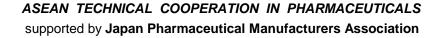


## ASEAN Reference Substance (ARS)





Coordinator of the Project

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Coordinating Country

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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 : Not more than 0.9%

benzothiadiazine related compound A)

Loss on drying : 0.07%

Assay : 99.71% of C<sub>7</sub>H<sub>8</sub>CIN<sub>3</sub>O<sub>4</sub>S<sub>2</sub>, 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