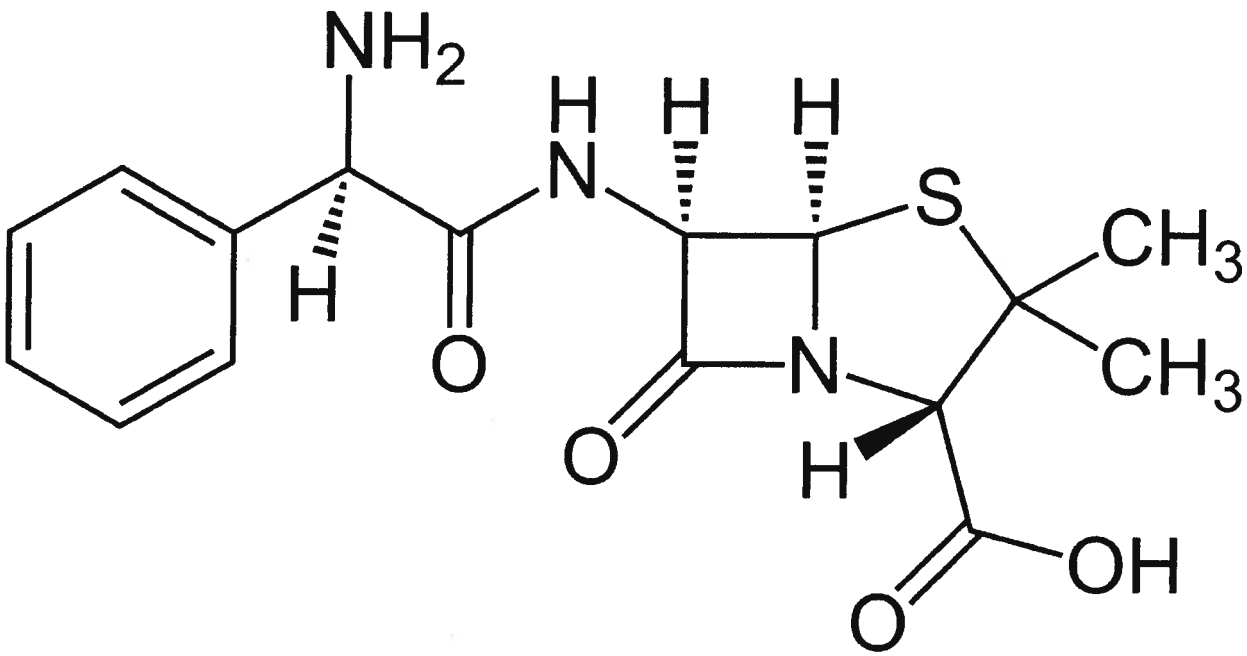
Stability Report

AMPICILLIN



$C_{16}H_{19}N_3O_4S$

Materials

Flavors		Lot#	Expiration
Watermelon		R0930	9/1/2019
Strawberry			11/1/2019
Banana			9/1/2019
Apple		R0927	9/1/2019
FLAVORx, INC **9475 Gerwig Lane, Columbia, MD 21046**			
Standards	**Part #**	**Lot #**	
Ampicillin Trihydrate	A5160	29325107	
LKT Laboratories, Inc. **545 Phalen Blvd.St. Paul, MN 55130**			
Reagents	**Part #**	**Lot #**	
Acetic Acid	338826	32196LMV	
Sigma-Aldrich			
Potassium Phosphate Monobasic	P286-1	A20X007	
Fisher Scientific			
Pharmaceutical	**NDC #**	**Lot #**	**Expiration**
Ampicillin for Oral Suspension(250mg/5mL)	7256-183-10	12004	4/1/2014
Dava Pharmecuticals Inc. **Parker Plaza** **400 Kelby Street, 10th Floor** **Fort Lee, New Jersey 07024**			

Results

Table 1: Average % Potency Relative to Bottle Value Sample

Sample	Average % Potency Relative to Bottle Value (250mg/5mL) vs. Time after FLAVORx Flavor Addition (± 95%)		
	Day 0	Day 7	Day 14
Control	98.47 (7.17)	101.72 (5.48)	101.45 (4.20)
Watermelon	95.60 (3.52)	102.25 (1.54)	98.29 (1.82)
Banana	93.52 (5.29)	96.92 (4.15)	96.21 (1.82)
Strawberry	97.87 (7.86)	106.20 (4.63)	101.71 (2.70)

