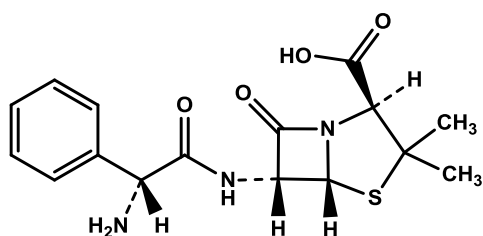




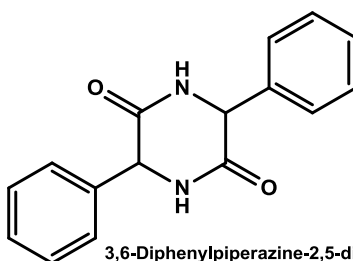
U.S. Pharmacopeia  
The Standard of Quality<sup>SM</sup>

# USP Certificate

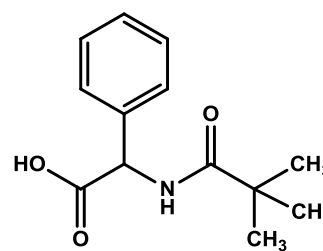
## Ampicillin System Suitability Mixture LOT F0L226



Ampicillin  
Chemical Formula:  $C_{16}H_{19}N_3O_4S$   
Molecular Weight: 349.40



3,6-Diphenylpiperazine-2,5-dione  
Chemical Formula:  $C_{16}H_{14}N_2O_2$   
Molecular Weight: 266.29



Pivaloyl phenylglycine  
Chemical Formula:  $C_{13}H_{17}NO_3$   
Molecular Weight: 235.28

### LABEL TEXT



Lot No.: F0L226



### REFERENCE STANDARD

AMPICILLIN SYSTEM SUITABILITY MIXTURE 10 mg

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

Do not dry. Keep container tightly closed. Protect from light. Store in a refrigerator. Material is hygroscopic. See accompanying typical chromatogram.



USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666  
CAT No. 1033247 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/sds](http://www.usp.org/sds).

Wash thoroughly after handling. Avoid breathing dust. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves. Wear eye/face protection. 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. Take off contaminated clothing and wash it before reuse. 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. 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



# TYPICAL CHROMATOGRAM

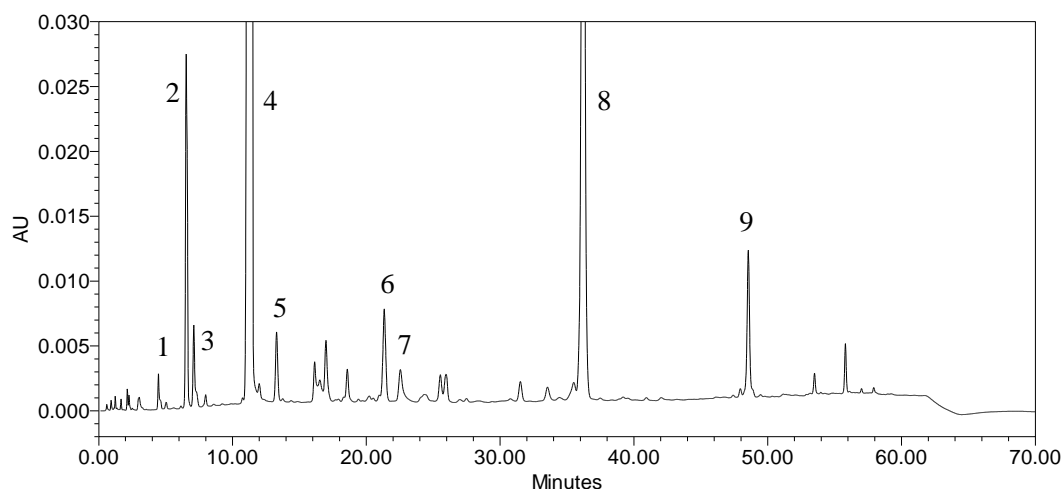
## USP Ampicillin System Suitability Mixture RS

Lot F0L226

**Monograph:** Ampicillin *PF 38(3)*

**Test:** Organic Impurities, Procedure 3

**Solution:** *System Suitability Solution*



- 1 – Ampicilloic acid 1
- 2 – Ampicilloic acid 2
- 3 – L-Ampicillin
- 4 – Ampicillin
- 5 – Ampilloic acid 1
- 6 – Pivaloyl phenylglycine
- 7 – Diphenyldiketopiperazine
- 8 – Ampicillin oligomer 1 (dimer)
- 9 – Ampicillin oligomer 1 (trimer)

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 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](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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