METAPHARMACEUTICAL IND SL
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SUCRALFATO (EUR. PH.)

PRODUCT CODE: 1603	CAS Nº: 54182-58-0	ANALYSIS Nº: 137/24	
MANUFACTURER BATCH:	3123010603	CERTIFICATE ID:	42.308
SUPPLIER BATCH:	----	MANUFACTURING DATE:	10/01/2023
METAPH BATCH:	0220524	RETEST DATE:	09/01/2027

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, amorphous powder	White amorphous powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
Impurity A	=< 5.0 %	0.5 %
Neutralising capacity	=< 14.0 mL of 0.1 M NaOH	12.0 mL of 0.1 M NaOH
Chlorides	=< 0.5 %	< 0.5 %
Assay		
Aluminium	15.5 - 18.5 %	17.8 %
Sucrose octasulfate	30.0 - 38.0 %	31.1 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliances with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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.

STORAGE

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

Analysis date: 29/08/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000498