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	**872122**	Formula	C7H8ClN3O4S2
Production date	**June 2018**	M.W.	297.7
Expiration Date	**June 2023**	T.S.	018.001
Analysis	**July 4 2018**		
Coa Number	**CA7.094**		

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 0.10(	0.006
IDENTIFICATIONS	IR spectrum	Conforms to standarc	COMPLIES
	UV spectrum - USP	Conforms to standarc	COMPLIES
	UV spectrum - EuPh	Abs ratio 273/323 between 5.4 - 5.7	COMPLIES
RESIDUE ON IGNITION		NMT 0.1 %	0.1
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 %	0.048
	Chlorothiazide (EP-A/USP)	NMT 0.500 %	0.010
	Dimer (EP-C/USP)	NMT 0.300 %	0.153
	Any unspecified impurity	NMT 0.100 %	0.011
	Total impurities (EP requirement)	NMT 1.00 %	0.23
	Total impurities excluding DSA (USP requirement)	NMT 0.900 %	0.179
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 41/EUPH 9

Approved by Qualified Person / Quality Director
Laura Bigini
07-04-2018

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