



Cambrex Profamaco Milano S.r.L.

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lote 0050520

Certificate of Analysis

Product	CROMOLYN SODIUM	C.A.S. n.	15826-37-6
Batch	014650	Formula	C23H14Na2O11
Production date	November 2019	M.W.	512.3
Expiration Date	July 2024	T.S.	015.002
Analysis	December 11 2019		
Coa Number	CA10.417		

DETERMINATION	SPECIFICATION	RESULT
DESCRIPTION	White crystalline powder	COMPLIES
SOLUBILITY	Hot water Water Buffer pH 7	Clear and colourless Clear and colourless Clear and colourless COMPLIES COMPLIES COMPLIES
COLOR	Abs. at 420 nm in water	NMT 0.100 0.039
APPEARANCE OF SOLUTION	Water	NMC than BY5 and NMO than RSII COMPLIES
IDENTIFICATIONS	IR spectrum Sodium (Rt by HPLC)	Conforms to standard Pass Conforms to standard COMPLIES COMPLIES COMPLIES
ACIDITY or ALKALINITY		Conforms to EuPh test COMPLIES
OXALATES		NMT 0.35 % COMPLIES
LOSS ON DRYING		NMT 10.0 % 6.0
WATER		NMT 10.0 % 6.8
ASSAY	By volumetric analysis (on anhydrous basis) By HPLC (on anhydrous basis)	98.0 / 101.0 % 98.0 / 101.0 % 100.1 99.2
RELATED SUBSTANCES BY HPLC	Diethyl-4,4'-dioxo-5,5'-(2-hydroxytrimethylen-dioxy) di(chromene-2-carboxylate)ester (CROMON ESTER, EP-B, USP-B) 1,3-bis-(2-acetyl-3-hydroxyphenoxy)-2-propanol (HYDROXY-PHENOXY, USP-A) Methyl derivative (EP-C, USP Cromolyn Specified Unidentified Impurity) Any unspecified impurity Total impurities	NMT 0.100 % NMT 0.100 % NMT 0.150 % NMT 0.100 % NMT 0.500 % ND ND 0.111 0.069 0.233
RESIDUAL SOLVENTS BY GLC	Methanol Chloroform	NMT 1000 ppm NMT 50 ppm 6 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
42/EuPh 10Approved by Qualified Person / Quality Director
Laura Bigini
01-07-2020 11:25

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