ASEAN Reference Substance (ARS)

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

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Certificate of Analysis **INDOMETHACIN** **Control No. T 321025**

Description	:	A white, crystalline powder
Identification		
Infrared absorption	:	Concordant with the reference spectrum of Indomethacin USPRS
Ultraviolet absorption	:	A solution (25 µg per mL) in hydrochloric acid and methanol (1 in 120) exhibits the absorptivities at 318nm do not differ by more than 3.0% compared with the reference spectrum of Indomethacin USPRS
Organic impurities		
- Indomethacin related compound A	:	Not more than 0.1% (HPLC method)
- Indomethacin related compound B	:	Not more than 0.5% (HPLC method)
- Any individual unspecified impurity	:	Not more than 0.10% (HPLC method)
- Total impurities	:	Not more than 1.0% (HPLC method)
Loss on drying	:	0.15%
Assay	:	99.62% of $C_{19}H_{16}ClNO_4$, calculated on the dried basis, determined by HPLC method, compared with USPRS
Intended use	:	For HPLC assay and identification
Direction for use	:	Dry at a pressure below 5 mm of mercury at 100^{o}C for 2 hours before use
Storage	:	Keep container tightly closed and protected from light, preferably at the temperature 2-8^{o}C

Date of Adoption	: 1 October 2021
Next Retest Date	: 1 October 2024