



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 200584**

Product:	CROMOLYN SODIUM
Lot:	200584
Expiry date:	02/03/2025
Reference:	Cumple PhEur10.1
Synonyms:	Cromoglicato disódico.
Formula:	C <sub>23</sub> H <sub>14</sub> Na <sub>2</sub> O <sub>11</sub>
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	=
Heavy metals	<= 20 ppm	<= 20 ppm	#
Oxalates	<= 0,35 %	<= 0,35%	=
Loss on drying reduced pressure	6,7 %	<= 10,0% (KF)	
Assay	99,5 %	98,0 - 101,0 % s.p.s	
Impurity C	<= 0,3 %	<= 0,3 %	=
Unspecified Impurities	<= 0,10 %	<= 0,10 %	=
Total impurities	0,10 %	<= 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: 24/04/2020

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00055

Manufacturer batch: 2050000675

Product	Name	Capacity	Batch
1177012	SODIO CROMOGLICATO (INACTIVO)	5 g	200584-E-1
1177012	SODIO CROMOGLICATO (INACTIVO)	5 g	200584-E-2
1177013	SODIO CROMOGLICATO	10 g	200584-F-1

1177013	SODIO CROMOGLICATO	10 g	200584-F-2
1177014	SODIO CROMOGLICATO	25 g	200584-G-1
1177014	SODIO CROMOGLICATO	25 g	200584-G-2
1177016	SODIO CROMOGLICATO	100 g	200584-J-1
1177016	SODIO CROMOGLICATO	100 g	200584-J-2
1177017	SODIO CROMOGLICATO	250 g	200584-N-1
1177019	SODIO CROMOGLICATO	1 kg	200584-P-1
M0017980	SODIO CROMOGLICATO	g	200584

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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