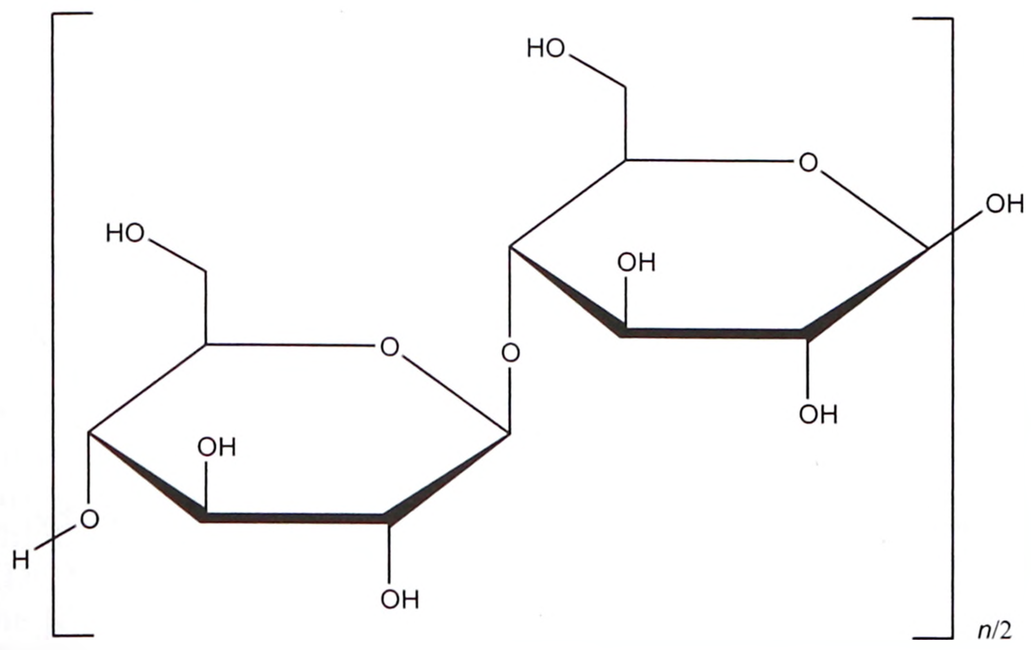
## 4 Empirical Formula and Molecular Weight

$(C_6H_{10}O_5)_n$ ≈243 000 where $n \approx 500$.

Since cellulose is derived from a natural polymer, it has variable chain length and thus variable molecular weight.

*See also* Sections 8 and 13.

## 5 Structural Formula




## 6 Functional Category

Adsorbent; glidant; suspending agent; tablet and capsule diluent; tablet and capsule disintegrant; viscosity-increasing agent.

## 7 Applications in Pharmaceutical Formulation or Technology

Powdered cellulose is used as a tablet diluent and filler in two-piece hard capsules; *see* Table I. In both contexts it acts as a bulking agent to increase the physical size of the dosage form for formulations containing a small amount of active substance.

Powdered cellulose has acceptable compression properties, although the flow properties of most brands are poor. However, low-crystallinity powdered cellulose has exhibited properties that are different from standard powdered cellulose materials, and has shown potential as a direct-compression excipient.[1]

In soft gelatin capsules, powdered cellulose may be used to reduce the sedimentation rate of oily suspension fills. It is also used as the powder base material of powder dosage forms, and as a suspending agent in aqueous suspensions for peroral delivery. It may also be used to reduce sedimentation during the manufacture of suppositories.

Powdered cellulose has been investigated as an alternative to microcrystalline cellulose as an agent to assist the manufacture of pellets by extrusion/spheronization.[2,3] However, powdered cellulose alone requires too much water and due to water movement during extrusion cannot be used as an extrusion/spheronization aid on its own.[4]

Powdered cellulose is also used widely in cosmetics and food products as an adsorbent and thickening agent.

**Table I:** Uses of powdered cellulose.

| Use | Concentration (%) |
|---|---|
| Capsule filler | 5–30 |
| Tablet and capsule binder | 5–40 (wet granulation)<br>10–30 (dry granulation) |
| Tablet disintegrant | 5–20 |
| Tablet glidant | 1–2 |

## 8 Description

Powdered cellulose occurs as a white or almost white, odorless and tasteless powder of various particle sizes, ranging from a free-flowing fine or granular dense powder, to a coarse, fluffy, nonflowing material.

## 9 Pharmacopeial Specifications

The pharmacopeial specifications for powdered 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 powdered cellulose.

| Test | JP XVII | PhEur 9.2[a] | USP 40–NF 35 S1 |
|---|---|---|---|
| Identification[b] | + | + | + |
| Characters[c] | + | + | – |
| Microbial limits[c] | | | |
| Aerobic | ≤$10^3$ cfu/g | ≤$10^3$ cfu/g | ≤$10^3$ cfu/g |
| Fungi and yeast | ≤$10^2$ cfu/g | ≤$10^2$ cfu/g | ≤$10^2$ cfu/g |
| pH (10% w/w suspension) | 5.0–7.5 | 5.0–7.5 | 5.0–7.5 |
| Loss on drying | ≤6.5% | ≤6.5% | ≤6.5% |
| Residue on ignition | ≤0.3% | ≤0.3% | ≤0.3% |
| Solubility | + | + | – |
| Ether-soluble substances | ≤15.0 mg | ≤0.15% | ≤15.0 mg |
| Water-soluble substances | ≤15.0 mg | ≤1.5% | ≤15.0 mg |
| Heavy metals[c] | ≤10 ppm | – | ≤10 ppm |

(a) The PhEur 9.2 also includes crystallinity, particle size distribution and powder flow under functionality-related characteristics.
(b) Degree of polymerization is ≥440 for JP XVII, PhEur 9.2 and USP 40–NF 35 S1.
(c) These tests have not been fully harmonized at the time of publication.

## 10 Typical Properties

*Density (bulk)* 0.15–0.41 g/cm$^3$, depending on the source and grade.

*Density (tapped)* 0.21–0.48 g/cm$^3$, depending on the source and grade.