

ASEAN Reference Substance (ARS)

ASEAN TECHNICAL COOPERATION IN PHARMACEUTICALS supported by Japan Pharmaceutical Manufacturers Association



Coordinator of the Project

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Certificate of Analysis

ATENOLOL

Control No. M 213108

Description

: A white, crystalline powder.

Infrared absorption

: Concordant with the reference spectrum of Atenolol USPRS.

Light absorption

: A solution (20 µg per mL) in methanol exhibits maxima and

minima at the same wavelengths as that of Atenolol USPRS.

Melting range

: Between 152° and 156.5°C

Chromatographic purity

: (HPLC method)

Any individual impurity

: Not more than 0.25%

Total impurities

: Not more than 0.5%

Loss on drying

: 0.4%

Assay

: 99.51% of $C_{14}H_{22}N_2O_3,$ 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 2-8°C

Date of Adoption

: 30 December 2013

Retested Date

: 9 November 2017

Next Retest Date

: 9 November 2020