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.(844) 825 5471 FAX. (844) 825 6911

Certificate of Analysis **CEFIXIME TRIHYDRATE** **Control No. V 115156**

Description	:	A white, crystalline powder
Identification		
Infrared absorption	:	Concordant with the reference spectrum of Cefixime USPRS
pH	:	3.05 (5% aqueous solution)
Related substances	:	(HPLC method)
Any individual impurity	:	Not more than 0.5%
Sum of all impurities	:	Not more than 3.0%
Ethanol	:	Not more than 1.0% (GC method)
Water	:	11.24% (Karl Fischer method)
Assay	:	99.72% of $C_{16}H_{15}N_5O_7S_2$, calculated on the anhydrous basis, determined by HPLC method, compared with USPRS
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	: 26 June 2015
Retested Date	: 25 June 2018
Next Retest Date	: 25 June 2021