

TECHNICAL DATA SHEET

1603-TDS-ENG-2026

| SUCRALFATO (EUR. PH.) | | |
|------------------------------|---|-----------------------------|
| DESCRIPTION DCI: sucralfate | | DESCRIPTION DOE: SUCRALFATO |
| CAS N°: 54182-58-0 | EC N°: 259-018-4 | AEMPS CODE: 77A |
| MOL. WEIGHT: 2086,70 | MOL. FORMULA: C ₁₂ H ₅₄ Al ₁₆ O ₇₅ S ₈ | ARTICLE CODE: 1603 |

| <u>ATTRIBUTES</u> | <u>SHOULD BE</u> |
|-----------------------|--|
| Appearance | White or almost white, amorphous powder |
| Solubility | Practically insoluble in water, in ethanol (96 %) and in methylene chloride. It dissolves in dilute solutions of mineral acids and alkali hydroxides |
| Identification A | Complies |
| Identification B | Complies |
| Identification C | Complies |
| Impurity A | =< 5.0 % |
| Neutralising capacity | =< 14.0 mL of 0.1 M NaOH |
| Chlorides | =< 0.5 % |
| Assay | |
| Aluminium | 15.5 - 18.5 % |
| Sucrose octasulfate | 30.0 - 38.0 % |

COMPLIES WITH

European Pharmacopoeia 12.2

STORAGE

Store the containers at room temperature, in a dry and well-ventilated place.

REMARKS

Sucralfate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.