



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 233513**

Product:	CROMOLYN SODIUM
Lot:	233513
Expiry date:	28/01/2028
Reference:	Cumple PhEur11.2
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	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.	6,0 %	<= 10,0 %	
Assay	100,2 %	98,0 - 101,0 % s.p.s	
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	< 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: 23/10/2023

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00055

Manufacturer batch: 2350000483

Product	Name	Capacity	Batch
1177014	SODIO CROMOGLICATO	25 g	233513-G-1
1177014	SODIO CROMOGLICATO	25 g	233513-G-2
1177016	SODIO CROMOGLICATO	100 g	233513-J-1

1177016	SODIO CROMOGLICATO	100 g	233513-J-2
1177017	SODIO CROMOGLICATO	250 g	233513-N-1
1177017	SODIO CROMOGLICATO	250 g	233513-N-2
1177018	SODIO CROMOGLICATO	500 g	233513-O-1
1177018	SODIO CROMOGLICATO	500 g	233513-O-2
1177019	SODIO CROMOGLICATO	1 kg	233513-P-1
1177019	SODIO CROMOGLICATO	1 kg	233513-P-2

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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