

SUZHOU AUSUN CHEMICAL CO., LTD.

NO.6, JINSHAN ROAD, HI-TECH INDUSTRIAL DEVELOPMENT ZONE, SUZHOU,JIANGSU, CHINA

CERTIFICATE OF ANALYSIS

PRODUCT NAME: HYDROCHLOROTHIAZIDE PHARMACEUTICAL RAW MATERIALS	STANDARD: USP43
BATCH NO.: 20211116	QUANTITY: 50KGS
MANUFACTURING DATE: NOV.02.2021	EXPIRY DATE:NOV.01.2025

Contents	Specification	Results
Characteristics	White or almost white Crystalline powder	Complies
Identification	A: as per infrared absorption B: as per ultraviolet absorption	Complies
Solubility	Freely soluble in sodium hydroxide solution,In n-butylamine,and in dimethylformamide;Very slightly soluble in water; sparingly soluble in methanol; insoluble in ether.in chloroform,and in dilutemineral acids	Complies
Chloride	$\leq 0.035\%$	Complies
Selenium	$< 0.003\%$ max	Complies
Related Substances	Benzothiadiazine related compound A $\leq 1.0\%$ Chlorothiazide $\leq 0.5\%$ 5-Chlorohydrochlorothiazide $\leq 0.5\%$ Hydrochlorothiazide dimer $\leq 0.5\%$ Any other individual impurity $\leq 0.5\%$ Total impurities $\leq 0.9\%$	0.22% ND 0.12% 0.29% 0.08% 0.53%
Heavy metal	$< 0.001\%$ max	Complies
Residue on ignition	$\leq 0.1\%$	0.08%
Loss on drying	$\leq 0.5\%$	0.19%
Assay	98.0-102.0%(on the dried basis sub)	99.30%
Residual Solvents	Methanol ≤ 3000 ppm Ethanol ≤ 5000 ppm	ND ND
Formaldehyde	≤ 15 ppm	5ppm
Conclusion: It complies with the requirements of the USP43		

REMARK: STORE IN A TIGHTLY CLOSED CONTAINER, PROTECTED FROM LIGHT.

INSPECTOR: LI XIAO HUI

APPROVER: WU WENYING

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