



METAPHARMACEUTICAL

N DE LOTE:

0270721

Certificate of Analysis

[Signature]
26/07/2021

Product name **SODIUM CROMOGLICATE**

Product Code C4050
Batch Number 2150002075
Batch Size 202,000 KG

Manufacturing date 08/07/2021
Re-test date 04/07/2026
Certificate Nr. 040000041218

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)	$\leq 0,05$	AU	0,02
WATER	$\leq 10,0$	%	7,1
LOSS ON DRYING	$\leq 10,0$	%	7,1
OXALATE	$\leq 0,35$ %		$\leq 0,35$ %
--	-		-
RELATED SUBSTANCES	-		-
Impurity 1 (rel.sub. HPLC)	$\leq 0,10$	%	0,02
Impurity 2 (rel.sub. HPLC)	$\leq 0,10$	%	< Disregard limit (0,01)
Impurity 3 (rel.sub. HPLC)	$\leq 0,10$	%	< Disregard limit (0,01)
Any other Impurity (rel.sub. HPLC)	$\leq 0,10$	%	0,07 (NOTE)
Any other Impurity 1 (rel.sub. HPLC)	$\leq 0,10$	%	0,02 (NOTE)
Any other Impurity 2 (rel.sub. HPLC)	$\leq 0,10$	%	0,01 (NOTE)
Sum of all Impurities (rel.sub. HPLC)	$\leq 0,30$	%	0,14
--	-		-
RESIDUAL SOLVENTS:	-		-
-Methanol (GC)	≤ 200	ppm	< LOQ (50)

Guido Colucci

Approved July 16, 2021

Agnese Messina

Qualified Person

Released July 16, 2021



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<u>Test</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
-Dimethylformamide (HPLC)	<= 100	ppm	< LOQ (5)
--	-	-	-
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
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ASSAY (HPLC) (calculated on the anhydrous basis)	98,0 - 101,0	%	99,4
ASSAY Ph.Eur. (pot.) (anhydrous substances)	99,0 - 101,0	%	100,1
ASSAY (JP)(pot.)(dried substance)	>= 98,0	%	100,1
<u>NOTE</u>			
RRT 1,15(any other impurity)EP			
<u>NOTE</u>			
RRT 1,46(any other impurity)EP			
<u>NOTE</u>			
RRT 1,07(any other impurity)EP			
<u>NOTE</u>			
RRT 1,25(any other impurity)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).

Guido Colucci Approved July 16, 2021	Agnese Messina Qualified Person Released July 16, 2021
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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

Modello: C4050-STD / 4

July 16, 2021

This CoA is electronically dated and signed by authorized personnel of the Quality Unit

July 16, 2021

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