



Certificate of Analysis

ASEAN Reference Substance (ARS)

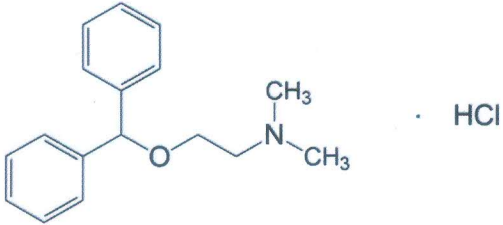
Issued by ASEAN Reference Substances Working Group (ARSWG)

Coordinating Country

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Coordinator of the Project

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DIPHENHYDRAMINE HYDROCHLORIDE	Control No. T 525021
 <chem>CN(C)CCOC(c1ccccc1)c2ccccc2.[Cl-]</chem>	CAS No. : 147-24-0 Molecular Formula : C ₁₇ H ₂₁ NO·HCl Molecular Weight : 291.82

Description	: A white, crystalline powder
Identification	
Infrared absorption	: Concordant with the reference spectrum of Diphenhydramine Hydrochloride USPRS
Test for chloride	: Positive
Loss on drying	: 0.05%
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	: 99.89% of C ₁₇ H ₂₁ NO·HCl, calculated on the dried basis, determined by HPLC method, compared with USPRS
Intended use	: For HPLC, chemical assay and identification
Direction for use	: Dry at 105 °C for 3 hours before use
Storage	: Keep container tightly closed and protected from light, preferably at the temperature 2-8 °C

Date of Adoption : 10 December 2025

Next Retest Date : 10 December 2028