ASEAN Reference Substance (ARS)

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

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Certificate of Analysis **LANSOPRAZOLE** **Control No. V 118159**

Description	:	A white, crystalline powder
Identification		
- Infrared absorption	:	Concordant with the reference spectrum of Lansoprazole JPRS.
- Ultraviolet absorption	:	A solution (1 in 100,000) in methanol exhibits similar intensities of absorption at the same wavelengths with the reference spectrum of Lansoprazole JPRS.
Related substances	:	(HPLC method)
- Impurity at RRT 1.1	:	Not detected
- Any other impurity	:	Not more than 0.1%
- Total impurities	:	Not more than 0.6%
Water	:	0.02% (Coulometric Titration)
Assay	:	99.98% of $C_{16}H_{14}F_3N_3O_2S$, calculated on the anhydrous basis, determined by HPLC method, compared with JPRS.
Intended use	:	For HPLC 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	: 27 June 2018
Retested Date	: 24 May 2022
Next Retest Date	: 24 May 2025