



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 210661

Product:	CROMOLYN SODIUM
Lot:	210661
Expiry date:	29/11/2025
Reference:	Cumple PhEur10.3
Synonyms:	Cromoglicato disódico.
Formula:	C ₂₃ H ₁₄ Na ₂ O ₁₁
Molecular weight:	512,3 g/mol

Assay	Result	Specification	
Impurity C	<= 0,3 %	<= 0,3 %	=
Identification	Conform (B,D)	Test PhEur (B,D)	
Residual solvent: Methanol	<= 3000 ppm	<= 3000 ppm	#
Organoleptic properties	Conform	PhEur	
Residual solvent: Dimethylformamide	<= 880 ppm	<= 880 ppm	#
Unspecified Impurities	<= 0,10 %	<= 0,10 %	=
Total impurities	<= 0,5 %	<= 0,5 %	=
Related substances (HPLC)	Conform	Test PhEur	=
Elemental impurities	Conform	Test PhEur	#
Appearance of solution S (aq. 2%)	Conform	Test Ph. Eur.	=
Acidity or alkalinity	Conform	Test PhEur	=
Assay	101,0 %	98,0 - 101,0 % s.p.s	
Oxalates	<= 0,35 %	<= 0,35%	=
Loss on drying reduced pressure	6,1 %	<= 10,0 %	

Organoleptic characteristics: White or almost white, hygroscopic, crystalline powder. Soluble in water, practically insoluble in ethanol 96%.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 23/03/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00055 OLON, S.P.A.

Manufacturer batch: 2050003625

Product	Name	Capacity	Batch
1177012	SODIO CROMOGLICATO (INACTIVO)	5 g	210661-E-1
1177014	SODIO CROMOGLICATO	25 g	210661-G-1
1177016	SODIO CROMOGLICATO	100 g	210661-J-1

1177016	SODIO CROMOGLICATO	100 g	210661-J-2
1177016	SODIO CROMOGLICATO	100 g	210661-J-3
1177016	SODIO CROMOGLICATO	100 g	210661-J-4
1177017	SODIO CROMOGLICATO	250 g	210661-N-1
1177018	SODIO CROMOGLICATO	500 g	210661-O-1
1177019	SODIO CROMOGLICATO	1 kg	210661-P-1
1177019	SODIO CROMOGLICATO	1 kg	210661-P-2
1177019	SODIO CROMOGLICATO	1 kg	210661-P-3
1177019	SODIO CROMOGLICATO	1 kg	210661-P-4

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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