



Certificate of Analysis

ASEAN Reference Substance (ARS)

Issued by ASEAN Reference Substances Working Group (ARSWG)

Coordinating Country

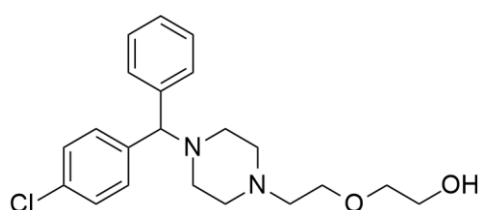
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Coordinator of the Project

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HYDROXYZINE HYDROCHLORIDE

Control No. S 125165



· 2 HCl

CAS No. : 2192-20-3

Molecular Formula : C₂₁H₂₇ClN₂O₂·2HCl

Molecular Weight : 447.83

Description	: A White, crystalline powder
Identification	
Infrared absorption	: Concordant with the reference spectrum of Hydroxyzine Hydrochloride USPRS
Water	: 2.41% (Karl Fischer Method)
Organic Impurities	: (HPLC method)
- Decloxizine	: Not more than 0.3%
- Hydroxyzine related compound A	: Not more than 0.3%
- 4-Chlorobenzophenone	: Not more than 0.2%
- Any individual unspecified impurity	: Not more than 0.2%
- Total impurities	: Not more than 0.75%
Assay	: 100.48% of C ₂₁ H ₂₇ ClN ₂ O ₂ ·2HCl, calculated on the anhydrous basis, determined by HPLC method, compared with USPRS
Intended use	: For HPLC, chemical assay and identification
Direction for use	: Do not dry before use
Storage	: Keep container tightly closed and protected from light, preferably at the temperature 2-8 °C

Date of Adoption : 30 June 2025

Next Retest Date : 30 June 2028