Cambrex Profarmaco Milano S.r.L.

Via Curiel 34, 20067 Paullo (MI) - ITALY Tel.: +39 02 90 62 60.1

Certificate of Analysis

Product	**HYDROCHLOROTHIAZIDE**	C.A.S. n.	58-93-5
Batch	**680103**	Formula	C7H8ClN3O4S2
Production date	**March 2017**	M.W.	297.7
Expiration Date	**March 2022**	T.S.	017.001
Analysis	**March 27 2017**		
Coa Number	**CA4.330**		

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	**0.013**
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 %	**0.0**
ASSAY	By HPLC (on dried basis)	98.0 / 102.0 %	**99.0**
RELATED SUBSTANCES BY HPLC	4-NH2-6-Cl-1,3-benzenedisulphonamide (DSA, USP-A/EP-B)	NMT 0.500 %	**0.029**
	Chlorothiazide (EP-A/USP)	NMT 0.500 %	**0.020**
	Dimer (EP-C/USP)	NMT 0.300 %	**0.102**
	Any unspecified impurity	NMT 0.100 %	**0.006**
	Total impurities (EP requirement)	NMT 1.00 %	**0.16**
	Total impurities excluding DSA (USP requirement)	NMT 0.900 %	**0.133**
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:
USP39 - EuPh9

Approved by Qualified Person / Quality Director
Roberto Baima
03-27-2017

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