

# Certificate

## AMOXICILLIN RELATED COMPOUND J

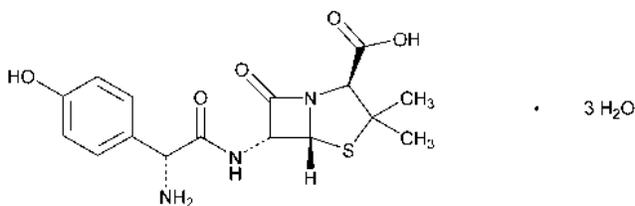
(Mixture of amoxicillin and open ring dimer)

USP Catalog No.: 1031605

USP Lot No.: R064U0

### Amoxicillin

((2S,5R,6R)-6-[(R)-(-)-2-Amino-2-(p-hydroxyphenyl)acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate)



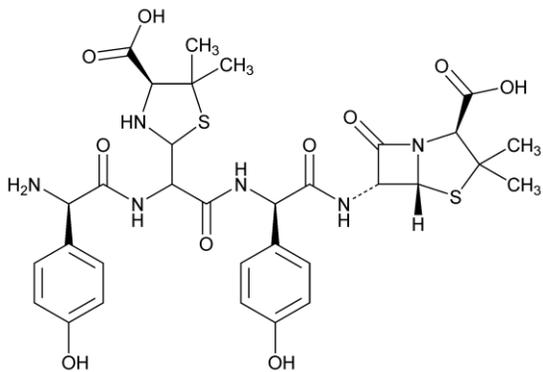
CAS No.: 61336-70-7

Molecular Formula: C<sub>16</sub>H<sub>19</sub>N<sub>3</sub>O<sub>5</sub>S·3H<sub>2</sub>O

Molecular Weight: 419.45

### Open ring dimer

((2S,5R,6R)-6-((2R)-2-{2-[(R)-2-Amino-2-(4-hydroxyphenyl)acetamido]-2-[(4S)-4-carboxy-5,5-dimethylthiazolidin-2-yl]acetamido}-2-(4-hydroxyphenyl)acetamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid))



CAS No.: N/A

Molecular Formula: C<sub>32</sub>H<sub>38</sub>N<sub>6</sub>O<sub>10</sub>S<sub>2</sub>

Molecular Weight: 730.81

**LABEL TEXT**

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



Lot: R064U0

**USP REFERENCE STANDARD**

**AMOXICILLIN RELATED COMPOUND J 15 mg**  
(Mixture of amoxicillin and amoxicillin related compound J (open ring dimer))



Danger!

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

Do not dry. This material contains approximately 77% amoxicillin, 11% amoxicillin related compound J, and 12% other impurities by HPLC area percent. Keep container tightly closed. Protect from light. Store in a freezer.

USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666  
Cat. No. 1031605 Material mfd. in Spain

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*

*Quality Assurance*

**Calculation Value**

If a value is not provided on the label or accompanying documentation and the Reference Standard has a quantitative USP compendial application, a value of 100.0% is used. The purity value is not applicable for qualitative uses. 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](http://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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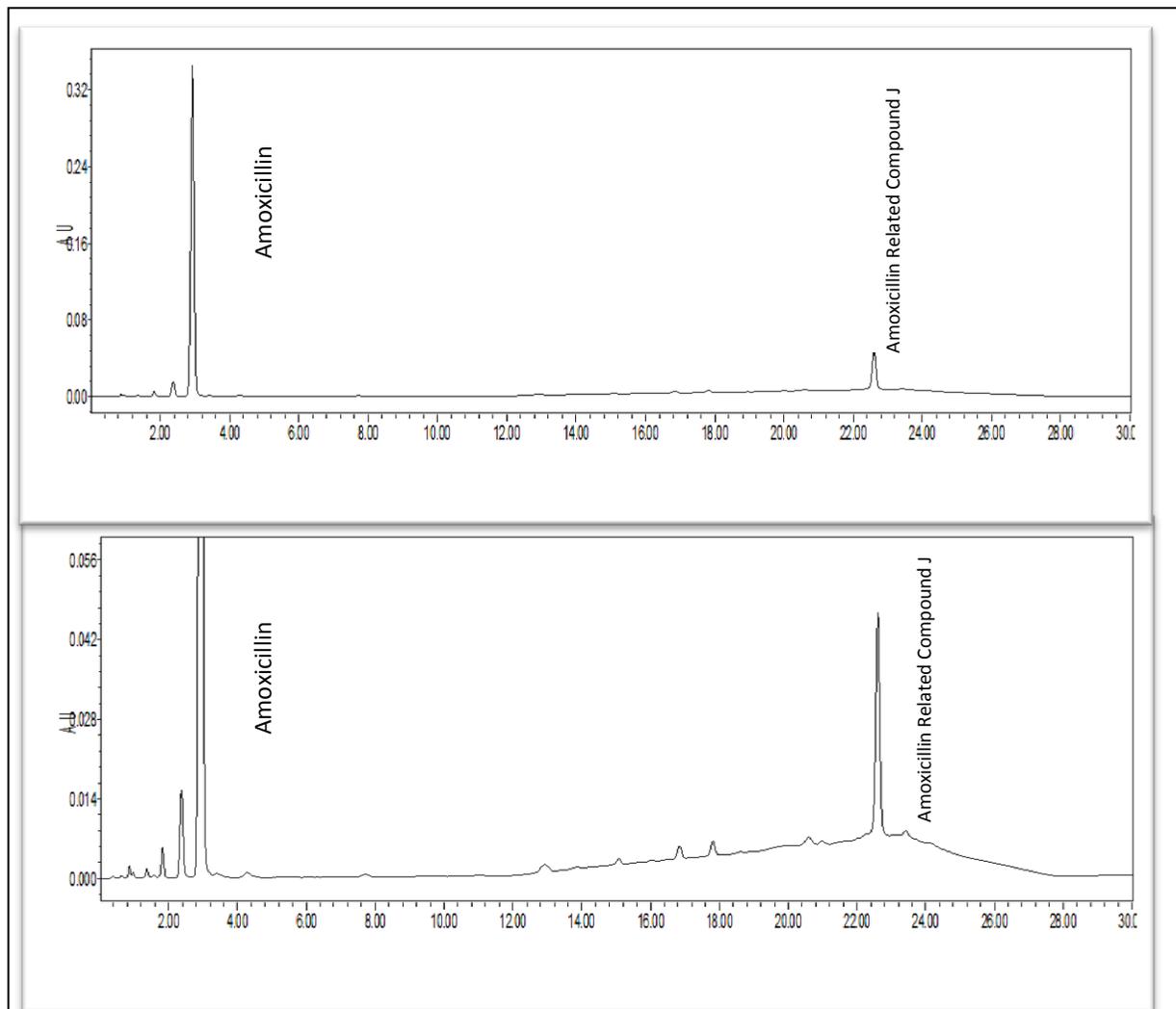
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# Typical Chromatogram

## USP Amoxicillin Related Compound J RS

<b>Catalog Number:</b> 1031605
<b>Lot:</b> R064U0
<b>Monograph:</b> Amoxicillin
<b>Publication:</b> USP 39/NF 34
<b>Test:</b> Organic Impurities
<b>Sample:</b> 0.25 mg/mL, in <i>Solution A</i>



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