

**SODIO CROMOGLICATO (EUR. PH.)**

PRODUCT CODE: 007903	CAS Nº: 15826-37-6	ANALYSIS Nº: 203/21
MANUFACTURER BATCH: 2150002075	CERTIFICATE ID: 32.446	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 08/07/2021	
METAPH BATCH: 0270721	RETEST DATE: 04/07/2026	

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 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.05 %
Oxalates	=< 0.35 %	< 0.35 %
Loss on drying	=< 10.0 %	6.7 %
Assay	98.0 - 101.0 %	99.6 %
Residual solvents [In-house]		(*) (**)
Methanol	=< 200 ppm	< LoQ (50 ppm)
Dimethylformamide	=< 200 ppm	< LoQ (5 ppm)

COMPLIES WITH

European Pharmacopoeia 10.4

REMARKS

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

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.

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

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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: 02/09/2021

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000353

OLON s.p.a.

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