ASEAN Reference Substance (ARS)

ASEAN TECHNICAL COOPERATION IN PHARMACEUTICALS
supported by **Japan Pharmaceutical Manufacturers Association**

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Certificate of Analysis **AMLODIPINE BESILATE** **Control No. T 117157**

Description	: A white, crystalline powder
Identification	
- Infrared absorption	: Concordant with the reference spectrum of Amlodipine Besilate Ph.Eur.RS.
- Ultraviolet absorption	: A solution (1 in 40,000) in 0.01M hydrochloric acid-methanol TS exhibits similar intensities of absorption at the same wavelengths with the reference spectrum of Amlodipine Besilate JPRS.
Melting point	: 198.4°C (with decomposition)
Related substances	: (HPLC method)
- Impurity at RRT 0.90	: Not more than 0.3%
- Any other impurity	: Not more than 0.1%
- Total impurities	: Not more than 0.81%
Water	: 0.11% (Karl Fischer Method)
Assay	: 100.06% of $C_{20}H_{25}ClN_2O_5 \cdot C_6H_6O_3S$, calculated on the anhydrous basis, determined by HPLC method, compared with JPRS
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	: 29 May 2017
Retested Date	: 30 September 2020, 30 September 2023
Next Retest Date	: 30 September 2026