



Cambrex Profarmaco Milano S.r.l.

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Certificate of Analysis

Product	SCDIUM PICOSULPHATE	C.A.S. n.	10040-45-6
Batch	160508	Formula	C18H13NNa2O8S2.H2O
Production date	January 2020	M.W.	499.4
Expiration Date	December 2024	T.S.	017.002
Analysis	February 4 2020	Coa issued on	March 17 2020
Coa Number	CA11.608		

CGA Number

CALL 608

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 6Y7 COMPLIES
COLOR	Abs.at 420 nm in water	NMT 0.030 0.016
IDENTIFICATIONS	IR spectrum UV spectrum Colorimetric reaction Sulphates Sodium	Conforms to standard Conforms to standard Pass Pass Pass COMPLIES COMPLIES COMPLIES COMPLIES COMPLIES
RESIDUE ON IGNITION		28 / 29 % 29
pH		7.4 / 9.4 8.2
ACIDITY OR ALKALINITY	NaOH 0.01N	NMT 0.25 ml COMPLIES
CHLORIDES		NMT 200 ppm COMPLIES
SULFATES		NMT 400 ppm COMPLIES
LOSS ON DRYING		NMT 5.0 % 0.1
WATER		3.0 / 5.0 % 3.9
HEAVY METALS		NMT 10 ppm COMPLIES
ASSAY	By titration (on anhydrous basis) By HPLC (on anhydrous basis)	98.5 / 100.5 % 98.0 / 102.0 % 100.2 101.7
RELATED SUBSTANCES BY TLC	Any secondary impurity	NMT 0.2 % ND
RELATED SUBSTANCES BY HPLC	4-[(Pyridin-2-yl)(4-OH-phenyl)methyl]phenyl sodium sulfate (MONOESTER, USP-A/EP-A) 4,4'-[(Pyridin-2-yl)-methylene]bisphenol (PHENOLALDEHYDE, USP/EP-B) Any unspecified impurity Total impurities	NMT 0.200 % NMT 0.200 % NMT 0.100 % NMT 0.500 % 0.021 ND ND 0.021
RESIDUAL SOLVENTS BY GLC	Ethanol Chloroform Methylene chloride	NMT 2000 ppm NMT 50 ppm NMT 100 ppm 315 ND 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: USP 43 /
EuPh 10

Approved by Qualified Person / Quality Director
Laura Bigini
05-04-2020 10:02

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