



Lot: 9031120

Certificate of Analysis

Product name **SODIUM CROMOGLICATE**

Product Code C4050
Batch Number 2050002651
Order 1192161
Quantity 50,000 KG

Manufacturing date 28/09/2020
Re-test date 27/09/2025
Certificate Nr. 100000012517
Batch Size 189,000 KG
Ref. Order PO 2019 - 1/352

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	%	6,5
LOSS ON DRYING	<= 10,0	%	6,2
OXALATE	≤ 0,35 %		≤ 0,35 %
--	-		-
RELATED SUBSTANCES	-		-
Impurity 1 (rel.sub. HPLC)	<= 0,10	%	< Disregard limit (0,01)
Impurity 2 (rel.sub. HPLC)	<= 0,10	%	< Disregard limit (0,01)
Impurity 3 (rel.sub. HPLC)	<= 0,10	%	< Disregard limit (0,01)
Any other Impurity (rel.sub. HPLC)	<= 0,10	%	0,05 (NOTE)
Any other Impurity 1 (rel.sub. HPLC)	<= 0,10	%	0,04 (NOTE)
Any other Impurity 2 (rel.sub. HPLC)	<= 0,10	%	0,02 (NOTE)
Sum of all Impurities (rel.sub. HPLC)	<= 0,30	%	0,12
--	-		-
RESIDUAL SOLVENTS:	-		-
-Methanol (GC)	<= 200	ppm	< LOQ (50)

Andrea Reboria QC Manager Approved October 28, 2020	Agnese Messina Qualified Person Released October 28, 2020
'Emission'	Agnese Messina Qualified Person October 29, 2020



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<u>Test</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
-Dimethylformamide (HPLC)	<= 100	ppm	24
--	-		-
ORGANIC IMPURITIES	-		-
2-Acetylresorcinol (rel.sub. HPLC USP)	<= 0,10	%	< Disregard limit (0,05)
Impurity A (rel. sub.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	%	0,06 (NOTE)
Sum of all Impurities (rel. sub. HPLC USP)	<= 0,30	%	0,06
--	-		-
ASSAY (pot.) (calculated on the dried basis)	99,0 - 101,0	%	99,5
ASSAY (HPLC) (calculated on the anhydrous basis)	98,0 - 101,0	%	100,3

NOTE

RRT 1,15 (any other impurity) EP

NOTE

RRT 1,21 (any other impurity) EP

NOTE

RRT 1,45 (any other impurity) EP

NOTE

RRT 1,6 (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).

Andrea Rebora QC Manager Approved October 28, 2020	Agnese Messina Qualified Person Released October 28, 2020	
'Emission'	Agnese Messina Qualified Person	October 29, 2020

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 / 3

October 29, 2020

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

October 29, 2020

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