Table 2: Average % Potency Relative to Control Sample

Sample	Average % Potency Relative to Control vs. Time after FLAVORx Flavor Addition (± 95%)		
	Day 0	Day 7	Day 14
Control	-	-	-
Watermelon	97.09 (4.87)	100.53 (2.61)	96.89 (2.40)
Banana	94.98 (6.57)	95.29 (2.84)	94.84 (2.46)
Strawberry	99.40 (0.78)	104.40 (3.47)	100.26 (1.49)

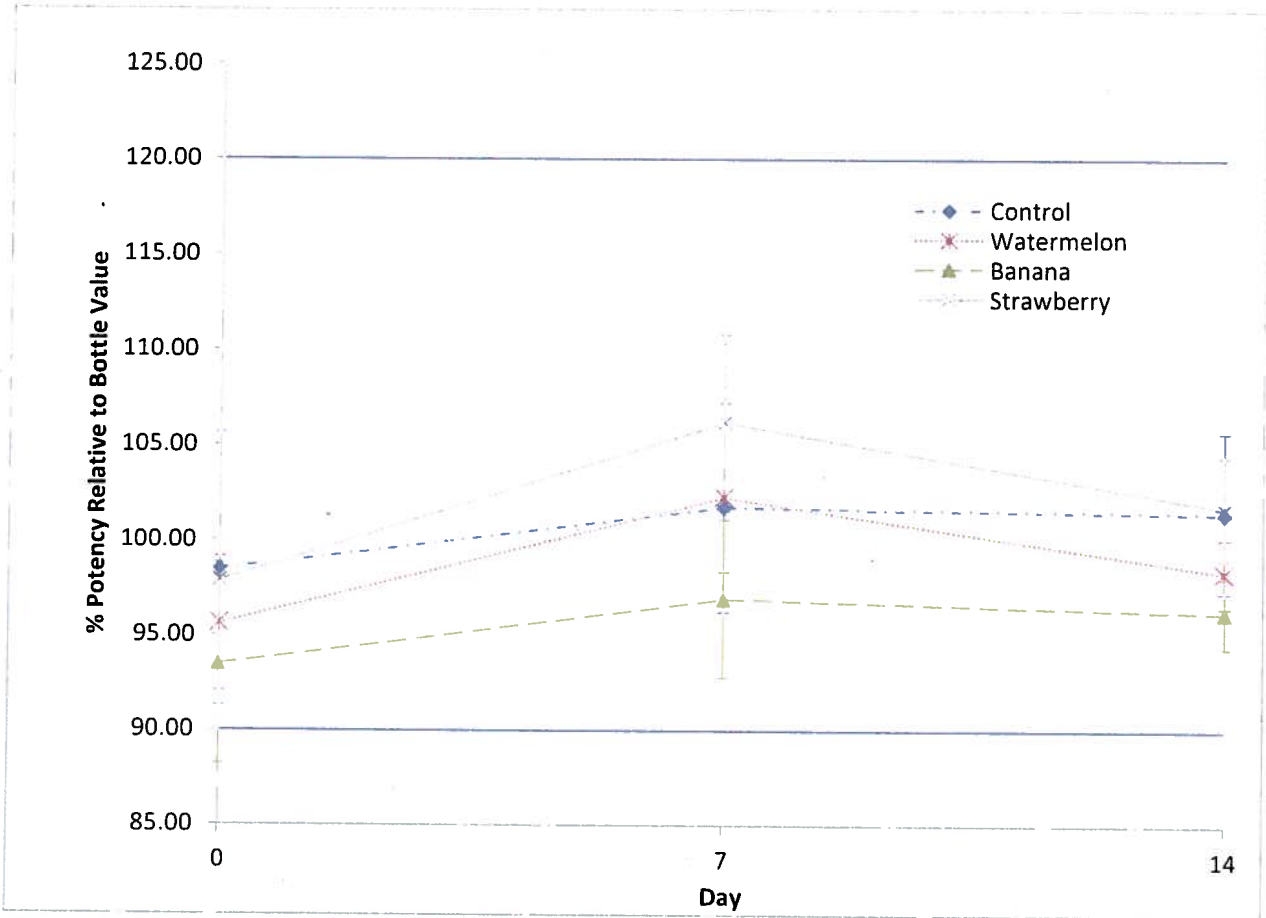


Figure 1: Average % Potency relative to Bottle Value over the 14 day shelf life of the medication. Lines do not represent a fit to an algorithm, they are presented for data clarity.

