

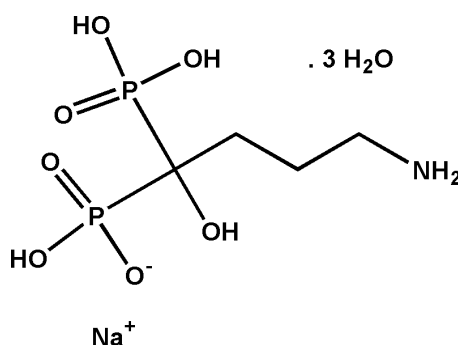


U.S. Pharmacopeia
The Standard of QualitySM

USP Certificate

Alendronate Sodium

LOT H0H004



Molecular Formula

$\text{C}_4\text{H}_{12}\text{NNaO}_7\text{P}_2 \cdot 3\text{H}_2\text{O}$

Molecular Weight

325.12

CAS Number

121268-17-5

LABEL TEXT

USP REFERENCE STANDARD
ALENDRONATE SODIUM 200 mg

Danger! Harmful if swallowed. Causes skin irritation. Causes serious eye damage. Suspected of damaging fertility or the unborn child. Causes damage to organs (Bone).

This is the trihydrate form. Do not dry. For quantitative applications, use a value of 0.833 mg of alendronate sodium per mg of material on the as is basis. Keep container tightly closed. Store in a desiccator at room temperature.

USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666
CAT No. 1012780 Material mfd in Ireland

Intentionally over-labeled for GHS compliance

Lot No.: H0H004

For use with specified USP compendial tests. Not for use as a drug. See SDS prior to use at www.usp.org/sds.

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor. If exposed or concerned: Get medical advice/attention.

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. Toth

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, 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.

LEGAL NOTICE

USP MAKES NO REPRESENTATION OR WARRANTY WITH RESPECT TO THE ACCURACY, COMPLETENESS, OR CURRENTNESS OF THIS CERTIFICATE; AND USP SPECIFICALLY DISCLAIMS ANY OTHER WARRANTY, EXPRESS, IMPLIED, OR STATUTORY, INCLUDING BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. USP DOES NOT WARRANT THAT THE INFORMATION CONTAINED HEREIN MEETS THE CUSTOMER'S REQUIREMENTS. USP SHALL NOT BE LIABLE ON ACCOUNT OF ANY SUCH ERRORS OR OMISSIONS.

USP Reference Standards are not intended for use as drugs, dietary supplements, or as medical devices.
This document is not a Material Safety Data Sheet.

This certificate may not be reproduced without the express written permission of USP.

Copyright 2008 The United States Pharmacopeial Convention, Inc. All rights reserved.