



SODIO CROMOGLICATO (EUR. PH.) (WHO-GMP)

PRODUCT CODE: 46433072	CAS Nº: 15826-37-6	ANALYSIS Nº: 186/24
MANUFACTURER BATCH: SKG3240003	CERTIFICATE ID: 42.923	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 06/05/2024	
METAPH BATCH: 0090724	RETEST DATE: 05/05/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, hygroscopic, crystalline powder	White, hygroscopic, crystalline powder
Solubility	Soluble in water, practically insoluble in ethanol (96 %)	Complies (*)
Identification B	Complies	Complies
Identification D	Complies	Complies
Appearance of solution	Not more opalescent than ref. sus. II and not more intensely coloured than ref. sol. BY5	Complies
Acidity or alkalinity	Complies	Complies
Related substances		
Impurity C	=< 0.3 %	0.07 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	0.07 %
Oxalates	=< 0.35 %	< 0.35 %
Water	=< 10.0 %	6.9 %
Assay	98.0 - 101.0 %	98.9 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

Store in a cool and well-ventilated place, away from heat, flames, sparks and other sources of ignition.

Analysis date: 11/07/2024
 Signature: Albert Sanchez Lopez (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001487

