

Lte: 00711/14

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Revision 4050-00

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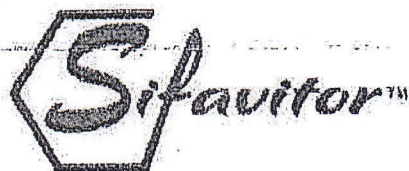
SODIUM CROMOGLICATE			
Batch N°:	4050/21/14	ANALYSIS CERTIFICATE N°	141941
Kg:	197.00	Formula:	C <sub>23</sub> H <sub>14</sub> Na <sub>2</sub> O <sub>11</sub>
Man. date:	08/10/2014	Retest date:	Oct/2019
		Date:	30/10/2014
		M.W.:	512.3
		Complies with:	Ph.Eur. BP USP JP
Solubility: <i>soluble in water; practically insoluble in ethanol (96 per cent) and in chloroform</i>			
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 <i>reference solution BY<sub>5</sub></i>	complies	
CLARITY OF SOLUTION	a 2.0% solution in water is not more opalescent than <i>reference suspension II</i>	complies	
COLOUR OF SOLUTION	Abs at 440 nm not more than 0.05 (5.0% solution)	0.01	
WATER	not more than 10.0%	6.6%	
LOSS ON DRYING	not more than 10.0%	6.4%	
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                      30/10/2014



Sifavitor srl  
Sede Legale / Registered Office  
Largo Guido Donegani, 2 - 20121 Milan (Italy)  
T: +39 02 777281 | F: +39 02 77728349

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



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## SODIUM CROMOGLICATE

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Man. date:	08/10/2014	Retest date:	Oct/2019	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 0.97: 0.02% RRT 1.14: 0.05% RRT 1.17: 0.01% RRT 1.23: 0.02% RRT 1.28: 0.01% RRT 1.45: 0.01%
	(5): sum of all impurities not more than 0.30%	0.12%
ASSAY	99.0% to 101.0% with reference to the dried substance (pot.) 98.0% to 101.0% calculated on the anhydrous basis (UV)	99.2% 100.0%
RESIDUAL SOLVENTS	(1): methanol not more than 200 ppm (GC) (2): dimethylformamide not more than 100 ppm (HPLC)	< LOQ < LOQ

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

Q.C. Manager

Q.A. Manager

Qualified Person

30/10/2014

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Stabilimento / Plant  
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T: +39 0371 739901 | F: +39 0371 73103  
sifavitor@infagroup.com | www.infagroup.com