Olon Spa Stab. Casaletto Lodig
Via Livelli 1
26852 Fraz. Mairano (LO)

PEC: olon@pec.olonspa.it
Tel. HQ: +39 02 9523.1
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Olon S.p.A. - Sede Legale
Strada Rivoltana Km 6/7
20053 Rodano (MI)

METAPHARMACEUTICAL

N DE LOTE:
0190921

16/09/2021

Certificate of Analysis

Product name **SODIUM CROMOGLICATE**

		Manufacturing date	08/07/2021
Product Code	C4050	Re-test date	06/07/2026
Batch Number	2150002080	Certificate Nr.	040000041252
Batch Size	222,000 KG		

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 BY_5	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	%	7,2
OXALATE	≤ 0,35 %		≤ 0,35 %
--	-		-
RELATED SUBSTANCES	-		-
Impurity 1 (rel.sub. HPLC)	<= 0,10	%	0,02
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	%	0,07 (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	%	0,15
--	-		-
RESIDUAL SOLVENTS:	-		-
-Methanol (GC)	<= 200	ppm	< LOQ (50)

Guido Colucci Approved July 16, 2021	Agnese Messina Qualified Person Released July 16, 2021

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Manufacturing date 08/07/2021
Re-test date 06/07/2026
Certificate Nr. 040000041252

Test	Specification	M.U.	Result
-Dimethylformamide (HPLC)	<= 100	ppm	< LOQ (5)
--	-		-
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	%	0,08 (NOTE)
Sum of all Impurities (rel. sub. HPLC USP)	<= 0,30	%	0,08
--	-		-
ASSAY (HPLC) (calculated on the anhydrous basis)	98,0 - 101,0	%	99,6
ASSAY Ph.Eur. (pot.) (anhydrous substances)	99,0 - 101,0	%	100,3
ASSAY (JP)(pot.)(dried substance)	>= 98,0	%	100,1

NOTE
RRT 1,15(any other impurity)EP
NOTE
RRT 1,46(any other impurity)EP
NOTE
RRT 1,07(any other impurity)EP
NOTE
RRT 1,25(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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