

## Technical Data Sheet (TDS)

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### 1. Product Overview

- **Product Name:** Sucralfate
- **CAS Number:** 54182-58-0
- **Molecular Formula:**  $C_{12}H_{54}Al_{16}O_7S_8$
- **Molecular Weight:** 2086.76 g/mol
- **Chemical Source:** Synthetic pharmaceutical raw material (synthesized via sulfation of sucrose and complexation with aluminum hydroxide; purified by precipitation and drying to ensure high purity and low impurity content; optimized process for good formulation compatibility for oral solid pharmaceutical preparations).
- **Product Trait:** White to off-white amorphous powder, practically odorless, slightly hygroscopic; practically insoluble in water and organic solvents, slightly soluble in dilute mineral acids; stable in dry, dark and weakly acidic environment, decomposes in strong acid/alkaline environment; good stability in pharmaceutical processing with low temperature and dry conditions.
- **Core Properties: Ion-exchange resin-type gastric mucosal protectant;** forms a viscous protective film on the surface of gastric ulcer by combining with gastric acid and damaged gastric mucosal proteins; inhibits the erosion of gastric acid and pepsin on the ulcer surface, promotes ulcer healing; low systemic absorption ( $\leq 5\%$ ), high safety for oral use; the classic pharmaceutical raw material for clinical treatment of gastric and duodenal ulcers.
- **Main Application:** Pharmaceutical raw material for human oral solid formulations (tablets, capsules, suspensions); treatment of gastric ulcer, duodenal ulcer, acute and chronic gastritis; pharmaceutical R&D reference reagent for gastroenterology and mucosal protection research.

### 2. Technical Specifications (Pharmaceutical Grade, Complies with USP/EP/CP)

Item	Specification
Appearance	White to off-white amorphous powder
Odor	Practically odorless
Assay (Sucralfate)	98.0-102.0%
Acidity (pH, 1% suspension, 25°C)	3.5-5.5
Loss on Drying	$\leq 10.0\%$
Residue on Ignition	40.0-43.0%
Heavy Metals (Pb)	$\leq 10$ ppm
Heavy Metals (As)	$\leq 2$ ppm
Chloride	$\leq 0.5\%$
Sulfate	$\leq 0.5\%$
Total Bacterial Count	$\leq 100$ CFU/g
E. coli	Negative
Yeast & Mold	$\leq 50$ CFU/g
Particle Size	95% passing 200 mesh
Bulk Density	1.70-1.75 g/cm <sup>3</sup>
Hygroscopy	Slightly hygroscopic (weight gain $\leq 5\%$ at 25°C, 75% RH for 7 days)
Solubility	Practically insoluble in water and ethanol

### 3. Product Advantages

1. **High Mucosal Protection Efficacy:** Forms a stable protective film on the ulcer surface, effectively isolating gastric acid, pepsin and food stimulation; promotes the regeneration and repair of gastric mucosal epithelial cells, with a high ulcer healing rate ( $\geq 85\%$  for clinical use).
2. **Low Systemic Absorption:** Oral administration has minimal systemic absorption ( $\leq 5\%$ ), most of the drug remains in the gastrointestinal tract to play a local role; no significant impact on systemic metabolism and organ function, high safety for long-term oral use.

- 3. Good Compatibility with Other Drugs:** No significant drug-drug interaction with common gastrointestinal drugs (antacids, proton pump inhibitors); can be used in combination to enhance the therapeutic effect of peptic ulcer, no adverse reactions caused by combination.
- 4. Pharmaceutical Grade Purity:** Meets USP/EP/CP pharmacopoeia standards; ultralow heavy metal and microbial limits; high assay (98.0-102.0%) and low inorganic ion impurities; suitable for GMP production of clinical oral solid pharmaceutical formulations.
- 5. Excellent Formulation Compatibility:** Good compatibility with common oral pharmaceutical excipients (lactose, starch, microcrystalline cellulose, magnesium stearate); easy to prepare tablets, capsules and oral suspensions; stable in granulation and tableting processes ( $\leq 80^{\circ}\text{C}$ ).
- 6. Stable Storage Property:** 36-month shelf life under sealed, dark and dry conditions; slightly hygroscopic with no significant impact on quality; no light protection required for storage; stable in pharmaceutical processing with dry low-temperature preparation ( $\leq 80^{\circ}\text{C}$ ).

## 4. Application Fields

### 4.1 Pharmaceutical Industry (Oral Gastrointestinal Formulations)

- Tablets/Capsules:** Core raw material for 0.5g/1.0g sucralfate tablets/capsules; first-line drug for the treatment of gastric ulcer and duodenal ulcer; 1.0g per dose, 3-4 times a day, taken on an empty stomach, high patient compliance.
- Oral Suspension:** Formulation for 10% (w/v) oral suspension; suitable for patients with difficulty in swallowing solid preparations (elderly, children); 10mL per dose, 3 times a day, good palatability and high bioavailability of local action.
- Combination Formulations:** Adjuvant raw material for gastrointestinal combination formulations (with omeprazole, ranitidine); simultaneous mucosal protection and acid inhibition, rapid relief of ulcer pain and promotion of healing, one product for multiple indications.

## 5. Usage & Formulation Guidelines

### 5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- Oral Tablets (Adults):** 0.5-1.0 g per tablet (pure sucralfate); 1-2 tablets per dose, 3-4 times a day, taken 1 hour before meals and at bedtime.
- Oral Capsules (Adults):** 0.5 g per capsule (pure sucralfate); 2 capsules per dose, 3 times a day, taken on an empty stomach.
- Oral Suspension (Adults):** 10% (w/v) aqueous suspension; 10 mL per dose (1.0 g pure sucralfate), 3 times a day, shaken well before use.

## 6. Packaging & Storage

### 6.1 Packaging Specifications (Pharmaceutical Grade, Moisture-Proof)

- 100 g/bottle: HDPE pharmaceutical bottle with plastic inner cap + aluminum foil seal (laboratory/R&D/analytical use, moisture-proof).
- 1 kg/bag: Aluminum foil vacuum bag with PE inner lining (moisture-proof, small-batch production use).
- 5 kg/25 kg/drum: HDPE pharmaceutical-grade drum with aluminum foil inner lining + sealed plastic cover + outer carton (moisture-proof, bulk industrial production use).
- Custom packaging (500 g/2 kg) available for R&D and custom formulation production needs (all **moisture-proof**).

## 7. Safety & Protection

- The product is a pharmaceutical gastric mucosal protectant with practically non-toxic and mild irritation effects; **all operations must be conducted by trained professional personnel** with the specified PPE (disposable dust mask, safety goggles, nitrile rubber gloves, clean lab coat).
- Avoid direct contact with eyes/skin/mucous membranes/respiratory tract; avoid inhaling dust and swallowing raw powder; operate in a well-ventilated dust-free fume hood with **moisture-proof measures**; keep the operation environment dry.
- Avoid high humidity and high temperature in the work area; keep the operation tools clean and dry; do not mix with other pharmaceutical raw materials (especially strong acid/alkaline drugs) randomly.
- In case of eye contact, **immediately rinse with plenty of running water for at least 10 minutes** and consult an ophthalmologist if irritation persists (mild redness/tearing may occur).