

SUCRALOSA (EUR. PH.) FARMACEUTICA

PRODUCT CODE: 46433144	CAS Nº: 56038-13-2	ANALYSIS Nº: 064/25
MANUFACTURER BATCH: K95884589	CERTIFICATE ID: 45.543	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 14/02/2024	
METAPH BATCH: 0170325	EXPIRY DATE: 28/02/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder (*)
Identification A	Complies	Complies (*)
Identification B	Complies	Complies (*)
Specific optical rotation	+84.0 / +87.5	+84.5 (*)
Impurities H and I		
Sum impurities H and I	=< 0.1 %	< 0.1 %
Related substances		
Impurity A	=< 0.5 %	< 0.5 %
Impurity B	=< 0.5 %	< 0.5 %
Impurity C	=< 0.5 %	< 0.5 %
Impurity D	=< 0.5 %	< 0.5 %
Impurity E	=< 0.5 %	< 0.5 %
Impurity F	=< 0.5 %	< 0.5 %
Impurity G	=< 0.5 %	< 0.5 %
Water	=< 2.0 %	0.08 % (*)
Sulfated ash	=< 0.7 %	< 0.7 %
Assay	98.0 - 102.0 %	100.4 % (*)

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

(*) Data controlled by Metapharmaceutical Industrial SL.

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.

STORAGE

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

Analysis date: 07/04/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies

Manufacturer: 40000389

