

METAPHARMACEUTICAL

N DE LOTE:

0120123

Certificate of Analysis

af 23/11/2023

Product name **SODIUM CROMOGLICATE**

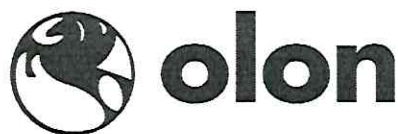
Product Code C4050
Batch Number 2250002654
Batch Size 192,000 KG

Manufacturing date 17/10/2022
Re-test date 11/10/2027
Certificate Nr. 040000059452

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	0,01
WATER	<= 10,0	%	7,6
LOSS ON DRYING	<= 10,0	%	6,8
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	%	0,03 (NOTE)
Any other Impurity 2 (rel.sub. HPLC)	<= 0,10	%	0,07 (NOTE)
Sum of all Impurities (rel.sub. HPLC)	<= 0,30	%	0,21
--	-		-
RESIDUAL SOLVENTS:	-		-
-Methanol (GC)	<= 200	ppm	70

Guido Colucci
QC Manager
Approved November 04, 2022

Agnese Messina
Qualified Person
Released November 07, 2022



Certificate of Analysis

Product name **SODIUM CROMOGLICATE**

Product Code C4050
Batch Number 2250002654
Batch Size 192,000 KG

Manufacturing date 17/10/2022
Re-test date 11/10/2027
Certificate Nr. 040000059452

<u>Test</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
-Dimethylformamide (HPLC)	<= 100	ppm	17
--	-		-
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)
Sum of all Impurities (rel. sub. HPLC USP)	<= 0,30	%	0,06
--	-		-
ASSAY (HPLC) (calculated on the anhydrous basis)	98,0 - 101,0	%	99,6
ASSAY Ph.Eur. (pot.) (anhydrous substances)	99,0 - 101,0	%	100,5
ASSAY (JP)(pot.)(dried substance)	>= 98,0	%	99,6
NOTE			
RRT 1,14 (EP)			
NOTE			
RRT 1,17 (EP)			
NOTE			
RRT 1,46 (EP)			
NOTE			
RRT(1,53)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
QC Manager
Approved November 04, 2022

Agnese Messina
Qualified Person
Released November 07, 2022