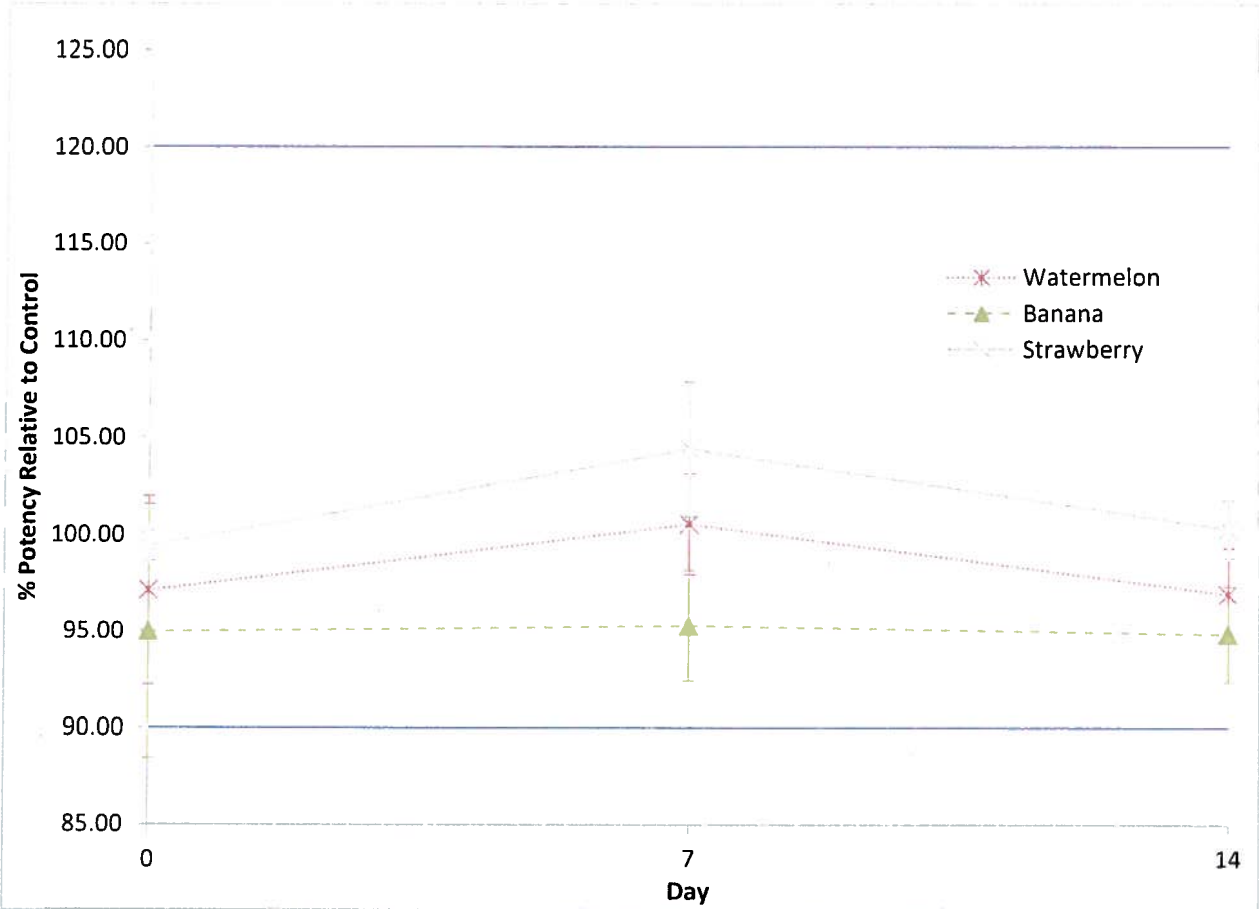


Figure 2: Average % Potency relative to the Control Sample over the 14 day shelf life of the medication. Lines do not represent a fit to an algorithm, they are presented for data clarity.

Physical Appearance/Observations

When reconstituted, the medication had an opaque, turbid appearance. While stored in the refrigerator some of the sample settled out of solution. When diluted in the sample preparation step prior to analysis each sample was cloudy. The smell of each sample was consistent over the two week trial.

