Lote art: 002045

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Revision 4050-00

SODIUM CROMOGLICATE

Batch N°:	4050/03/15	**ANALYSIS CERTIFICATE N°**	150304	**Date:**	27/02/2015
Kg:	211.00	Formula:	$C_{23}H_{14}Na_2O_{11}$	M.W.:	512.3
Man. date:	03/02/2015	Retest date:	Feb/2020	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_5	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)	0.04
WATER	not more than 10.0%	4.9%
LOSS ON DRYING	not more than 10.0%	4.0%
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 ..... 02/03/15 Q.A. Manager ..... 02/03/15 Qualified Person 02/03/2015

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Solubility: *soluble in water; practically insoluble in ethanol (96 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: 0.06% RRT 1.17: 0.01% RRT 1.21: 0.04% RRT 1.24: 0.01% RRT 1.29: 0.01% RRT 1.45: 0.02%
	(5): sum of all impurites not more than 0.30%	0.16%
ASSAY	99.0% to 101.0% with reference to the dried substance (pot.)	100.4%
	98.0% to 101.0% calculated on the anhydrous basis (UV)	99.7%
RESIDUAL SOLVENTS	(1): methanol not more than 200 ppm (GC)	< LOQ
	(2): dimethylformamide not more than 100 ppm (HPLC)	8 ppm

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

Q.C. Manager ..... 02/03/15 **Q.A. Manager** ..... 02/03/15 **Qualified Person** 02/03/2015

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