

QUALITY DIVISION
CERTIFICATE OF ANALYSIS

METAPHARMACEUTICAL

N DE LOTE:

0016824

01/08/2024

NAME OF THE PRODUCT : HYDROCHLOROTHIAZIDE Ph. Eur.		
BATCH No. : 24020HC10R11	BATCH SIZE : 455.00 Kgs.	
MFG. DATE : Mar. 2024	A.R. No. : IBD - 241236	
EXP. DATE : Feb. 2029	DATE : 10/04/2024	
SPECIFICATION No. / REV. No. : TS/API/HC10/COS/ 3.0		
CUSTOMER NAME / ITEM CODE : NA		
TESTS	SPECIFICATIONS	RESULTS
CHARACTERS	A white or almost white, crystalline powder.	White crystalline powder Conforms
IDENTIFICATION	Very slightly soluble in water, soluble in acetone, sparingly soluble in ethanol (96%). It dissolves in dilute solutions of alkali hydroxides. The infrared absorption spectrum of sample and standard are concordant.	Conforms
ACIDITY OR ALKALINITY	The solution is yellow. NMT 0.4 ml of 0.01M hydrochloric acid is required to change the colour of the indicator to red.	0.3 ml
RELATED SUBSTANCES (By HPLC)	4-Amino-6-Chloro-1,3-Benzenedisulfonamide : NMT 0.50% [Impurity B] 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] Chlorothiazide [Impurity A] : NMT 0.50% Any Unspecified Impurity : NMT 0.10% Sum of all Impurities : NMT 1.0%	< 0.05% 0.05% < 0.05% < 0.05% 0.1%
CHLORIDES	NMT 100 ppm.	< 100 ppm
LOSS ON DRYING (at 105°C)	NMT 0.5% w/w	0.25% w/w
SULPHATED ASH	NMT 0.1% w/w	0.08% w/w
RESIDUAL SOLVENT	Methanol : NMT 500 ppm	BDL
FORMALDEHYDE CONTENT	NMT 50 ppm	BQL
ASSAY (By HPLC)	97.5% - 102.0% w/w of $C_7H_8ClN_3O_4S_2$ (on dried basis)	100.4%w/w (odb)
REMARKS : The above sample CONFORMS as per R1-CEP 2004-013 - Rev 06 specifications.		

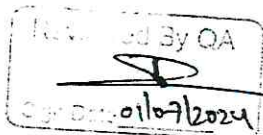
Note : BDL - Below Detection Limit

BQL - Below Quantitation Limit

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PREPARED BY

DATE : 01/07/2024



MANAGER/QUALITY CONTROL

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