ASEAN Reference Substance (ARS)

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

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Certificate of Analysis **ENALAPRIL MALEATE** **Control No. V 216111**

Description	: A white, crystalline powder
Identification	
- Infrared absorption	: Concordant with the reference spectrum of Enalapril Maleate USPRS
- HPLC	: The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.
Specific optical rotation	: - 42.1° (10 mg/mL, in methanol)
Organic impurities	: (HPLC method)
- Any impurity RRT 1.10	: Not more than 1.0%
- Any other individual impurity	: Not more than 0.3%
- Total impurities	: Not more than 2%
Loss on drying	: 0.07%
Assay	: 99.64% of $C_{20}H_{28}N_2O_5 \cdot C_4H_4O_4$, calculated on the dried basis, determined by HPLC method, compared with USPRS
Intended use	: For HPLC, chemical assay and identification
Direction for use	: Dry under vacuum at a pressure not exceeding 5 mm of mercury at 60°C for 2 hours before use.
Storage	: Keep container tightly closed and protected from light, preferably at the temperature 2-8 °C

Date of Adoption	: 10 May 2016
Retested Date	: 7 October 2019
Next Retest Date	: 7 October 2022