



## ASEAN Reference Substance (ARS)

ASEAN TECHNICAL COOPERATION IN PHARMACEUTICALS  
supported by Japan Pharmaceutical Manufacturers Association



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### Certificate of Analysis

### CIMETIDINE

Control No. M 213066

Description : A white, crystalline powder

Infrared absorption : Concordant with the reference spectrum of Cimetidine USPRS

Light absorption : A solution (1 in 80,000) in 0.1 N sulfuric acid exhibits maxima and minima at the same wavelengths as that of a similar solution of USPRS

Melting range : 141 °C

Chromatographic purity : (HPLC)

Any single impurity : Not more than 0.2%

Total impurities : Not more than 1.0%

Loss on drying : 0.1%

Assay : 100.02% of  $C_{10}H_{16}N_6S$ , calculated on the dried basis, determined by HPLC method, compared with USPRS

Intended use : For HPLC, chemical assay and identification

Direction for use : Dry at 110°C for 2 hours before use

Storage : Keep container tightly closed and protected from light, preferably at the temperature 2 - 8 °C

Date of Adoption : 25 February 2013

Retested Date : 21 March 2016, 1 October 2019, 31 August 2022

Next Retest Date : 31 August 2025