

Sodium Starch Glycolate

1 Nonproprietary Names

BP: Sodium starch glycolate

PhEur: Carboxymethylamyllum natricum

USPNF: Sodium starch glycolate

2 Synonyms

Carboxymethyl starch, sodium salt; *Explotab*; *Primojel*; *Vivastar P*.

3 Chemical Name and CAS Registry Number

Sodium carboxymethyl starch [9063-38-1]

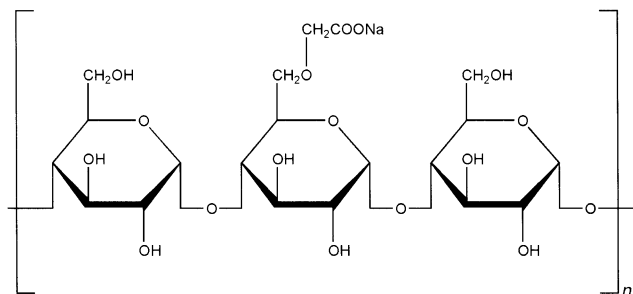
4 Empirical Formula Molecular Weight

The USPNF 20 states that sodium starch glycolate is the sodium salt of a carboxymethyl ether of starch. The molecular weight is typically 5×10^5 – 1×10^6 .

The PhEur 2002 describes three types of material; Type A, equivalent to the USPNF 20 material, containing 2.8–4.2% of sodium; Type B containing 2.0–3.4% of sodium; and Type C containing 2.8–5.0% of sodium.

Sodium starch glycolate may be characterized by the degree of substitution and crosslinking.

5 Structural Formula



6 Functional Category

Tablet and capsule disintegrant.

7 Applications in Pharmaceutical Formulation or Technology

Sodium starch glycolate is widely used in oral pharmaceuticals as a disintegrant in capsule^(1–6) and tablet formulations.^(7–10) It is commonly used in tablets prepared by either direct-compression^(11–13) or wet-granulation processes.^(14–16) The usual concentration employed in a formulation is between 2% and 8%, with the optimum concentration about 4%, although in many cases 2% is sufficient. Disintegration occurs by rapid uptake of water followed by rapid and enormous swelling.^(17–20)

Although the effectiveness of many disintegrants is affected by the presence of hydrophobic excipients such as lubricants, the disintegrant efficiency of sodium starch glycolate is unimpaired. Increasing the tablet compression pressure also appears to have no effect on disintegration time.^(10–14)

Sodium starch glycolate has also been investigated for use as a suspending vehicle.^(21,22)

8 Description

Sodium starch glycolate is a white to off-white, odorless, tasteless, free-flowing powder. It consists of oval or spherical granules, 30–100 μm in diameter, with some less-spherical granules ranging from 10–35 μm in diameter.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for sodium starch glycolate.

Test	PhEur 2002	USPNF 20
Identification	+	+
Characters	+	—
Appearance of solution	+	—
pH	+	3.0–5.0 or 5.5–7.5
Type A	5.5–7.5	—
Type B	3.0–5.9	—
Heavy metals	≤ 20 ppm	$\leq 0.002\%$
Iron	≤ 20 ppm	$\leq 0.002\%$
Loss on drying	+	+
Type A	$\leq 10.0\%$	$\leq 10.0\%$
Type B	$\leq 10.0\%$	$\leq 10.0\%$
Type C	$\leq 7.0\%$	—
Microbial limits	+	+
Sodium chloride	+	+
Type A	$\leq 7.0\%$	$\leq 7.0\%$
Type B	$\leq 7.0\%$	$\leq 7.0\%$
Type C	$\leq 1.0\%$	—
Sodium glycolate	+	—
Assay (of Na)	+	—
Type A	2.8–4.2%	—
Type B	2.0–3.4%	—
Type C	2.8–5.0%	—

10 Typical Properties

Acidity/alkalinity: pH = 3.0–5.0 or pH = 5.5–7.5 for a 3.3% w/v aqueous dispersion. See Section 18.

Ash: $\leq 15\%$

Density (bulk): 0.756 g/cm³

Density (tapped): 0.945 g/cm³

Density (true): 1.443 g/cm³

Melting point: does not melt, but chars at approximately 200°C.

Particle size distribution: 100% of particles less than 104 μm in size. Average particle size is 42 μm for *Explotab*.

Solubility: sparingly soluble in ethanol (95%); practically insoluble in water. At a concentration of 2% w/v sodium starch glycolate disperses in cold water and settles in the form of a highly hydrated layer.

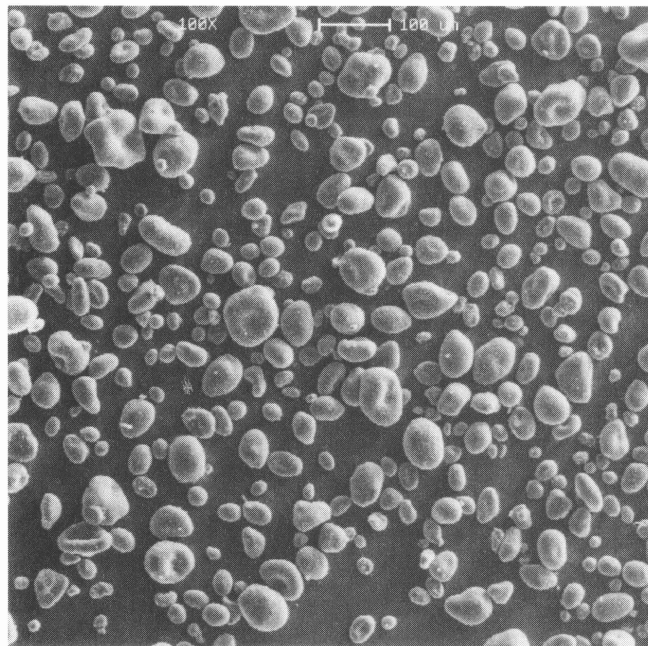
Specific surface area: 0.24 m²/g

Swelling capacity: in water, sodium starch glycolate swells to up to 300 times its volume.

