



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 201914

Product:	CROMOLYN SODIUM
Lot:	201914
Expiry date:	30/09/2025
Reference:	Cumple PhEur10.2
Synonyms:	Cromoglicato disódico.
Formula:	C ₂₃ H ₁₄ Na ₂ O ₁₁
Molecular weight:	512,3 g/mol

Assay	Result	Specification	
Assay	99,2 %	98,0 - 101,0 % s.p.s	
Loss on drying reduced pressure	6,4 %	<= 10,0 %	
Related substances (HPLC)	Conform	Test PhEur	=
Acidity or alkalinity	Conform	Test PhEur	=
Oxalates	<= 0,35 %	<= 0,35%	=
Elemental impurities	Conform	Test PhEur	#
Identification	Conform (B,D)	Test PhEur (B,D)	
Residual solvent: Methanol	<= 3000 ppm	<= 3000 ppm	#
Total impurities	0,13 %	<= 0,5 %	=
Appearance of solution S (aq. 2%)	Conform	Test Ph. Eur.	=
Organoleptic properties	Conform	PhEur	
Residual solvent: Dimethylformamide	<= 880 ppm	<= 880 ppm	#
Unspecified Impurities	<= 0,10 %	<= 0,10 %	=
Impurity C	0,04 %	<= 0,3 %	=

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: 13/11/2020

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00055 OLON, S.P.A.

Manufacturer batch: 2050002761

Product	Name	Capacity	Batch
1177012	SODIO CROMOGLICATO (INACTIVO)	5 g	201914-E-1
1177013	SODIO CROMOGLICATO	10 g	201914-F-1
1177014	SODIO CROMOGLICATO	25 g	201914-G-1

1177016	SODIO CROMOGLICATO	100 g	201914-J-1
1177016	SODIO CROMOGLICATO	100 g	201914-J-2
1177017	SODIO CROMOGLICATO	250 g	201914-N-1
1177019	SODIO CROMOGLICATO	1 kg	201914-P-1

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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