

METAPHARMACEUTICAL

N DE LOTE:

0210924

Certificate of Analysis

25/09/2024

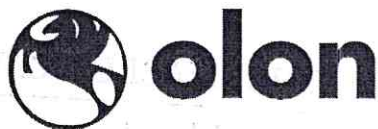
Product name **SODIUM CROMOGLICATE**

Product Code C4050
Batch Number 0024501966
Order 1231996
Quantity 201,000 KG

Manufacturing date 27/07/2024
Re-test date 04/07/2029
Certificate Nr. 100000035524
Batch Size 201,000 KG
Ref. Order B-2230646

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	%	7,1
LOSS ON DRYING	<= 10,0	%	6,2
OXALATE	≤ 0,35 %		≤ 0,35 %
-	-		-
RELATED SUBSTANCES	-		-
Impurity 1 (rel.sub. HPLC)	<= 0,10	%	< Disregard limit (0,05)
Impurity 2 (rel.sub. HPLC)	<= 0,10	%	< Disregard limit (0,05)
Impurity 3 (rel.sub. HPLC)	<= 0,10	%	< Disregard limit (0,05)
Any other Impurity (rel.sub. HPLC)	<= 0,10	%	0,05 (NOTE)
Sum of all Impurities (rel.sub. HPLC)	<= 0,30	%	0,05
-	-		-
RESIDUAL SOLVENTS:	-		-
-Methanol (GC)	<= 3000	ppm	< LOQ (50)
-Dimethylformamide (HPLC)	<= 880	ppm	< LOQ (5)
-	-		-

Guido Colucci QC Manager Approved September 06, 2024	Agnese Messina Qualified Person Released September 06, 2024		
'Emission'	Agnese Messina	Qualified Person	September 13, 2024



Certificate of Analysis

Product name **SODIUM CROMOGLICATE**

Product Code C4050
Batch Number 0024501966
Order 1231996
Quantity 201,000 KG

Manufacturing date 27/07/2024
Re-test date 04/07/2029
Certificate Nr. 100000035524
Batch Size 201,000 KG
Ref. Order B-2230646

<u>Test</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
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	%	0,07 (NOTE)
Sum of all Impurities (rel. sub. HPLC USP)	<= 0,30	%	0,07
---	-		-
ASSAY (HPLC) (calculated on the anhydrous basis)	98,0 - 101,0	%	100,2
ASSAY Ph.Eur. (pot.) (anhydrous substances)	99,0 - 101,0	%	100,2
ASSAY (JP)(pot.)(dried substance)	>= 98,0	%	99,2
NOTE			
RRT 1,15 (EP)			
NOTE			
RRT 1,64 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 September 06, 2024	Agnese Messina Qualified Person Released September 06, 2024		
'Emission'	Agnese Messina	Qualified Person	September 13, 2024

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 / 6

September 13, 2024

This CoA is electronically dated and signed by authorized personnel of the Quality UnitSeptember 13, 2024 Pag. 2 / 2