

Lte: 00711/14



Revision 4050-00

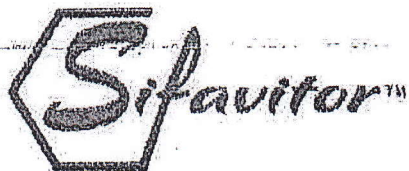
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SODIUM CROMOGLICATE			
Batch N°:	4050/21/14	ANALYSIS CERTIFICATE N°	141941
Date:	30/10/2014		
Kg:	197.00	Formula:	C ₂₃ H ₁₄ Na ₂ O ₁₁
M.W.:	512.3		
Man. date:	08/10/2014	Retest date:	Oct/2019
Complies with:	Ph.Eur. BP USP JP		
Solubility: <i>soluble 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 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)	0.01	
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



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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 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%
ASSAY	(5): sum of all impurities not more than 0.30% 99.0% to 101.0% with reference to the dried substance (pot.) 98.0% to 101.0% calculated on the anhydrous basis (UV)	0.12% 99.2% 100.0%
RESIDUAL SOLVENTS	(1): methanol not more than 200 ppm (GC) (2): dimethylformamide not more than 100 ppm (HPLC)	< LOQ < LOQ

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