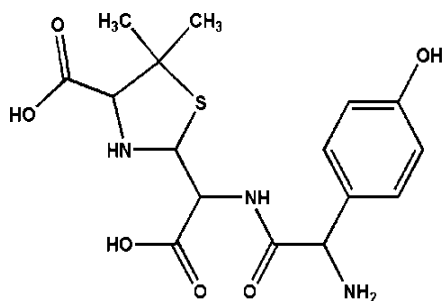




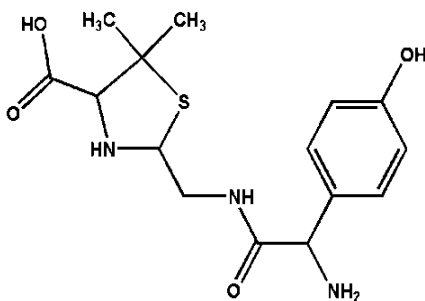
U.S. Pharmacopeia
The Standard of QualitySM

USP Certificate

Amoxicillin Related Compounds D and E Mixture LOT F0J382



Amoxicillin Related Compound D
 $C_{16}H_{21}N_3O_6S$
Mol. Wt.: 383.42
CAS # 57457-65-5



Amoxicillin Related Compound E
 $C_{15}H_{21}N_3O_4S$
Mol. Wt.: 339.41
CAS # 57414-05-8

Molecular Formula

Mixture

Molecular Weight

n/f

CAS Number

n/f

LABEL TEXT



Lot No.: F0J382

USP[®] REFERENCE STANDARD

AMOXICILLIN RELATED COMPOUNDS D AND E MIXTURE 15 mg
(A mixture of 2-((2-amino-2-(4-hydroxyphenyl)acetamido)(carboxymethyl)-5,5-dimethylthiazolidine-4-carboxylic acid isomers and 2-((2-amino-2-(4-hydroxyphenyl)acetamido)(methyl)-5,5-dimethylthiazolidine-4-carboxylic acid isomers)



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. Store in a freezer.

USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0686
CAT No. 1031558 Material mfd in Spain

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.

Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.

Jeri L. Joth

QA Director



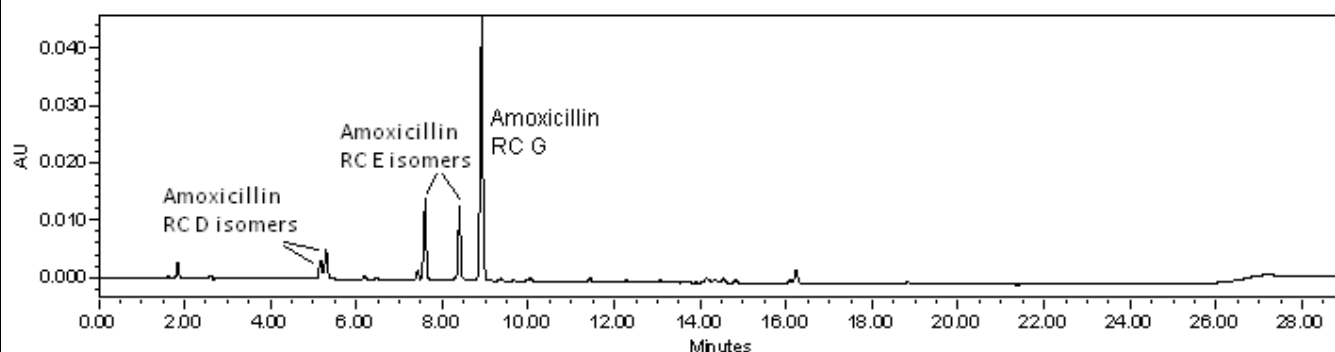
TYPICAL CHROMATOGRAM

USP Amoxicillin Related Compounds D and E Mixture RS

Lot F0J382 (Cat. 1031558)

Reference: Amoxicillin for Oral Suspension (as published in *PF* 36(4)[July – Aug. 2010], pg. 894-896)

Test: Organic Impurities, *System suitability solution*



The resolution requirement for this monograph is between the second Amoxicillin RC E isomer and USP Amoxicillin Related Compound G.

This chromatogram is supplied for information only, unless otherwise specified in an applicable monograph or general chapter.

Calculation Value

Unless otherwise stated on the Reference Standard label, a value of 100.0% should be used in the 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 current USP Catalog. In some cases, the previous lot may still be considered valid for use. If so, it is identified in the column marked "Previous Lot/Valid Use Date."

It is the responsibility of each user to determine that this lot is current or valid when used. For the most up-to-date information, please refer to the USP Store at www.usp.org.

Instructions for Use

Follow the instructions on the label of the USP Reference Standard and in the appropriate USP documentary standard(s).

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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