



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241968

Product:	CROMOLYN SODIUM
Lot:	241968
Expiry date:	04/07/2029
Reference:	Cumple PhEur11.5
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.	6,5 %	<= 10,0 %	
Assay	99,8 %	98,0 - 101,0 %	
Impurity C	0,05 %	<= 0,3 %	=
Unspecified Impurities	0,05 %	<= 0,10 %	=
Total impurities	0,05 %	<= 0,5 %	=
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Dimethylformamide	< 890 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: 09/10/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00055 OLON, S.P.A.

Manufacturer batch: 0024501966

Product	Name	Capacity	Batch
1177013	SODIO CROMOGLICATO	10 g	241968-F-1
1177013	SODIO CROMOGLICATO	10 g	241968-F-2

1177013	SODIO CROMOGLICATO	10 g	241968-F-3
1177014	SODIO CROMOGLICATO	25 g	241968-G-1
1177014	SODIO CROMOGLICATO	25 g	241968-G-2
1177014	SODIO CROMOGLICATO	25 g	241968-G-3
1177014	SODIO CROMOGLICATO	25 g	241968-G-4
1177016	SODIO CROMOGLICATO	100 g	241968-J-1
1177016	SODIO CROMOGLICATO	100 g	241968-J-2
1177016	SODIO CROMOGLICATO	100 g	241968-J-3
1177017	SODIO CROMOGLICATO	250 g	241968-N-1
1177017	SODIO CROMOGLICATO	250 g	241968-N-2
1177018	SODIO CROMOGLICATO	500 g	241968-O-1
1177018	SODIO CROMOGLICATO	500 g	241968-O-2
1177019	SODIO CROMOGLICATO	1 kg	241968-P-1
1177019	SODIO CROMOGLICATO	1 kg	241968-P-2
1177019	SODIO CROMOGLICATO	1 kg	241968-P-3

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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Date of edition: 22/04/2026

