

ASEAN Reference Substance (ARS)

ASEAN TECHNICAL COOPERATION IN PHARMACEUTICALS supported by Japan Pharmaceutical Manufacturers Association



Coordinator of the Project

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Certificate of Analysis

PYRIDOXINE HYDROCHLORIDE

Control No. M 214096

Description

: A white, crystalline powder.

Infrared absorption

: Concordant with the reference spectrum of

Pyridoxine Hydrochloride USPRS.

Tests for chloride

: Positive

Related substances

: (TLC method)

Any individual impurity

: Not more than 0.25%

Loss on drying

: 0.2%

Assay

: 99.95% of C₈H₁₁NO₃•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 in vacuum over silica gel for 4 hours before use.

Storage

: Keep container tightly closed and protected from light, preferably

at the temperature 2-8°C

Date of Adoption

: 2 January 2014

Retested Date

: 26 December 2018

Next Retest Date

: 26 December 2021