



# Certificate of Analysis

## ASEAN Reference Substance (ARS)

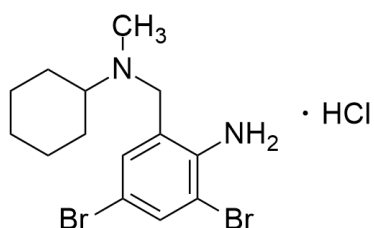
Issued by ASEAN Reference Substances Working Group (ARSWG)

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### BROMHEXINE HYDROCHLORIDE

### Control No. T 225150



CAS No. : 611-75-6  
Molecular Formula : C<sub>14</sub>H<sub>21</sub>Br<sub>2</sub>ClN<sub>2</sub>  
Molecular Weight : 412.6

Description	: A white, crystalline powder
Identification	
Infrared absorption	: Concordant with the reference spectrum of Bromhexine Hydrochloride Ph. Eur. RS
Test for chloride	: Positive
Loss on drying	: 0.08%
Related substances	: (HPLC method)
- Impurity C	: Not more than 0.15%
- Unspecified impurities: for each impurity	: Not more than 0.10%
- Total impurities	: Not more than 0.2%
Assay	: 99.68% of C <sub>14</sub> H <sub>21</sub> Br <sub>2</sub> ClN <sub>2</sub> , calculated on the dried basis, determined by HPLC method, compared with Ph. Eur. RS
Intended use	: For HPLC, chemical assay and identification
Direction for use	: Dry at 105 °C to constant weight before use
Storage	: Keep container tightly closed and protected from light, preferably at the temperature 2-8 °C

Date of Adoption : 21 May 2025  
Next Retest Date : 21 May 2028