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Olon S.p.A. - Sede Legale
Strada Rivoltana Km 6/7
Rodano (MI)



Lte: 0180920

Certificate of Analysis

Product name **SODIUM CROMOGLICATE**

Product Code C4050
Batch Number 2050002205
Order 1192156
Quantity 50,000 KG

Manufacturing date 04/08/2020
Re-test date 02/08/2025
Certificate Nr. 100000011441
Batch Size 187,000 KG
Ref. Order PO B-2190487

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	0,00
WATER	<= 10,0	%	8,3
LOSS ON DRYING	<= 10,0	%	7,2
OXALATE	≤ 0,35 %		≤ 0,35 %
--	-		-
RELATED SUBSTANCES	-		-
Impurity 1 (rel.sub. HPLC)	<= 0,10	%	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	%	0,02 (NOTE)
Any other Impurity 2 (rel.sub. HPLC)	<= 0,10	%	0,02 (NOTE)
Sum of all Impurities (rel.sub. HPLC)	<= 0,30	%	0,13
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RESIDUAL SOLVENTS:	-		-
-Methanol (GC)	<= 200	ppm	< LOQ (50)

Andrea Rebora QC Manager Approved September 01, 2020	Agnese Messina Qualified Person Released September 01, 2020
'Emission'	Agnese Messina Qualified Person September 02, 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 - 20090 Rodano (MI) ITALY - Capitale sociale € 1.200.000 i.v.- C.F. e P.IVA 11155530964

Modello: C4050-STD / 3

September 02, 2020

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

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<u>Test</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
-Dimethylformamide (HPLC)	<= 100	ppm	98
--	-	-	-
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	%	99,4
ASSAY (HPLC) (calculated on the anhydrous basis)	98,0 - 101,0	%	99,8
<u>NOTE</u>			
RRT 1,14 (any other impurity EP)			
<u>NOTE</u>			
RRT 1,45 (any other impurity EP)			
<u>NOTE</u>			
RRT 1,07 (any other impurity EP)			
<u>NOTE</u>			
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).

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