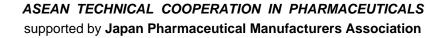


ASEAN Reference Substance (ARS)





Coordinator of the Project : Bureau of Drug and Narcotic. Department of Medical Sciences. Ministry of Public Health

Nonthaburi 11000, Thailand TEL.(662)9510000 ext. 99102, 99103 FAX.(662)5805733

Coordinating Country : Bureau of Drug and Narcotic. Department of Medical Sciences. Ministry of Public Health

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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 HCI

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 C₁₄H₂₀Br₂N₂•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 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 September 2010

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

Next Retest Date : 20 February 2023