



Corn Starch and Pregelatinized Starch, Coprocessed

1 Nonproprietary Names

None adopted.

2 Synonyms

StarCap 1500, Starch 1500, SuperStarch 200, Lycatab C, Lycatab C-LM.

3 Chemical Name and CAS Registry Number

See Starch, and Starch, Pregelatinized.

4 Empirical Formula and Molecular Weight

See Starch, and Starch, Pregelatinized.

5 Structural Formula

See Starch, and Starch, Pregelatinized.

6 Functional Category

Direct compression excipient; tablet and capsule diluent; tablet and capsule disintegrant.

7 Applications in Pharmaceutical Formulation or Technology

Coprocessed corn starch and pregelatinized starch can be used in both capsules and tablets to improve flowability, enhance disintegration, and improve hardness. Good compactibility and disintegration of tablets is best achieved in combination with common excipients (soluble or insoluble), such as lactose, microcrystalline cellulose or dibasic calcium phosphate.⁽¹⁾

8 Description

Coprocessed corn starch and pregelatinized starch occurs as a white free-flowing powder. It is a coprocessed mixture of predominantly corn starch together with pregelatinized starch. See also Starch, and Starch, Pregelatinized.

9 Pharmacopeial Specifications

Both corn starch and pregelatinized starch are listed as separate monographs in the JP, PhEur, and USP–NF, but the combination is not listed. The pharmacopeial specifications for corn starch have undergone harmonization for many attributes for JP, PhEur, and USP–NF.

See Starch, and Starch, Pregelatinized. See also Section 18.

10 Typical Properties

Acidity/alkalinity 4.5–7.0 for *StarCap 1500*

Iron ≤0.001% for *StarCap 1500*

Loss on drying 7–13% for *StarCap 1500*

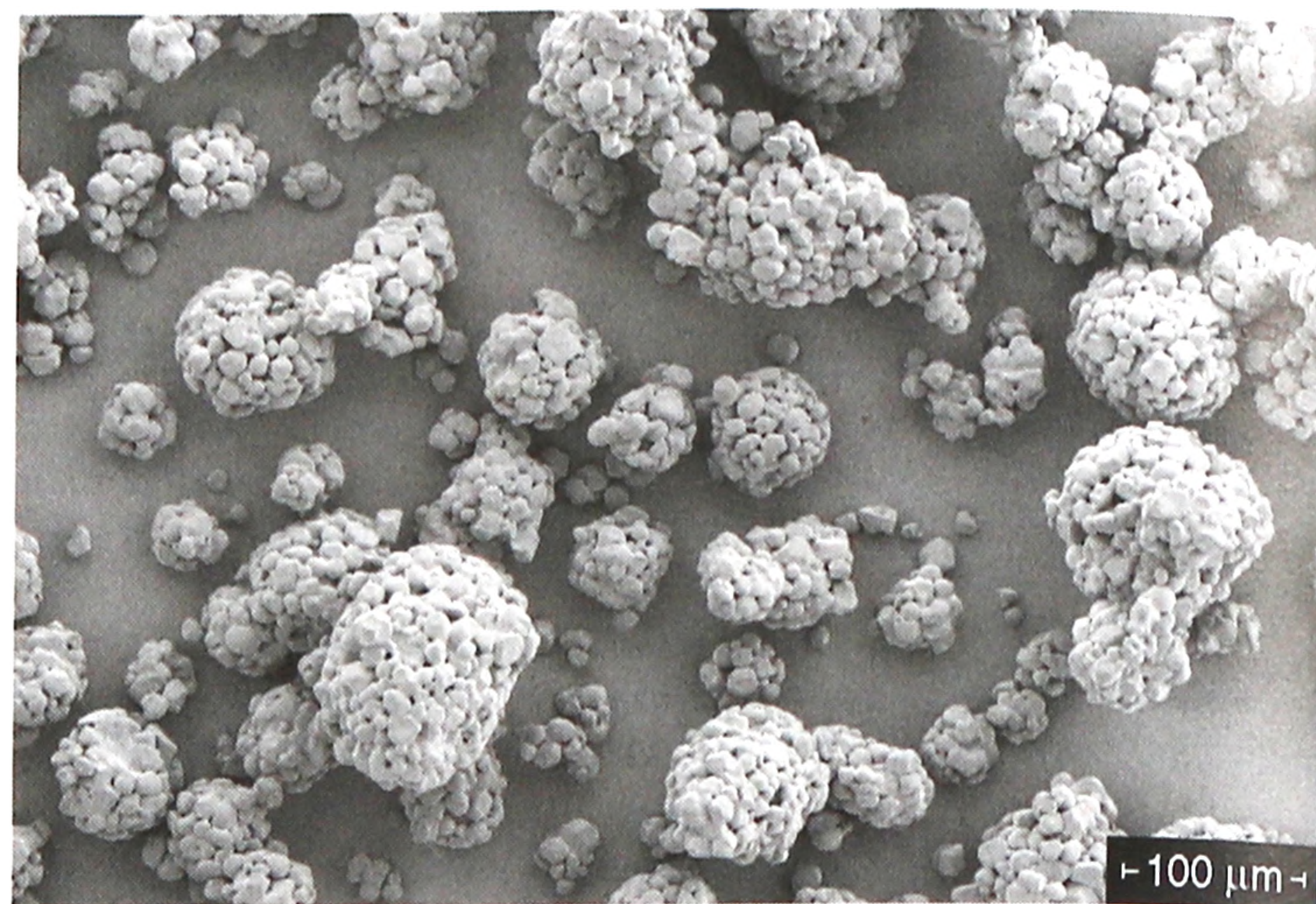
Microbial content Total aerobes count ≤100 cfu/g; molds and yeasts ≤100 cfu/g (*Escherichia coli*, *Pseudomonas aeruginosa*, and *Salmonella* species absent) for *StarCap 1500*.

