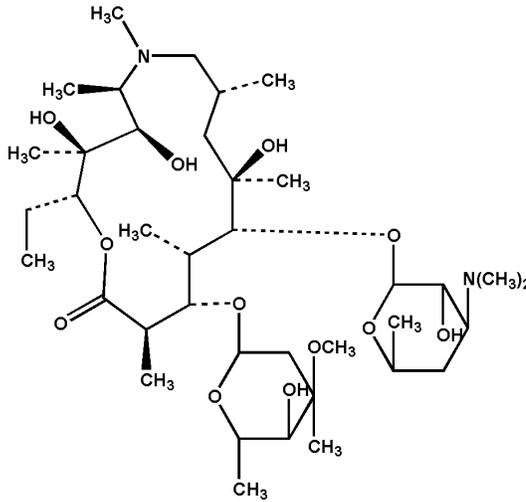




U.S. Pharmacopeia
The Standard of QualitySM

USP Certificate

Azithromycin Identity LOT F0G111



Molecular Formula

C₃₈H₇₂N₂O₁₂

Molecular Weight

748.98

CAS Number

83905-01-5

LABEL TEXT



USP[®] REFERENCE STANDARD

AZITHROMYCIN IDENTITY 75 mg

Danger! May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.



Do not dry. Keep container tightly closed. Protect from light. Store in a freezer.

USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666

CAT No. 1046067

Material mfd in Israel

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/sds.

Avoid breathing dust. In case of inadequate ventilation wear respiratory protection. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. 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. Ioth

QA Director



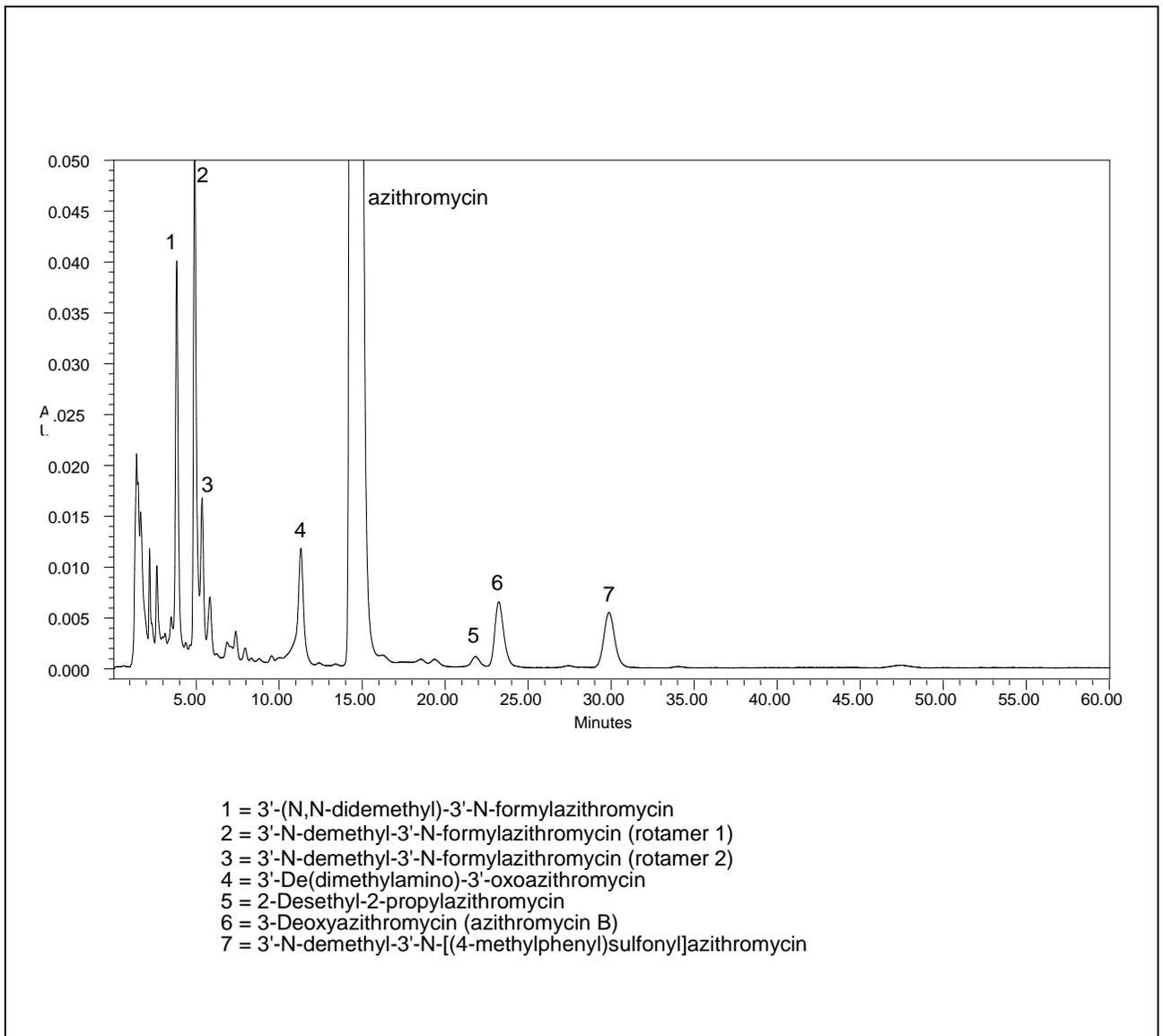
TYPICAL CHROMATOGRAM

USP Azithromycin Identity RS

Lot F0G111 (Cat. 1046067)

USP Monograph: Azithromycin, USP 31/NF 26

Test: Limit of related substances, TEST 2



This chromatogram is supplied for information only to assist in identifying peaks and does not constitute any legal requirement.

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.

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