

Lte: 030713

Mod.05/01-8 REV.4 del 17/07/2012

Sifavitor S.r.l.

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CERTIFICATE OF ANALYSIS

This batch has been produced following current good manufacturing practices

SODIUM CROMOGLICATE

Revision: 23/11/2012

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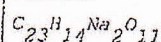
Analysis Number 130930

Analysis Date 05/04/2013

Batch: 4050/04/13

Kg: 196.00

Formula:



M.W:

512.34

Manufacturing Date 25/03/2013

Retest Date 03/2018

Complies with:

Ph.Eur.-BP-USP-JP-IP

TEST	RESULTS	SPECIFICATIONS
DESCRIPTION Aspetto	complies	White or almost white hygroscopic crystalline powder, odorless.
IDENTIFICATION Identificazione	complies complies complies	(1) IR spectrum (2) UV spectrum (3) reaction of sodium
ACIDITY OR ALKALINITY Acidità o alcalinità	complies complies	(1) complies EP test (2) complies USP test
APPEARANCE OF SOLUTION Aspetto della soluzione	complies	a 2% solution in water is not more opalescent than reference suspension II and not more intensely coloured than reference solution BY5
CLARITY OF SOLUTION Limpidezza della soluzione	complies	Not more opalescent than reference suspension II (2% solution)
COLOUR OF SOLUTION Colore della soluzione	0.02	Abs at 440 nm not more than 0.05 (5% solution)
WATER Acqua	6.18%	Not more than 10.0%
LOSS ON DRYING Perdita all'essiccamento	5.75%	Not more than 10.0%
OXALATE Ossalati	complies	Not more than 0.35%
HEAVY METALS Metalli pesanti	complies	Not more than 20 ppm
RELATED SUBSTANCES (TLC) Impurezze organiche (TLC)	no impurities detected	Each impurity nmt 0.5%

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Analysis Date 05/04/2013

Batch: 4050/04/13

Kg: 196.00

Formula:

 $C_{23}H_{14}Na_2O_{12}$

M.W:

512.34

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Complies with:

Ph.Eur.-BP-USP-JP-IP

TEST	RESULTS	SPECIFICATIONS
RELATED SUBSTANCES (HPLC) Impurezze organiche (HPLC)	(1): < 0.01% (2): < 0.01% (3): < 0.01% (4): RRT 0.97: 0.01% RRT 1.15: 0.05% RRT 1.24: 0.01% RRT 1.28: 0.01% RRT 1.45: 0.01% (5): 0.09%	(1) imp.1 or DHA nmt 0.10% (2) imp.2 or Cromo 01 nmt 0.10% (3) imp.3 or diethylester der. nmt 0.10% (4) Each unknown impurity nmt 0.10% (5) Sum of all impurities nmt 0.30%
ASSAY Titolo	A: 99.96% B: 99.94%	A: Btw 99.0% and 101.0% with reference to the dried substance (pot.) B: Btw 98.0% and 101.0% calculated on the anhydrous basis (UV)
RESIDUAL SOLVENTS Solventi residui	methanol: < LOQ dimethylformamide: 19 ppm	A: methanol not more than 200 ppm (GC) B: dimethylformamide not more than 100 ppm (HPLC)

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Issue: QUALITY CONTROL Dr. Andrea Rebora	Control: QUALITY ASSURANCE Dr. Attilio Virgili	Approval: QUALIFIED PERSON Dott.ssa Chiara Magnone