ASEAN Reference Substance (ARS)

ASEAN TECHNICAL COOPERATION IN PHARMACEUTICALS
supported by **Japan Pharmaceutical Manufacturers Association**

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Certificate of Analysis **HYDROCHLOROTHIAZIDE** **Control No. T 218148**

Description	:	A white, crystalline powder.
Identification		
- Infrared absorption	:	Concordant with the reference spectrum of Hydrochlorothiazide USPRS.
- Ultraviolet absorption	:	A Solution (10 μg per mL) in methanol exhibits a maximum and minimum absorption at the same wavelength with the reference spectrum of Hydrochlorothiazide USPRS.
Organic impurities	:	(HPLC method)
- Benzothiadiazine related compound A	:	Not more than 1.0%
- Chlorothiazide	:	Not more than 0.5%
- 5-Chlorohydrochlorothiazide	:	Not more than 0.5%
- Hydrochlorothiazide dimer	:	Not more than 0.5%
- Any other individual impurity	:	Not more than 0.5%
- Total impurities (excluding benzothiadiazine related compound A)	:	Not more than 0.9%
Loss on drying	:	0.07%
Assay	:	99.71% of $C_7H_8ClN_3O_4S_2$, calculated on the dried basis, determined by HPLC method, compared with USPRS.
Intended use	:	For HPLC assay and identification.
Direction for use	:	Dry at 105°C for 1 hour before use.
Storage	:	Keep container tightly closed and protected from light, preferably at the temperature 2-8°C.

Date of Adoption	:	16 November 2018
Retested Date	:	27 June 2022
Next Retest Date	:	27 June 2025