



METAPHARMACEUTICAL

N DE LOTE:

0340325

Agnesina
31/03/2025

Certificate of Analysis

Product name **SODIUM CROMOGLICATE**

Product Code C4050
Batch Number 0024502803
Order 1240200
Quantity 106,950 KG

Manufacturing date 13/11/2024
Re-test date 13/10/2029
Certificate Nr. 100000037056
Batch Size 207,000 KG
Ref. Order B-2240046

Test	Specification	M.U.	Result
DESCRIPTION: white or almost white hygroscopic crystalline powder	complies		complies
IDENTIFICATION (IR)	complies		complies
IDENTIFICATION (UV)	complies		complies
IDENTIFICATION (HPLC retention time)	complies		complies
IDENTIFICATION (sodium reaction)	complies		complies
ACIDITY/ALKALINITY	complies to Ph.Eur.		complies
ACIDITY/ALKALINITY	complies to JP		complies
APPEARANCE OF SOLUTION: a 2.0% solution in water is not more intensely coloured than reference solution BYs	complies		complies
CLARITY OF SOLUTION: a 2.0% solution in water is not more opalescent than reference suspension II	complies		complies
COLOUR OF SOLUTION: Abs at 440 nm (5.0% solution)	<= 0,05	AU	0,02
WATER	<= 10,0	%	6,8
LOSS ON DRYING	<= 10,0	%	5,8
OXALATE	≤ 0,35 %		≤ 0,35 %
-	-		-
RELATED SUBSTANCES	-		-
Impurity 1 (rel.sub. HPLC)	<= 0,10	%	< Disregard limit (0,05)
Impurity 2 (rel.sub. HPLC)	<= 0,10	%	< Disregard limit (0,05)
Impurity 3 (rel.sub. HPLC)	<= 0,10	%	< Disregard limit (0,05)
Any other Impurity (rel.sub. HPLC)	<= 0,10	%	0,06 (NOTE)
Sum of all Impurities (rel.sub. HPLC)	<= 0,30	%	0,06
-	-		-
RESIDUAL SOLVENTS:	-		-
-Methanol (GC)	<= 3000	ppm	< LOQ (50)
-Dimethylformamide (HPLC)	<= 880	ppm	< LOQ (5)
-	-		-

Guido Colucci QC Manager Approved November 22, 2024	Agnese Messina Qualified Person Released November 26, 2024		
'Emission'	Agnese Messina	Qualified Person	November 29, 2024

Capitale Sociale € 40.000.000 i.v. - R.I. Milano Cod. Fisc. e P.IVA n. 08101100157 - R.E.A. Milano n. 1201640

Società Capogruppo P. & R. Principi Attivi S.p.A.

Società con Socio unico - Strada Rivoltana km. 6/7 - 20053 Rodano (MI) ITALY - Capitale sociale € 1.200.000 i.v.- C.F. e P.IVA 11155530964



Certificate of Analysis

Product name	SODIUM CROMOGLICATE	Manufacturing date	13/11/2024
Product Code	C4050	Re-test date	13/10/2029
Batch Number	0024502803	Certificate Nr.	100000037056
Order	1240200	Batch Size	207,000 KG
Quantity	106,950 KG	Ref. Order	B-2240046

Test	Specification	M.U.	Result
ORGANIC IMPURITIES	-		-
2-Acetylresorcinol (rel.sub. HPLC USP)	<= 0,10	%	< Disregard limit (0,05)
Impurity A (rel. sub.HPLC USP)	<= 0,10	%	< Disregard limit (0,05)
Impurity B (rel. sub. HPLC USP)	<= 0,10	%	< Disregard limit (0,05)
Any other individual unspecified impurity and Cromolyn tricarboxylic acid analog (rel. sub. HPLC USP)	<= 0,10	%	0,07 (NOTE)
Sum of all Impurities (rel. sub. HPLC USP)	<= 0,30	%	0,07
-	-		-
ASSAY (HPLC) (calculated on the anhydrous basis)	98,0 - 101,0	%	99,3
ASSAY Ph.Eur. (pot.) (anhydrous substances)	99,0 - 101,0	%	99,7
ASSAY (JP)(pot.)(dried substance)	>= 98,0	%	98,7
NOTE			
RRT 1,15 (EP)			
NOTE			
RRT 1,73 (USP)			

Solubility: soluble in water; practically insoluble in ethanol (96 per cent) and in chloroform.

Complies with: Ph.Eur. BP USP JP

This material has been prepared following the current Good Manufacturing Practice (cGMP).

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