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 $C_{20}H_{28}N_2O_5 \bullet C_4H_4O_4$, 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, 6 December 2022
Next Retest Date	:	6 December 2025