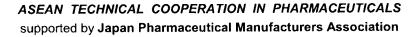


ASEAN Reference Substance (ARS)





Coordinator of the Project

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Coordinating Country

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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