Standards Preparation

Standards were prepared by serial dilution. The final volume of all standard solutions prepared was 10mL. To prepare the first standard solution, a quantity of ampicillin trihydrate equivalent to approximately 20mg of ampicillin anhydrous was weighed out in a 10mL volumetric flask. The ampicillin trihydrate was then diluted to the mark with Diluent to a final concentration of approximately 2mg/mL ampicillin anhydrous. Serial dilutions from this initial solution were made to concentrations of approximately 1mg/mL, 0.5mg/mL, 0.1mg/mL and 0.01mg/mL. An aliquot of each standard was transferred to a 2mL glass sample vial to be used with the HPLC.

Sample Preparation

The Ampicillin for Oral Suspension was reconstituted as directed on the bottle. The reconstitution directions instruct that the medication be reconstituted with 70mL of water. 2.3mL of water was removed from this total to account for the addition of the flavors. The medication was then shaken to ensure proper mixing. From the medication bottle, 3 aliquots of 24.425mL of medication were removed and placed into 3 separate containers. Each container will have one flavor and a total volume of 25mL. To prepare the Watermelon flavor, 0.150mL of Watermelon, 0.150mL of Apple and 0.275mL of Sweetening Enhancer were added to one container. To prepare the Banana flavor, 0.275mL of Banana, 0.025mL of water and 0.275mL of Sweetening Enhancer were added to the second container. To prepare the Strawberry flavor, 0.150mL of Strawberry Cream, 0.150mL of water and 0.275mL of Sweetening Enhancer were added to the third container. To the original medication bottle 0.575mL of water was added. This bottle served as the control sample. The final concentration of each solution was 250mg/5mL ampicillin anhydrous.

To prepare the samples for analysis by HPLC each sample needed to be diluted. To prepare these dilutions, 2mL of each sample was transferred into a 100mL volumetric flask. The flask was then brought to volume using Diluent. The final concentration was 1mg/mL. An aliquot of each sample was transferred to a 2mL glass sample vial to be used with the HPLC.

The samples were stored refrigerated for the duration of the analysis. On each day of testing the samples were removed from the refrigerator and shaken prior to dilution in fresh Diluent.

Blank Preparation

For a blank of the Diluent, an aliquot was transferred to a 2mL volumetric flask. Blanks of each of the flavors were prepared by adding the correct quantity of each flavor to a volumetric flask and diluting to the mark with Diluent. Each flavor blank had the same concentration of flavor as each sample. An aliquot was then transferred to a 2mL glass sample vial.

Mobile Phase Composition:

The mobile phase was prepared following the published USP method for Ampicillin.
Water: Acetonitrile: 1M Potassium Phosphate Monobasic: 1N Acetic Acid
(909:80:10:1)

Diluent Composition:

The Diluent was prepared following the published USP method for Ampicillin.
Water: 1M Potassium Phosphate Monobasic: 1N Acetic Acid (989:10:1)

Instrument:

PerkinElmer Flexar HPLC with Quaternary LC Pump and FX UV/VIS UHPLC Detector.

Column:

Phenomenex Gemini-NX 5µm C18, 250x4.60mm
Part #: 00G-4454-E0
S/N: 612008-10

Guard Column:

Phenomenex SecurityGuard Cartridge System
Part #: KJO-4282
Cartridge: Gemini-NX C18 4x3.0mm
Part #: AJO-8368

HPLC Method:

AutoSampler:
Injection Volume: 10µL
Tray Temperature: 4°C
Pump:
Isocratic: 0.700mL/min
Equilibration: 10 minutes
Run Time: 20 minutes
Column Oven:
Isothermal: 30°C
Detector:
UV at a wavelength of 254nm

The blank solutions of the flavors were analyzed only on day 0 to determine how many peaks in the spectrum would be attributed to each flavor. Each sample and standard was injected in triplicate for each day of testing. Potency relative to the control and bottle value was determined from the calibration curve.

Conclusion

The results of this testing showed no significant variation in potency or physical appearance between the control sample and the flavored samples. USP states that Ampicillin for Oral suspension contain not less than 90% and not more than 120% of the labeled amount of Ampicillin when constituted as directed. The physical appearance of the flavored and control samples was consistent over the entire trial. Based on this analysis, ampicillin for oral suspension from any manufacture that has the same formulation and concentration as the medication tested is appropriate to use with these flavors.

Tested By: _____ Date 2/19/2014
Greg Winter

Reviewed By: _____ Date 4/9/2014
William R. LaCourse, Ph.D.