Particle size distribution 9–42% retained on #120 mesh (125 μm), 25–50% retained on #200 mesh (74 μm), 20–55% passing #200 mesh (74 μm) for *StarCap 1500*.

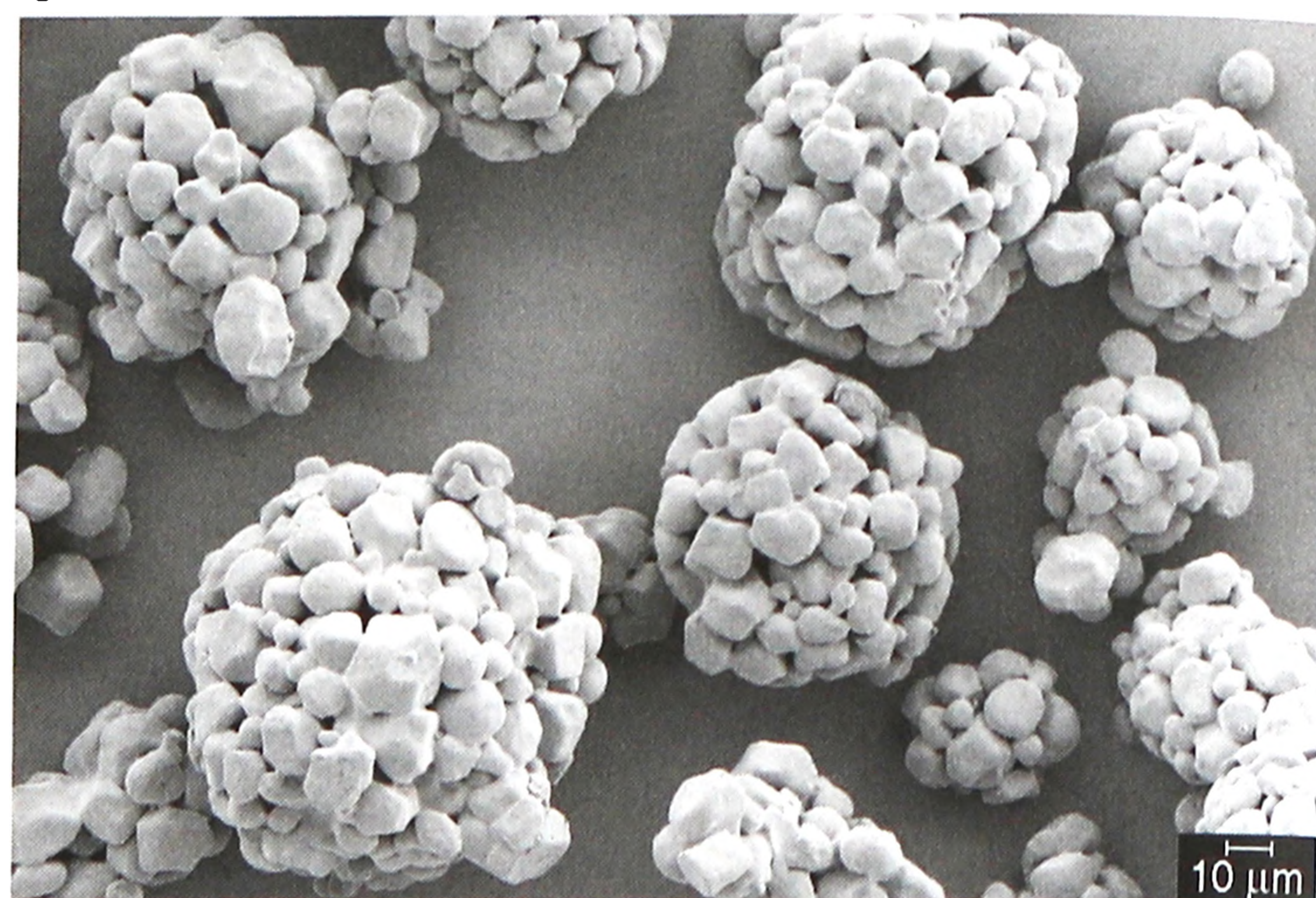
Solubility Insoluble in water for *StarCap 1500*

Sulfur dioxide ≤0.005% for *StarCap 1500*

SEM 1: Excipient: *StarCap 1500*; manufacturer: Colorcon; magnification: 200×; voltage: 3 kV.



SEM 2: Excipient: *StarCap 1500*; manufacturer: Colorcon; magnification: 500×; voltage: 3 kV.



11 Stability and Storage Conditions

Store in sealed containers at below 30°C, avoiding high humidity.

12 Incompatibilities

See Starch, and Starch, Pregelatinized.

13 Method of Manufacture

Coprocessed corn starch and pregelatinized starch is produced by a proprietary spray-drying technique.

14 Safety

See Starch, and Starch, Pregelatinized.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled.

16 Regulatory Status

Corn starch and pregelatinized starch is a coprocessed mixture of two materials both of which are regarded as nontoxic: