

Croscarmellose Sodium

1 Nonproprietary Names

BP: Croscarmellose Sodium
JP: Croscarmellose Sodium
PhEur: Croscarmellose Sodium
USP–NF: Croscarmellose Sodium

2 Synonyms

Ac-Di-Sol; carmellosum natricum conexum; crosslinked carboxymethylcellulose sodium; *Explocel*; *Kiccolate*; modified cellulose gum; *Nymcel ZSX*; *Pharmacel XL*; *Primellose*; *Solutab*; *Vivasol*.

3 Chemical Name and CAS Registry Number

Cellulose, carboxymethyl ether, sodium salt, crosslinked [74811-65-7]

4 Empirical Formula and Molecular Weight

Croscarmellose sodium is a crosslinked polymer of carboxymethylcellulose sodium.

See Carboxymethylcellulose sodium.

5 Structural Formula

See Carboxymethylcellulose sodium.

6 Functional Category

Tablet and capsule disintegrant.

7 Applications in Pharmaceutical Formulation or Technology

Croscarmellose sodium is used in oral pharmaceutical formulations as a disintegrant for capsules,^(1,2) tablets,^(3–14) and granules.

In tablet formulations, croscarmellose sodium may be used in both direct-compression and wet-granulation processes. When used in wet granulations, the croscarmellose sodium should be added in both the wet and dry stages of the process (intra- and extra-granularly) so that the wicking and swelling ability of the disintegrant is best utilized.^(11,12) Croscarmellose sodium at concentrations up to 5% w/w may be used as a tablet disintegrant, although normally 2% w/w is used in tablets prepared by direct compression and 3% w/w in tablets prepared by a wet-granulation process.

Croscarmellose sodium and other superdisintegrants have been evaluated for fast dissolving and melt-in-mouth tablet formulations.^(15–19)

See Table I.

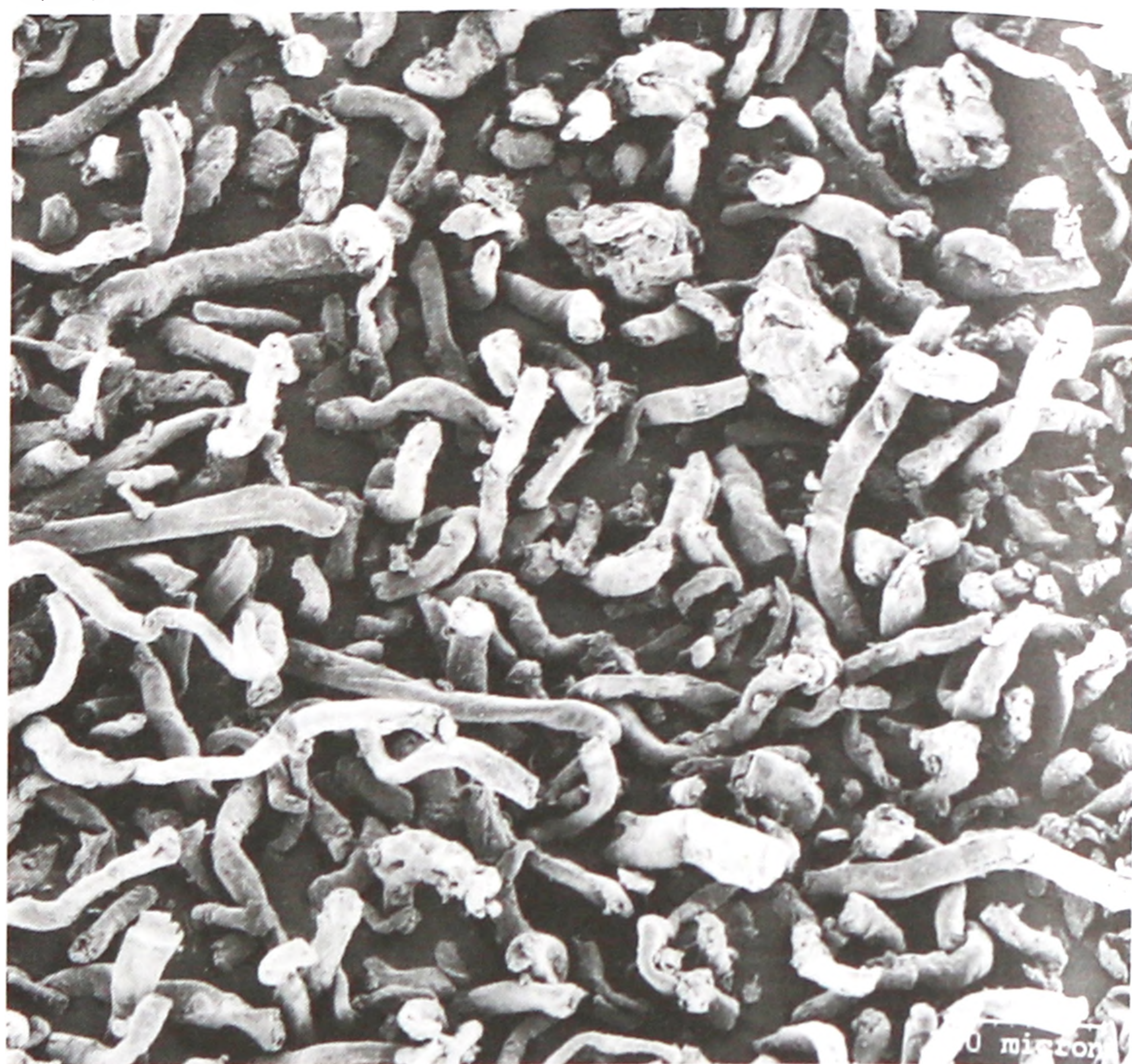
Table I: Uses of croscarmellose sodium.

Use	Concentration (%)
Disintegrant in capsules	10.0–25.0
Disintegrant in tablets	0.5–5.0

8 Description

Croscarmellose sodium occurs as an odorless, white or grayish-white powder.

SEM 1: Excipient: croscarmellose sodium (*Ac-Di-Sol*); manufacturer: FMC Biopolymer; magnification: 100 \times .



SEM 2: Excipient: croscarmellose sodium (*Ac-Di-Sol*); manufacturer: FMC Biopolymer; magnification: 1000 \times .



9 Pharmacopeial Specifications

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

See Table II. See also Section 18.

10 Typical Properties

Acidity/alkalinity pH = 5.0–7.0 in aqueous dispersions.