

SODIUM CROMOGLICATE

Batch N°:	1860001605	ANALYSIS CERTIFICATE N°	181302	Date:	14/06/2018
Kg:	182 00	Formula:	C ₂₃ H ₁₄ Na ₂ O ₁₁	M.W.:	512.3
Man. date:	22/05/2018	Retest date:	May/2023	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 <i>reference solution BY₅</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)	0.02
WATER	not more than 10.0%	8.2%
LOSS ON DRYING	not more than 10.0%	7.6%
OXALATE	not more than 0.35%	complies

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

Q.C. Manager

Q.A. Manager

Qualified Person

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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 1.15: 0.06% RRT 1.24: 0.02% RRT 1.45: 0.03%
	(5): sum of all impurities not more than 0.30%	0.11%
ASSAY	99.0% to 101.0% with reference to the dried substance (pot.) 98.0% to 101.0% calculated on the anhydrous basis (UV)	100.3% 98.4%
RESIDUAL SOLVENTS	(1): methanol not more than 200 ppm (GC) (2): dimethylformamide not more than 100 ppm (HPLC)	< LOQ 17 ppm

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