Lote. 9030216

A member of Infa Group

Sifavitor™

Revision 4050-00

SODIUM CROMOGLICATE

Batch N°:	**4050/22/15**	**ANALYSIS CERTIFICATE N°**	**160040**	**Date:**	**20/01/2016**
Kg:	210.00	Formula:	$C_{23}H_{14}Na_2O_{11}$	M.W.:	512.3
Man. date:	30/11/2015	Retest date:	Nov/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)	0.02
WATER	not more than 10.0%	7.0%
LOSS ON DRYING	not more than 10.0%	6.2%
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 ..... 21/01/16 **Q.A. Manager** ..... 21/01/16 **Qualified Person** 21/01/2016

Sifavitor srl
Sede Legale / Registered Office
Largo Guido Donegani, 2 - 20121 Milan (Italy)
T. +39 02 777781 | F. +39 02 77778449

Stabilimento / Plant
Via Livelli, 1 - 26852 Casaletto Lodigiano fraz. Mairano (Lodi), (Italy)
T. +39 0371 739901 | F. +39 0371 73108
sifavitor@infagroup.com | www.infagroup.com

SODIUM CROMOGLICATE

Batch N°:	**4050/22/15**	**ANALYSIS CERTIFICATE N°**	**160040**	**Date:**	**20/01/2016**
Kg:	210.00	Formula:	$C_{23}H_{14}Na_2O_{11}$	M.W.:	512.3
Man. date:	30/11/2015	Retest date:	Nov/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
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 0.91: 0.01% RRT 1.15: 0.05% RRT 1.17: 0.02% RRT 1.21: 0.06% RRT 1.24: 0.01% RRT 1.45: 0.06%
	(5): sum of all impurites not more than 0.30%	0.21%
ASSAY	99.0% to 101.0% with reference to the dried substance (pot.) 98.0% to 101.0% calculated on the anhydrous basis (UV)	100.1% 100.4%
RESIDUAL SOLVENTS	(1): methanol not more than 200 ppm (GC) (2): dimethylformamide not more than 100 ppm (HPLC)	52 ppm 53 ppm

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

Q.C. Manager ..... 21/01/16 **Q.A. Manager** ..... 21/01/16 **Qualified Person** 21/01/2016

Sifavitor srl
Sede Legale / Registered Office
Largo Guido Donegani, 2 - 20121 Milan (Italy)
T: +39 02 7772781 | F: +39 02 77728349

Stabilimento / Plant
Via Livelli, 1 - 26852 Casaletto Lodigiano Fraz. Mairano (Lodi), (Italy)
T: +39 0371 739901 | F: +39 0371 73108
sifavitor@infagroup.com | www.infagroup.com