Lotti 90/09/17

olon s.p.a.

Revision 4050-00

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 .....

27/03/17 28.03.17 28/03/17

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olon s.p.a.

Revision 4050-00

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%	< 0.01%
	(2): impurity 2 not more than 0.10%	< 0.01%
	(3): impurity 3 not more than 0.10%	< 0.01%
	(4): any other impurity not more than 0.10%	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 impurites not more than 0.30%	0.14%
ASSAY	99.0% to 101.0% with reference to the dried substance (pot.)	99.6%
	98.0% to 101.0% calculated on the anhydrous basis (UV)	99.0%
RESIDUAL SOLVENTS	(1): methanol not more than 200 ppm (GC)	122 ppm
	(2): dimethylformamide not more than 100 ppm (HPLC)	23 ppm

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

Q.C. Manager ..... 27/03/17 Q.A. Manager ..... 28.03.17 Qualified Person 28/03/17

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