Ide 070112

Sifavitor S.r.l.
Via Livelli 1 - 26852 Casaletto Lodigiano Fraz. Mairano (ITALY)
Tel: 0371-73991 - Fax: 0371-73108 - e-mail: sifavitor@infagroup.com

CERTIFICATE OF ANALYSIS

This batch has been produced following current good manufacturing practices

SODIUM CROMOGLICATE

Revision: *21/09/2010* | Page *1 of 2*

Analysis Number *112528* Analysis Date *20/12/2011*	Batch: *4050/24/11*	Kg: *187.00*	Formula: $C_{23}H_{14}Na_2O_{11}$	M.W: *512.34*
Manufacturing Date *19/12/2011*	Retest Date *12/2016*		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**	*4.63%*	Not more than 10.0%
LOSS ON DRYING **Perdita all'essiccamento**	*4.23%*	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)**	*(1): no impurities detected* *(2): no impurities detected*	(1) Each impurity nmt 0.10% [EP] (2) Each impurity nmt 0.50% [USP]

CROMOGLICATE			Revision: *21/09/2010*	Page *2 of 2*
Analysis Number *112528* Analysis Date *20/12/2011*	Batch: *4050/24/11*	Kg: *187.00*	Formula: $C_{23}H_{14}Na_2O_{11}$	M.W: *512.34*
Manufacturing Date *19/12/2011*		Retest Date *12/2016*	Complies with: *Ph.Eur.-BP-USP-JP-IP*	

TEST	RESULTS	SPECIFICATIONS
RELATED SUBSTANCES (HPLC) **Impurezze organiche (HPLC)**	*(1): < LOD* *(2): < LOD* *(3): < LOD* *(4): RRT 0.91: 0.01%* *RRT 0.97: 0.01%* *RRT 1.15: 0.05%* *RRT 1.17: 0.01%* *RRT 1.23: 0.01%* *RRT 1.28: 0.01%* *RRT 1.45: 0.02%* *(5): 0.12%*	(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: 99.21%* *B: 100.11%*	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: 57 ppm* *dimethylformamide: < LOQ*	A:methanol not more than 200 ppm (GC) B:dimethylformamide not more than 100 ppm (HPLC)

Rebora 20/12/11	20/12/11	20/12/2011
Issue: QUALITY CONTROL Dr. Andrea Rebora	Control: QUALITY ASSURANCE Dr. Attilio Virgili	Approval: QUALIFIED PERSON Dott.ssa Chiara Magnone