was validated according to the International Conference on Harmonisation Q2 (R1). Four syringes for each condition were prepared. Physical stability was evaluated by visual and subvisual inspection (turbidity by UV spectrophotometry at 350, 410 and 550 nm).

Results For each solvent, solutions at 125 mg/mL retained more than 90% of the initial concentration for 24 hours: for 0.9% NaCl (minimum 96.57%±1.69%; maximum 95.96%±1.38%) and for D5W (94.96%±1.38%; 98.08%±0.48%). After 48 hours of storage, the solutions contained <90% of cloxacinil: a minimum of 89.58%±0.43% for 0.9% NaCl and 89.47%±0.79% for D5W. During the study, pH values decreased progressively during the 48 hours of storage and pH differences were >1 pH unit after 48 hours for both solvents. During the subvisual examination, absorbance values at 410 and 550 nm increased after 48 hours. A colour change was observed at 48 hours (from colourless to very slight yellow) in 0.9% NaCl. In D5W, the solutions stained more quickly; a very slight yellow colouration was visible after 6 hours of storage which intensified after 24 and 48 hours.

Conclusion and relevance Cloxacinil solutions at 125 mg/mL in 0.9% NaCl and D5W were stable in polypropylene syringes for 24 hours at room temperature. The solutions were unstable after 48 hours of storage.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of interest No conflict of interest

3PC-063 PERFORMANCE QUALIFICATION OF ROBOTIC SYSTEM FOR CYTOTOXIC DRUG PREPARATION IN A FULLY GMP COMPLIANT HOSPITAL PHARMACY

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Background and importance A robotic system for automated preparation of cytotoxic drugs, such as APOTECAhemo, ensures reduced occupational exposure to toxic substances and aseptic conditions. The most critical operations are performed by a robotic arm; the operator’s intervention is limited to loading/unloading materials in a rotating warehouse through an unloading/loading area enclosed within a laminar airflow barrier. In European hospital pharmacies which comply with good manufacturing practice (GMP), the performances of the robot are assessed by GMP qualification to confirm that the technology meets the set quality standards.

Aim and objectives The aim of this study was to evaluate microbiological performances and environmental conditions during fully automated preparation with APOTECAhemo in a grade B cleanroom.

Material and methods Effectiveness of laminar airflow retention was checked by potassium iodide (KI) discus test in the unloading/loading area of the APOTECAhemo robot. Aseptic preparation of cytotoxic drugs was evaluated with media fill simulation tests on three consecutive days. In total, 240 products (180 infusion bags, 30 syringes, 30 elastomeric pumps) were automatically filled with single/double strength tryptic soy broth in lieu of drug products. Microbiological environmental controls were performed by passive air sampling (settle plates, four locations), surface sampling (contact plates/swabs, 14 locations), and active air sampling (three locations). Samples were taken for each shift. Media fill products were