



ASEAN CERTIFIED REFERENCE MATERIAL

ASEAN TECHNICAL COOPERATION IN PHARMACEUTICALS

supported by U.S. Pharmacopeial Convention

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

DIPHENHYDRAMINE HYDROCHLORIDE

Control No. T 414021

Description : A white, crystalline powder.

Infrared absorption : Concordant with the reference spectrum of
Diphenhydramine HCl USPRS.

Organic impurities : (HPLC method)

- Diphenhydramine related compound A : Not more than 0.5%
- 4-Methyldiphenhydramine : Not more than 0.3%
- 4-Bromodiphenhydramine : Not more than 0.3%
- Benzhydrol : Not more than 0.3%
- Benzophenone : Not more than 0.3%
- Any other unspecified impurity : Not more than 0.10%
- Total impurities : Not more than 1.0%

Assay : 99.9% of $C_{17}H_{21}NO \cdot HCl$, calculated on the as is basis,
determined by HPLC method, compared with USPRS.

Intended use : For HPLC assay and identification.

Direction for use : Do not dry.

Storage : Keep container tightly closed and protected from light,
preferably at the temperature about 5°C.

Date of Adoption : October 2011

Retested Date : 21 October 2014, 5 April 2018, 30 April 2021

Next Retest Date : 30 April 2024