

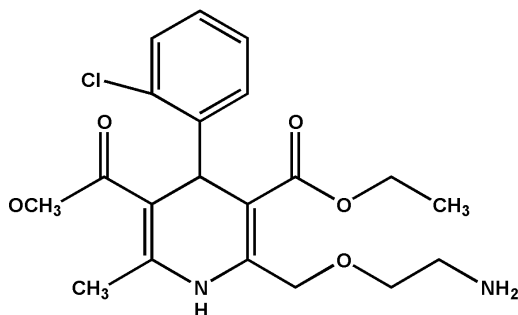


U.S. Pharmacopeia  
The Standard of Quality<sup>SM</sup>

# USP Certificate

## Amlodipine Besylate

LOT H0I102



### Molecular Formula

$C_{20}H_{25}ClN_2O_5 \cdot C_6H_6O_3S$

### Molecular Weight

567.05

### CAS Number

111470-99-6

### LABEL TEXT



Lot No.: H0I102

### USP<sup>®</sup> REFERENCE STANDARD

#### AMLODIPINE BESYLATE 350 mg

Warning! Harmful if swallowed. Causes serious eye irritation.

Determine the water content titrimetrically at the time of use. For quantitative applications, use a value of 0.998 mg of amlodipine besylate per mg of material on the anhydrous basis. Keep container tightly closed.

Protect from light. Store in a refrigerator.



USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0868  
CAT No. 1029501 Material mfd in India

**Intentionally over-labeled for GHS compliance**

For use with specified USP compendial tests. Not for use as a drug. See SDS prior to use at [www.usp.org/ids](http://www.usp.org/ids).

Wash thoroughly after handling. Wear eye/face protection. If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Dispose of contents/container in accordance with local/regional/national/international regulations.

USP certifies that the USP Reference Standards Committee, in accordance with their rules and procedures, determined that this USP Reference Standard lot is suitable to assess compliance with the monograph standards for which it is specified. The critical characteristics of this lot are usually determined independently in three or more laboratories, including USP, government, academic, and industrial collaborators.

Jeri L. Joth

QA Director

### Calculation Value

Unless otherwise stated on the Reference Standard label, a value of 100.0% should be used in USP or NF compendial applications for which the use of this Reference Standard is intended. Please refer to the specific Reference Standard label for further information.

### Expiration

Current lots are identified in the Official USP Reference Standards catalog. In some cases, the previous lot may still be considered official. If so, it is identified in the column marked "Previous Lot/Valid Use Date." Ordinarily, the previous lot is carried in official status for about one year after the current lot enters distribution.

It is the responsibility of each user to determine that this lot is current when used. To ensure up-to-date information, USP publishes the Official USP Reference Standards Catalog, which contains official lot designations. This information is also available on the USP web site, at [www.usp.org](http://www.usp.org), as well as in the bimonthly subscription publication, *Pharmacopeial Forum*.

### Instructions for Use

Follow the instructions in the appropriate USP or NF Monographs and General Requirements for Tests and Assays of the current *USP–NF*. In the event that instructions on the label of this lot differ from those found in the current *USP–NF*, those on the label supersede any instructions listed in Chapter <11>.

### Non-Monograph Use

The suitability of this Reference Standard for use in non-compendial applications is solely the responsibility of the user.

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