



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251843

Product:	CROMOLYN SODIUM
Lot:	251843
Expiry date:	24/02/2030
Reference:	Cumple PhEur11.8
Synonyms:	Cromoglicato disódico.
Formula:	C ₂₃ H ₁₄ Na ₂ O ₁₁
Molecular weight:	512,3 g/mol

Assay	Result	Specification	
Identification	Conform (B,D)	Test PhEur (B,D)	
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform	Test PhEur	=
Acidity or alkalinity	Conform	Test PhEur	=
Related substances (HPLC)	Conform	Test PhEur	=
Elemental impurities	Conform	Test PhEur	#
Oxalates	<= 0,35 %	<= 0,35%	=
Moisture - K.F.	6,6 %	<= 10,0 %	
Assay	99,3 %	98,0 - 101,0 %	
Impurity C	< 0,05 %	<= 0,3 %	=
Unspecified Impurities	0,07 %	<= 0,10 %	=
Total impurities	0,07 %	<= 0,5 %	=
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Dimethylformamide	< 880 ppm	<= 880 ppm	#
Nitrosamine impurities	Conform	Test PhEur	#

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: 06/10/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00055 OLON, S.P.A.

Manufacturer batch: 0025500518

Product	Name	Capacity	Batch
1177016	SODIO CROMOGLICATO	100 g	251843-J-1
1177017	SODIO CROMOGLICATO	250 g	251843-N-1

1177018	SODIO CROMOGLICATO	500 g	251843-O-1
1177019	SODIO CROMOGLICATO	1 kg	251843-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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