

Certificate of Analysis

Product	SODIUM PICOSULPHATE	C.A.S. n.	10040-45-6
Batch	941720	Formula	C18H13NNa2O8S2.H2O
Production date	May 2015	M.W.	499.4
Expiration Date	May 2020	T.S.	015.002
Analysis	May 27 2015		
Coa Number	CA266		

DETERMINATION	SPECIFICATION	RESULT
DESCRIPTION	White or almost white crystalline powder	COMPLIES
SOLUBILITY	In methanol	Clear solution COMPLIES
CLARITY AND COLOUR	In water	Clear solution COMPLIES
APPEARANCE OF SOLUTION	In water	Clear and NMCT GY7 COMPLIES
COLOR	Abs.at 420 nm in water	NMT 0.030 COMPLIES
IDENTIFICATIONS	IR spectrum	Conforms to standard COMPLIES
	UV spectrum	Conforms to standard COMPLIES
	Colorimetric reaction	Pass COMPLIES
	Sulphates	Pass COMPLIES
	Sodium	28 / 29 % 28
RESIDUE ON IGNITION		7.4 / 9.4 8.8
pH		NMT 0.25 ml COMPLIES
ACIDITY OR ALKALINITY	NaOH 0.01N	
CHLORIDES		NMT 200 ppm COMPLIES
SULFATES		NMT 400 ppm COMPLIES
LOSS ON DRYING		NMT 5.0 % 0.7
WATER		3.0 / 5.0 % 3.6
HEAVY METALS		NMT 10 ppm COMPLIES
ASSAY	By titration (on anhydrous basis)	98.5 / 100.5 % 99.9
	By HPLC (on anhydrous basis)	98.0 / 102.0 % 100.5
RELATED SUBSTANCES	Any secondary impurity	NMT 0.2 % ND
BY TLC		
RELATED SUBSTANCES	4-[(Pyridin-2-yl)(4-OH-phenyl)methyl]phenyl sodium sulfate (MONOESTER, USP-A/EP-A)	NMT 0.200 % ND
BY HPLC	4,4'-[(Pyridin-2-yl)-methylene]bisphenol (PHENOLALDEHYDE, USP/EP-B)	NMT 0.200 % ND
	Any unspecified impurity	NMT 0.100 % ND
	Total impurities	NMT 0.500 % ND
RESIDUAL SOLVENTS	Ethanol	NMT 2000 ppm 312
BY GLC	Chloroform	NMT 50 ppm ND
	Methylene chloride	NMT 100 ppm ND

This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline Volume 4 Part II (ICHQ7)

The product conforms to requirements of:
EuPh8.0
USP38

Approved by Qualified Person / Quality Director
Roberto Baima
05-27-2015

This Certificate of Analysis has been approved by the Qualified Person / Quality Director and produced automatically with validated electronic signature