



TECHNICAL DATA SHEET

1603-TDS-ENG-2024

SUCRALFATO (EUR. PH.)		
DESCRIPTION DCI: sucralfate		DESCRIPTION DOE: SUCRALFATO
CAS Nº: 54182-58-0	EC Nº: 259-018-4	AEMPS CODE: 77A
MOL. WEIGHT: 2086,70	MOL. FORMULA: C ₁₂ H ₅₄ Al ₁₆ O ₇ S ₈	ARTICLE CODE: 1603

ATTRIBUTES	SHOULD BE
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 11.0

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.