Cambrex Profarmaco Milano S.r.L.

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Certificate of Analysis

Product	**HYDROCHLOROTHIAZIDE**	C.A.S. n.	58-93-5
Batch	**033739**	Formula	C7H8ClN3O4S2
Production date	**July 2019**	M.W.	297.7
Expiration Date	**July 2024**	T.S.	018.002
Analysis	**July 18 2019**		
Coa Number	**CA9.423**		

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	**0.012**
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**
LOSS ON DRYING		NMT 0.5 %	**0.1**
WATER		NMT 0.5 %	**0.1**
ASSAY	By HPLC (on dried basis)	98.0 / 102.0 %	**100.2**
RELATED SUBSTANCES BY HPLC	4-NH2-6-Cl-1,3-benzenedisulphonamide (DSA, USP-A/EP-B)	NMT 0.500 %	**0.015**
	Chlorothiazide (EP-A/USP)	NMT 0.500 %	**0.008**
	Dimer (EP-C/USP)	NMT 0.300 %	**0.074**
	Any unspecified impurity	NMT 0.100 %	**ND**
	Total impurities (EP requirement)	NMT 1.00 %	**0.10**
	Total impurities excluding DSA (USP requirement)	NMT 0.900 %	**0.082**
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 42/EUPH 9

Approved by Qualified Person / Quality Director
Laura Bigini
07-19-2019 9:53

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