F&A PHARMA TEL. : 07412 – 276649, 278244
07412 –278000

Ipca Laboratories Limited

P.O. SEJAVTA 457 001. DIST. RATLAM (M. P.)

ipca

METAPHARMACEUTICAL
N DE LOTE: 0190725
10/07/2025

QUALITY DIVISION
CERTIFICATE OF ANALYSIS

NAME OF THE PRODUCT :	**HYDROCHLOROTHIAZIDE Ph. Eur.**		
BATCH No.	**: 25014HC10RII**	**BATCH SIZE**	**: 491.90 Kgs.**
MFG. DATE	**: Feb. 2025**	**A.R. No.**	**: IBD – 251045**
EXP. DATE	**: Jan. 2030**	**DATE**	**: 27/03/2025**
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. Very slightly soluble in water, soluble in acetone, sparingly soluble in ethanol (96%). It dissolves in dilute solutions of alkali hydroxides.	White crystalline powder Conforms
IDENTIFICATION	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 **[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%	< 0.05% < 0.05% < 0.05% < 0.05% < 0.05%
CHLORIDES	NMT 100 ppm.	< 100 ppm
LOSS ON DRYING (at 105°C)	NMT 0.5% w/w	0.16% w/w
SULPHATED ASH	NMT 0.1% w/w	0.06% 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)	100.2%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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COPY QA APPROVED
Date 07.06.25
Signature
F&A PHARMA Handels GmbH

PREPARED BY
DATE : 07/06/25

Reviewed By C.A
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MANAGER QUALITY CONTROL
DATE : 07/06/25