Cambrex Profarmaco Milano S.r.l.

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Certificate of Analysis

Product	**HYDROCHLOROTHIAZIDE**	C.A.S. n.	58-93-5
Batch	**750932**	Formula	C7H8ClN3O4S2
Production date	**September 2017**	M.W.	297.7
Expiration Date	**September 2022**	T.S.	017.002
Analysis	**October 6 2017**		
Coa Number	**CA5.398**		

DETERMINATION	SPECIFICATION		RESULT
DESCRIPTION	White or almost white crystalline powder		COMPLIES
SOLUBILITY	NaOH sol.	Clear solution	COMPLIES
	n-Butylamine	Clear solution	COMPLIES
	Dimethylformamide	Clear solution	COMPLIES
COLOR	Abs. at 420 nm in NaOH sol.	NMT 0.100	0.017
IDENTIFICATIONS	IR spectrum	Conforms to standard	COMPLIES
	UV spectrum - USP	Conforms to standard	COMPLIES
	UV spectrum - EuPh	Abs ratio 273/323 between 5.4 - 5.7	COMPLIES
RESIDUE ON IGNITION		NMT 0.1 %	0.0
HEAVY METALS		NMT 10 ppm	COMPLIES
LOSS ON DRYING		NMT 0.5 %	0.1
WATER		NMT 0.5 %	0.1
ASSAY	By HPLC (on dried basis)	98.0 / 102.0 %	100.4
RELATED SUBSTANCES BY HPLC	4-NH2-6-Cl-1,3-benzenedisulphonamide (DSA, USP-A/EP-B)	NMT 0.500 %	0.030
	Chlorothiazide (EP-A/USP)	NMT 0.500 %	0.015
	Dimer (EP-C/USP)	NMT 0.300 %	0.086
	Any unspecified impurity	NMT 0.100 %	0.024
	Total impurities (EP requirement)	NMT 1.00 %	0.16
	Total impurities excluding DSA (USP requirement)	NMT 0.900 %	0.125
CHLORIDES		NMT 100 ppm	COMPLIES
SELENIUM		NMT 30 ppm	NOT USED
ACIDITY-ALKALINITY	0.01M HCl	NMT 0.4 ml	COMPLIES

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 40/EUPH 9

Approved by

Qualified Person	Quality Control Manager
Edoardo Gianolli	Stefania Targa
10-09-2017	10-09-2017

This certificate of Analysis has been approved and produced automatically with a validated electronic signature