

宁波旗诚化学有限公司

CERTIFICATE OF ANALYSIS

PRODUCT NAME: HYDROCHLOROTHIAZIDE PHARMACEUTICAL RAW MATERIALS	STANDARD: USP38
BATCH NO.: 20191014	QUANTITY: 25KGS
MANUFACTURING DATE: OCT.20.2019	EXPIRY DATE:OCT.19.2023

Contents	Specification	Results
Characteristics	White or almost white Crystalline powder	Complies
Identification	A: as per infrared absorption B: as per ultraviolet absorption	Complies
Solubility	Very slightly soluble in water, soluble in acetone, sparingly soluble in ethanol (96 per cent). It dissolves in dilute solutions of alkali hydroxides.	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 $\leq 0.9\%$	0.43% ND 0.01% 0.11% 0.03% 0.60%
Heavy metal	$< 0.001\%$ max	Complies
Residue on ignition	$\leq 0.1\%$	0.09%
Loss on drying	$\leq 0.5\%$	0.23%
Organic volatile impurities	Meets the requirements	Complies
Assay	98.0-102.0%(on the dried basis sub)	99.38%
Conclusion: It complies with the requirements of the USP38		

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

INSPECTOR: LI XIAO HUI

APPROVER: WU WENYING