Cambrex Profarmaco Milano S.r.L.

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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	Clear and colourless	**COMPLIES**
	Water	Clear and colourless	**COMPLIES**
	Buffer pH 7	Clear and colourless	**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	Conforms to standard	**COMPLIES**
	Sodium	Pass	**COMPLIES**
	(Rt by HPLC)	Conforms to standard	**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)	98.0 / 101.0 %	**100.1**
	By HPLC (on anhydrous basis)	98.0 / 101.0 %	**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)	NMT 0.100 %	**ND**
	1,3-bis-(2-acetyl-3-hydroxyphenoxy)-2-propanol (HYDROXY-PHENOXY, USP-A)	NMT 0.100 %	**ND**
	Methyl derivative (EP-C, USP Cromolyn Specified Unidentified Impurity)	NMT 0.150 %	**0.111**
	Any unspecified impurity	NMT 0.100 %	**0.069**
	Total impurities	NMT 0.500 %	**0.233**
RESIDUAL SOLVENTS BY GLC	Methanol	NMT 1000 ppm	**6**
	Chloroform	NMT 50 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: USP 42/EuPh 10

Approved 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