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Stability of Ampicillin in Normal Saline Following Refrigerated Storage and 24-hour Pump Recirculation

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Huskey, Mariah A.; Lewis, Paul O.; and Brown, Stacy D., "Stability of Ampicillin in Normal Saline Following Refrigerated Storage and 24-hour Pump Recirculation" (2020). *Appalachian Student Research Forum.* 8. https://dc.etsu.edu/asrf/2020/presentations/8

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Stability of ampicillin in normal saline following refrigerated storage and 24-hour pump recirculation

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PURPOSE

 Use of ampicillin in outpatient parenteral antimicrobial therapy (OPAT) has historically been complicated by frequent dosing and short beyond use dates. This study investigates the possibility of preparing ampicillin in normal saline for continuous infusion and storing it prior to use.

METHODS

HPLC-UV

- Stability-indicating method development
- Linearity, precision, accuracy, repeatability, and forced degradation

Ampicillin preparation

- 2g vials reconstituted with 10mL SWFI then injected into 250mL NS
- 4 batches per experiment
- · Initial concentrations determined prior to storage

Storage Experiment

- Immediate use
- 24-hour refrigerator storage
- 72-hour refrigerator storage
- 7-day refrigerator storage

Pump circulation

- Continuous circulation (duration 24-hours) through medical grade tubing
- 1-mL aliquots pulled from each batch during recirculation at time 0, 4, 8, 12 and 24 hours

Samples

- Filtered using a 0.22-micron syringe filter
- Analyzed in triplicate with a fresh calibration curve using HPLC method
- Peak area used to determine % recovery
- Acceptable percent recovery was defined as 90-110% of initial concentration

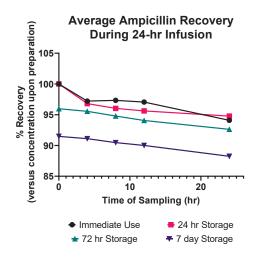
Ampicillin can be prepared and stored in a refrigerator for up to 72-hours prior to continuously infusing at room temperature over 24-hours with less than a 10% loss of potency.



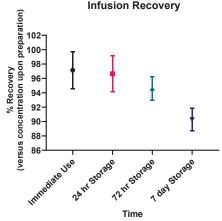


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RESULTS



95% Confidence Intervals for Ampicillin Infusion Recovery



 Percent recovery remained above 90% for all batches and time points except for the 7-day storage experiment after 4 hours of circulation through the medical grade tubing

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