

TECHNICAL DATA SHEET

46433144-TDS-ENG-2025

SUCRALOSA (EUR. PH.) FARMACEUTICA				
DESCRIPTION DCI:		DESCRIPTION DOE:		
CAS Nº: 56038-13-2	EC Nº: 259-952-2		AEMPS CODE:	
MOL. WEIGHT: 397,63	MOL. FORMULA: C12H19Cl3O8		ARTICLE CODE: 46433144	

ATTRIBUTES	SHOULD BE		
Appareance	White or almost white, crystalline powder		
Solubility	Freely soluble in water, soluble in anhydrous ethanol, slightly soluble in ethyl acetate		
Identification A	Complies		
Identification B	Complies		
Specific optical rotation	+84.0 / +87.5		
Impurities H and I			
Sum impurities H and I	=< 0.1 %		
Related substances			
Impurity A	=< 0.5 %		
Impurity B	=< 0.5 %		
Impurity C	=< 0.5 %		
Impurity D	=< 0.5 %		
Impurity E	=< 0.5 %		
Impurity F	=< 0.5 %		
Impurity G	=< 0.5 %		
Water	=< 2.0 %		
Sulfated ash	=< 0.7 %		
Assay	98.0 - 102.0 %		
COMPLETE			

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Store in a cool place. Keep the container tightly closed, in a dry and well-ventilated place.

REMARKS

Sucralose is subjected to the requirements of the ICH Q3D "Elemental Impurities".

The product is not of animal origin and no animal product is used in its production, so it is risk-free BSE/TSE.

The product is not derived from GMO. No genetically modified organism is used in its production and no GMO product comes in contact with the product during any stage of production.