



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 201105

Product:	CROMOLYN SODIUM
Lot:	201105
Expiry date:	02/08/2025
Reference:	Cumple PhEur10.2
Synonyms:	Cromoglicato disódico.
Formula:	C23H14Na2O11
Molecular weight:	512,3 g/mol

Assay	Result	Specification	
Identification	Conform (B,D)	Test PhEur (B,D)	
Organoleptic properties	Conform	PhEur	
Appearance of solution S (aq. 2%)	Conform	Test Ph. Eur.	
Acidity or alkalinity	Conform	Test PhEur	
Related substances (HPLC)	Conform	Test PhEur	
Elemental impurities	Conform	Test PhEur	#
Oxalates	<= 0,35 %	<= 0,35%	
Loss on drying reduced pressure	6,5 %	<= 10,0% (KF)	
Assay	99,7 %	98,0 - 101,0 % s.p.s	
Impurity C	<= 0,05 %	<= 0,3 %	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Total impurities	<= 0,5 %	<= 0,5 %	
Residual solvent: Methanol	<= 3000 ppm	<= 3000 ppm	#
Residual solvent: Dimethylformamide	<= 880 ppm	<= 880 ppm	#

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: 18/09/2020

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00055

Manufacturer batch: 2050002205

Product	Name	Capacity	Batch
1177012	SODIO CROMOGLICATO (INACTIVO)	5 g	201105-E-1
1177013	SODIO CROMOGLICATO	10 g	201105-F-1
1177014	SODIO CROMOGLICATO	25 g	201105-G-1

1177016	SODIO CROMOGLICATO	100 g	201105-J-1
1177017	SODIO CROMOGLICATO	250 g	201105-N-1
1177018	SODIO CROMOGLICATO	500 g	201105-O-1
M0017980	SODIO CROMOGLICATO	g	201105

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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