Viscosity (dynamic): ≤ 200 mPa s (200 cP) for a 4% w/v aqueous dispersion. Viscosity is 4.26 mPa s for a 2% w/v aqueous dispersion.

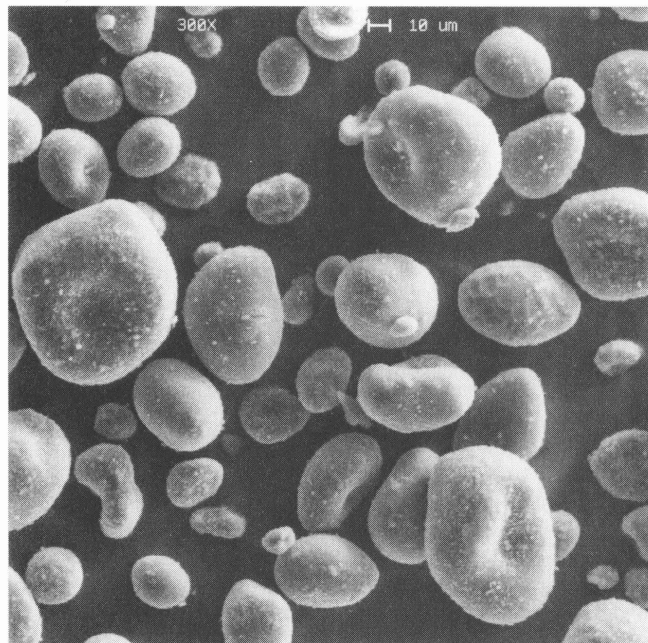
SEM 1

Excipient: Sodium starch glycolate
Manufacturer: Penwest Pharmaceuticals
Lot No.: E7834
Magnification: 100 \times
Voltage: 10kV



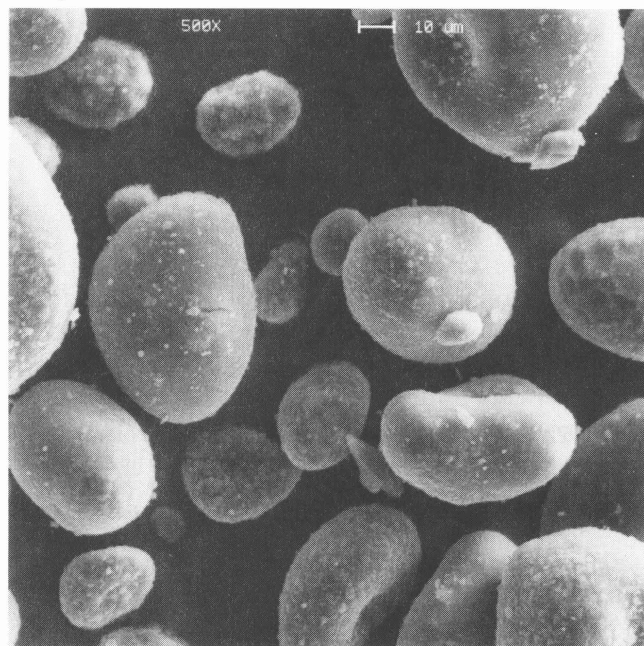
SEM 2

Excipient: Sodium starch glycolate
Manufacturer: Penwest Pharmaceuticals
Lot No.: E7834
Magnification: 300 \times
Voltage: 10kV



SEM 3

Excipient: Sodium starch glycolate
Manufacturer: Penwest Pharmaceuticals
Lot No.: E7834
Magnification: 500 \times
Voltage: 10kV



11 Stability and Storage Conditions

Tablets prepared with sodium starch glycolate have good storage properties.⁽²³⁻²⁵⁾ Sodium starch glycolate is stable and should be stored in a well-closed container in order to protect it from wide variations of humidity and temperature, which may cause caking.

The physical properties of sodium starch glycolate remain unchanged for up to 4 years if it is stored at moderate temperatures and humidity.

12 Incompatibilities

Sodium starch glycolate is incompatible with ascorbic acid.⁽²⁶⁾

13 Method of Manufacture

Sodium starch glycolate is a substituted and crosslinked derivative of potato starch.

Starch is carboxymethylated by reacting it with sodium chloroacetate in an alkaline medium followed by neutralization with citric acid or some other acid. Crosslinking may be achieved either by physical methods or chemically by using reagents such as phosphorus oxytrichloride or sodium trimetaphosphate.⁽²⁷⁾

14 Safety

Sodium starch glycolate is widely used in oral pharmaceutical formulations and is generally regarded as a nontoxic and nonirritant material. However, oral ingestion of large quantities may be harmful.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Sodium starch glycolate may be irritant to the eyes; eye protection and gloves are recommended. A dust mask or respirator is recommended for processes that generate a large quantity of dust.

16 Regulatory Acceptance

Included in the FDA Inactive Ingredients Guide (oral capsules and tablets). Included in nonparenteral medicines licensed in the UK.

17 Related Substances

Pregelatinized starch; starch.

18 Comments

The physical properties of sodium starch glycolate, and hence its effectiveness as a disintegrant, are affected by the degree of crosslinkage and extent of carboxymethylation.

19 Specific References

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21 Author

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22 Date of Revision

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