



ASEAN Reference Substance (ARS)

ASEAN TECHNICAL COOPERATION IN PHARMACEUTICALS
supported by Japan Pharmaceutical Manufacturers Association



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Certificate of Analysis

BROMHEXINE HYDROCHLORIDE

Control No. T 110150b

Description : A white, crystalline powder

Infrared absorption : Concordant with the reference spectrum of Bromhexine HCl
Ph. Eur. RS

Related substances : (HPLC)

- Any impurity : Not more than 0.2%

- Total impurities : Not more than 0.3%

Loss on drying : 0.05%

Assay : 99.71% of $C_{14}H_{20}Br_2N_2 \cdot HCl$, calculated on the dried basis,
determined by acid-base titration method.

Intended use : For chemical assay and identification.

Direction for use : Dry at $105^{\circ}C$ to constant weight before use.

Storage : Keep container tightly closed and protected from light, preferably at
the temperature $2 - 8^{\circ}C$.

Date of Adoption : 21 September 2010

Retested Date : 4 September 2013, 11 November 2016, 20 February 2020

Next Retest Date : 20 February 2023