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 Quality Control Laboratory of Drug and Food. National Agency of Drug and Food Control
Jalan Percetakan Negara No.23 Jakarta 10560, Indonesia TEL.(6221) 4245075
FAX.(6221) 4245150

Certificate of Analysis **FLAVOXATE HYDROCHLORIDE** **Control No. I 121162**

Description	:	A white, crystalline powder
Identification		
Infrared absorption	:	Concordant with the reference spectrum of Flavoxate Hydrochloride USPRS
HPLC	:	Corresponds to the retention time of Flavoxate Hydrochloride USPRS
Related substances	:	(HPLC)
- Impurity A	:	Not more than 0.3%
- Impurity B	:	Not more than 0.15%
- Any unspecified impurities	:	Not more than 0.10%
- Total of unspecified impurities	:	Not more than 0.5%
Loss on drying	:	0.11%
Assay	:	99.84% of $C_{24}H_{25}NO_4 \cdot HCl$, calculated on the dried basis, determined by HPLC method, compared with USPRS.
Intended use	:	For HPLC, chemical assay and identification
Direction for use	:	Dry at 105 °C to constant weight before use
Storage	:	Keep container tightly closed and protected from light, preferably at the temperature at 2 - 8 °C

Date of Adoption	:	21 July 2021
Next Retest Date	:	21 July 2024