



Lote: 0100920

Certificate of Analysis

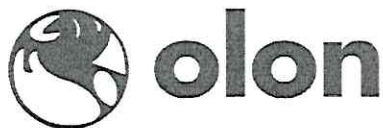
Product name **SODIUM CROMOGLICATE**

Product Code C4050
Batch Number 2050002201
Order 1192161
Quantity 50,000 KG

Manufacturing date 03/08/2020
Re-test date 02/08/2025
Certificate Nr. 100000011468
Batch Size 188,000 KG
Ref. Order PO 2019 - 1/352

<u>Test</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
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	%	6,3
LOSS ON DRYING	<= 10,0	%	5,9
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	%	0,03 (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	60

Andrea Rebora QC Manager Approved September 01, 2020	Agnese Messina Qualified Person Released September 01, 2020		
'Emission'	Agnese Messina	Qualified Person	September 04, 2020



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-Dimethylformamide (HPLC)	<= 100	ppm	7
--	-	-	-
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	%	100,2
ASSAY (HPLC) (calculated on the anhydrous basis)	98,0 - 101,0	%	98,7
<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).

Andrea Rebora QC Manager Approved September 01, 2020	Agnese Messina Qualified Person Released September 01, 2020		
'Emission'	Agnese Messina	Qualified Person	September 04, 2020