

QUALITY DIVISION
CERTIFICATE OF ANALYSIS

NAME OF THE PRODUCT : HYDROCHLOROTHIAZIDE Ph.Eur.		
BATCH SIZE : 105.0 Kgs	BATCH No. : 1005HC8RII	
MFG. DATE : Aug. 2011	A.R. No. : IBD – 112811	
RETEST DATE : Jul. 2016	DATE : 18/12/2012	
TESTS	SPECIFICATIONS	RESULTS
CHARACTERS	A white or almost white, crystalline powder, very slightly soluble in water, soluble in acetone, sparingly soluble in ethanol (96%). It dissolves in dilute solutions of alkali hydroxides.	Conforms
IDENTIFICATION	The infrared absorption spectrum of sample and standard are concordant.	Conforms
ACIDITY OR ALKALINITY RELATED SUBSTANCES (By HPLC)	The solution is yellow. NMT 0.4 ml of 0.01M hydrochloric acid is required to change the colour of the indicator to red. 4-Amino-6-Chloro-1,3-Benzenedisulfonamide [Impurity B] : NMT 0.50% 6-chloro-N-[(6-chloro-7-sulphamoyl-2,3-dihydro-4H-1,2,4-benzothiadiazin-4-yl)1,1-dioxide)methyl]-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulphonamide 1,1-dioxide [Impurity C] : NMT 0.50% Chlorothiazide [Impurity A] : NMT 0.50% Any unspecified impurity : NMT 0.10% Sum of all impurities : NMT 1.0%	0.15% 0.20% < 0.05% < 0.05% 0.35%
CHLORIDES	NMT 100 ppm.	< 100 ppm
LOSS ON DRYING (at 105°C)	NMT 0.5% w/w	0.30% w/w
SULPHATED ASH	NMT 0.1% w/w	0.08% w/w
RESIDUAL SOLVENT	Methanol : NMT 1500 ppm	Not Detected
FORMALDEHYDE CONTENT	NMT 50 ppm	33 ppm
ASSAY (By HPLC)	97.5% - 102.0% w/w of C ₇ H ₈ ClN ₃ O ₄ S ₂ (on dried basis)	99.2% (odb)
PARTICLE SIZE (By Malvern)	MV : 25 – 60 µm SD : Maximum 72 µm d10 : Minimum 7 µm d50 : For Information d90 : For Information	43 µm 31 µm 14 µm 39 µm 77 µm
Additional USP Requirements : IDENTIFICATION	A Infrared absorption spectrum of test and standard are concordant B The UV absorption spectra of a 10µg/ml solution of tests and standard in methanol, exhibit maxima and minima at the same wavelengths.	Conforms Conforms
LOSS ON DRYING	NMT 0.5% w/w	0.27% w/w
RESIDUE ON IGNITION	NMT 0.1% w/w	0.08% w/w
CHLORIDE	NMT 0.035% w/w	< 0.035% w/w
SELENIUM	NMT 0.003% w/w	< 0.003% w/w
HEAVY METALS	NMT 0.001% w/w	< 0.001% w/w
RELATED COMPOUNDS (BY HPLC)	Benzothiadiazine Related Compound A : NMT 1.0% Any other impurity : NMT 0.50% Total other impurities excluding Benzothiadiazine : NMT 0.90%	0.15% 0.31% 0.47%
ASSAY (BY HPLC)	Related Compound A 98.0% - 102.0% of C ₇ H ₈ ClN ₃ O ₄ S ₂ (on dried basis)	99.5% (odb)
REMARKS : The above sample CONFORMS as per above specifications.		


PRADEEP RAIKWAR
ANALYST
DATE : 07/01/2015

043JKQ



8 of 8


NAVEEN BHAVSAR
MANAGER QUALITY CONTROL
DATE OF PRINT : 07/01/2015