



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 ₂₃ H ₁₄ Na ₂ O ₁₁
Molecular weight:	512,3 g/mol

Assay	Result	Specification	
Moisture - K.F.	6,0 %	<= 10,0 %	
Assay	100,2 %	98,0 - 101,0 % s.p.s	
Elemental impurities	Conform	Test PhEur	#
Oxalates	< 0,35 %	<= 0,35%	
Acidity or alkalinity	Conform	Test PhEur	
Related substances (HPLC)	Conform	Test PhEur	
Organoleptic properties	Conform	PhEur	
Residual solvent: Dimethylformamide	< 880 ppm	<= 880 ppm	#
Appearance of solution	Conform	Test PhEur	
Total impurities	< 0,05 %	<= 0,5 %	
Identification	Conform (B,D)	Test PhEur (B,D)	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Impurity C	< 0,05 %	<= 0,3 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	

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 OLON, S.P.A.

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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