

Carboxymethylcellulose Calcium

1 Nonproprietary Names

BP: Carmellose calcium
 JP: Carmellose calcium
 PhEur: Carmellosum calcicum
 USPNF: Carboxymethylcellulose calcium

2 Synonyms

Calcium carboxymethylcellulose; calcium CMC; *ECG 505*; *Nymcel ZSC*.

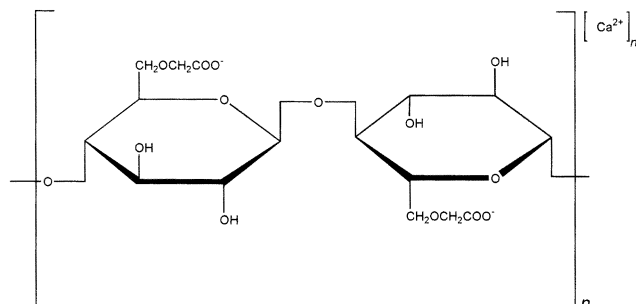
3 Chemical Name and CAS Registry Number

Cellulose, carboxymethyl ether, calcium salt [9050-04-8]

4 Empirical Formula Molecular Weight

The USPNF 20 describes carboxymethylcellulose calcium as the calcium salt of a polycarboxymethyl ether of cellulose.

5 Structural Formula



Structure shown with a degree of substitution (DS) of 1.0.

6 Functional Category

Stabilizing agent; suspending agent; tablet and capsule disintegrant; viscosity-increasing agent; water-absorbing agent.

7 Applications in Pharmaceutical Formulation or Technology

The main use of carboxymethylcellulose calcium is in tablet formulations (*see* Table I), where it is used as a binder, diluent, and disintegrant.⁽¹⁻³⁾ Although carboxymethylcellulose calcium is insoluble in water, it is an effective tablet disintegrant as it swells to several times its original bulk on contact with water. Concentrations up to 15% w/w may be used in tablet formulations; above this concentration, tablet hardness is reduced.

Carboxymethylcellulose calcium is also used in other applications similarly to carboxymethylcellulose sodium; for example, as a suspending or viscosity-increasing agent in oral and topical pharmaceutical formulations.

Table I: Uses of carboxymethylcellulose calcium.

Use	Concentration (%)
Tablet binder	5–15
Tablet disintegrant	1–15

8 Description

Carboxymethylcellulose calcium occurs as a white to yellowish-white, hygroscopic, fine powder.

9 Pharmacopeial Specifications

See Table II.

Table II: Pharmacopeial specifications for carboxymethylcellulose calcium.

Test	JP 2001	PhEur 2002	USPNF 20
Identification	+	+	+
Characters	—	+	—
Alkalinity	+	+	+
pH	4.5–6.0	—	—
Loss on drying	≤ 10.0%	≤ 10.0%	≤ 10.0%
Residue on ignition	10.0–20.0%	10.0–20.0%	10.0–20.0%
Chloride	≤ 0.36%	≤ 0.50%	≤ 0.36%
Silicate	≤ 0.5%	≤ 0.60%	≤ 1.5%
Sulfate	≤ 0.96%	≤ 1.0%	≤ 0.96%
Arsenic	≤ 10 ppm	—	—
Heavy metals	≤ 20 ppm	≤ 20 ppm	≤ 0.002%
Starch	+	—	+
Organic volatile impurities	—	—	+

10 Typical Properties

Acidity/alkalinity: pH = 4.5–6.0 for a 1% w/v aqueous dispersion.

Particle size distribution: 95% through a 73.7 μm sieve (#200 mesh).

Solubility: practically insoluble in acetone, chloroform, ethanol (95%), and ether. Insoluble in water, but swells to twice its volume to form a suspension. Insoluble in 0.1 mol/L hydrochloric acid, but slightly soluble in 0.1 mol/L sodium hydroxide.

11 Stability and Storage Conditions

Carboxymethylcellulose calcium is a stable, though hygroscopic material. It should be stored in a well-closed container in a cool, dry place.

See also Carboxymethylcellulose sodium.

12 Incompatibilities

See Carboxymethylcellulose sodium.

13 Method of Manufacture

Cellulose, obtained from wood pulp or cotton fibers, is carboxymethylated, followed by conversion to the calcium salt. It is then graded on the basis of its degree of carboxymethylation and pulverized.

14 Safety

Carboxymethylcellulose calcium is used in oral and topical pharmaceutical formulations, similarly to carboxymethylcellulose sodium, and is generally regarded as a nontoxic and nonirritant material. However, as with other cellulose derivatives, oral consumption of large amounts of carboxymethylcellulose calcium may have a laxative effect.

See also Carboxymethylcellulose sodium.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Carboxymethylcellulose calcium may be irritant to the eyes; eye protection is recommended.

16 Regulatory Status

Accepted for use as a food additive in Japan at concentrations up to 2% w/w. Included in the FDA Inactive Ingredients Guide (oral tablets). Included in nonparenteral medicines licensed in the UK.

17 Related Substances

Carboxymethylcellulose sodium; croscarmellose sodium.

18 Comments

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19 Specific References

- 1 Khan KA, Rooke DJ. Effect of disintegrant type upon the relationship between compressional pressure and dissolution efficiency. *J Pharm Pharmacol* 1976; 28(8): 633-636.
- 2 Kitamori N, Makino T. Improvement in pressure-dependent dissolution of trepibutone tablets by using intragranular disintegrants. *Drug Dev Ind Pharm* 1982; 8(1): 125-139.
- 3 Roe TS, Chang KY. The study of Key-Jo clay as a tablet disintegrator. *Drug Dev Ind Pharm* 1986; 12(11-13): 1567-1585.

20 General References

Doelker E. Cellulose derivatives. *Adv Polym Sci* 1993 107: 199-265.

21 Author

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22 Date of Revision

18 October 2002.