

SODIUM CROMOGLICATE			
Batch N°:	4050/10/17	ANALYSIS CERTIFICATE N°	170697
Date:	27/03/2017		
Kg:	215.00	Formula:	$C_{23}H_{14}Na_2O_{11}$
M.W.:	512.3		
Man. date:	02/03/2017	Retest date:	Mar/2022
Complies with:	Ph.Eur. BP USP JP		
Solubility: soluble in water; practically insoluble in ethanol (96 per cent) and in chloroform			
TESTS	SPECIFICATIONS		RESULTS
DESCRIPTION	white or almost white hygroscopic crystalline powder		complies
IDENTIFICATION	(1): IR spectrum (2): UV spectrum (3): sodium reaction		complies complies complies
ACIDITY OR ALKALINITY	(1): complies to Ph. Eur. test (2): complies to USP test		complies complies
APPEARANCE OF SOLUTION	a 2.0% solution in water is not more intensely coloured than reference solution BY ₆		complies
CLARITY OF SOLUTION	a 2.0% solution in water is not more opalescent than reference suspension II		complies
COLOUR OF SOLUTION	Abs at 440 nm not more than 0.05 (5.0% solution)		0.01
WATER	not more than 10.0%		7.6%
LOSS ON DRYING	not more than 10.0%		7.2%
OXALATE	not more than 0.35%		complies
HEAVY METALS	not more than 20 ppm		complies
This material has been prepared following the current Good Manufacturing Practice (cGMP).			

Q.C. Manager ...

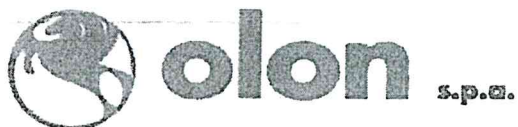
Q.A. Manager ...

Qualified Person ...

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28/03/17
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Revision 4050-00

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SODIUM CROMOGLICATE

Batch N°: 4050/10/17	ANALYSIS CERTIFICATE N° 170897	Date: 27/03/2017	
Kg: 215.00	Formula: $C_{23}H_{14}Na_2O_{11}$	M.W.: 512.3	
Man. date: 02/03/2017	Retest date: Mar/2022	Complies with: Ph.Eur. BP USP JP	
Solubility: soluble in water; practically insoluble in ethanol (95 per cent) and in chloroform			

TESTS	SPECIFICATIONS	RESULTS
RELATED SUBSTANCES (TLC)	each impurity not more than 0.5%	no impurities detected
RELATED SUBSTANCES (HPLC)	(1): impurity 1 not more than 0.10% (2): impurity 2 not more than 0.10% (3): impurity 3 not more than 0.10% (4): any other impurity not more than 0.10%	< 0.01% < 0.01% < 0.01% RRT 0.97: 0.01% RRT 1.15: 0.05% RRT 1.17: 0.03% RRT 1.23: 0.01% RRT 1.29: 0.02% RRT 1.45: 0.02%
	(5): sum of all impurities not more than 0.30%	0.14%
ASSAY	99.0% to 101.0% with reference to the dried substance (pot.) 98.0% to 101.0% calculated on the anhydrous basis (UV)	99.6% 99.0%
RESIDUAL SOLVENTS	(1): methanol not more than 200 ppm (GC) (2): dimethylformamide not more than 100 ppm (HPLC)	122 ppm 23 ppm

This material has been prepared following the current Good Manufacturing Practice (cGMP).

Q.C. Manager

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