Abstract:
OBJECTIVES: To investigate the effect of pH and buffers on the degradation rate of flucloxacillin and to determine if flucloxacillin can be stabilised using a buffered diluent for up to 14 days when stored at 2°C-8°C including a 24-hour infusion period at 32°C in two elastomeric devices (Accufuser and INfusor LV) filled to 240 mL. Testing as per the NHS Pharmaceutical Quality Assurance Committee Yellow Cover Document (YCD) requirements.

METHODS: A validated stability indicating high-performance liquid chromatography method was used for assessing the stability of flucloxacillin diluted in 0.3% w/v citrate-buffered saline pH 7.0 when stored at 2°C-8°C in two ambulatory devices (Accufuser and INfusor LV). Flucloxacillin at 10 and 50 mg/mL diluted in 0.3% w/v citrate-buffered saline pH 7.0 to a final volume of 240 mL and stored at 2°C-8°C, including 24 hours at 32°C, was tested from two batches in replicate (n=3) at five time points for up to 14 days according to the requirements of the YCD.

RESULTS: Greater than 95% of the zero-time concentration of flucloxacillin at 10 and 50 mg/mL remained when stored at 2°C-8°C after 14 days including 24 hours at 32°C in both Accufuser and INfusor LV devices.

CONCLUSIONS: Flucloxacillin sodium stability was improved, and complied with UK national standards, by using a diluent of 0.3% w/v citrate-buffered saline pH 7 in both Accufuser and INfusor LV ambulatory devices when filled to 240 mL. The data support assigning a shelf-life of up to 14 days (13 days stored at 2°C-8°C and 24 hours at 32°C). Flucloxacillin may now be used appropriately as a continuous 24-hour infusion in outpatient parenteral antimicrobial therapy services, providing further opportunity to avoid or shorten patient hospital stays, as well as support ideal antimicrobial stewardship principles.

Reference:
Full Text