



Certificate of Analysis

ASEAN Reference Substance (ARS)

Issued by ASEAN Reference Substances Working Group (ARSWG)

Coordinating Country

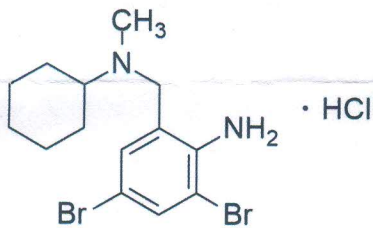
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Coordinator of the Project

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BROMHEXINE HYDROCHLORIDE

Control No. T 225150



CAS No. : 611-75-6
Molecular Formula : C₁₄H₂₁Br₂ClN₂
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 ₁₄ H ₂₁ Br ₂ ClN ₂ , 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