ASEAN Reference Substance (ARS)

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

Coordinator of the Project : Bureau of Drug and Narcotic. Department of Medical Sciences. Ministry of Public Health Nonthaburi 11000, Thailand TEL.(662)9510000 ext. 99102, 99103 FAX.(662)5805733

Coordinating Country : National Institute of Drug Quality Control. Ministry of Health. 48 Hai Ba Trung street Hanoi, Vietnam TEL.(8424) 3825 5471 FAX. (8424) 3825 6911

Certificate of Analysis **DICLOFENAC SODIUM** **Control No. V 214067**

Description	:	A white, slightly hygroscopic, crystalline powder
Identification		
Infrared absorption	:	Concordant with the reference spectrum of Diclofenac Sodium USPRS
HPLC	:	Correspond to the principle peak in the chromatogram obtained with the standard solution of Diclofenac Sodium USPRS
Reaction of sodium	:	Sodium positive
Acidity	:	pH 7.5 (1% solution)
Related substances	:	(HPLC method)
Related Compound A	:	Less than 0.2%
Each other impurity	:	Less than 0.2%
Total	:	Less than 0.5%
Loss on drying	:	0.18%
Assay	:	99.83% of $C_{14}H_{10}Cl_2NNaO_2$, calculated on the dried basis, determined by HPLC method, compared with USPRS
Intended use	:	For HPLC assay and identification
Direction for use	:	Dry at 105-110 °C for 3 hours before use
Storage	:	Keep container tightly closed and protected from light, preferably at the temperature 2-8 °C

Date of Adoption	: 11 April 2014
Retested Date	: 31 July 2017
Next Retest Date	: 31 July 2020