

METAPHARMACEUTICAL

N DE LOTE:

0370523

Certificate of Analysis

Product name **SODIUM CROMOGLICATE**

Product Code C4050
Batch Number 2250002682
Batch Size 195,000 KG

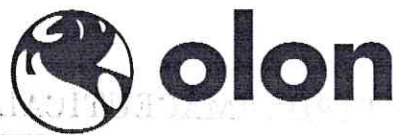
Manufacturing date 18/10/2022
Re-test date 16/10/2027
Certificate Nr. 040000059513

af 30/05/2023

<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	0,02
WATER	<= 10,0	%	7,3
LOSS ON DRYING	<= 10,0	%	6,5
OXALATE	≤ 0,35 %		≤ 0,35 %
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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	%	0,08 (NOTE)
Any other Impurity 2 (rel.sub. HPLC)	<= 0,10	%	0,03 (NOTE)
Sum of all Impurities (rel.sub. HPLC)	<= 0,30	%	0,19
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RESIDUAL SOLVENTS:	-		-
-Methanol (GC)	<= 200	ppm	51

Guido Colucci
QC Manager
Approved November 04, 2022

Agnese Messina
Qualified Person
Released November 07, 2022



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<u>Test</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
-Dimethylformamide (HPLC)	<= 100	ppm	20
--	-		-
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	%	0,06 (NOTE)
Any other Impurity 1 (rel.sub. HPLC USP)	<= 0,10	%	0,09 (NOTE)
Sum of all Impurities (rel. sub. HPLC USP)	<= 0,30	%	0,15
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ASSAY (HPLC) (calculated on the anhydrous basis)	98,0 - 101,0	%	100,7
ASSAY Ph.Eur. (pot.) (anhydrous substances)	99,0 - 101,0	%	100,2
ASSAY (JP)(pot.)(dried substance)	>= 98,0	%	99,3
NOTE			
RRT 1,14 (EP)			
NOTE			
RRT 1,17 (EP)			
NOTE			
RRT 1,46 (EP)			
NOTE			
RRT(1,55)USP			
NOTE			
RRT(2,27)USP			

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

Complies with: Ph.Eur. BP USP JP

Guido Colucci QC Manager Approved November 04, 2022	Agnese Messina Qualified Person Released November 07, 2022
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This material has been prepared following the current Good Manufacturing Practice (cGMP).

Guido Colucci
QC Manager
Approved November 04, 2022

Agnese Messina
Qualified Person
Released November 07, 2022

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