28TH EAHP CONGRESS
20-21-22 MARCH 2024
Bordeaux
Sustainable healthcare - Opportunities & strategies

GPI Number: PC13348 bojan.zagar@kclj.si

univerzitetni klinični center ljubljana
University Medical Centre Ljubljana

THE DEVELOPMENT OF HOSPITAL MANUFACTURED READY-TO-USE CEFAZOLIN 100 MG/ML INJECTIONS

B. Žagar, M. Tršan, M. Vehovc, B. Vehar; University medical centre Ljubljana, Pharmacy, Ljubljana, Slovenia

1.**WHAT** WAS DONE?

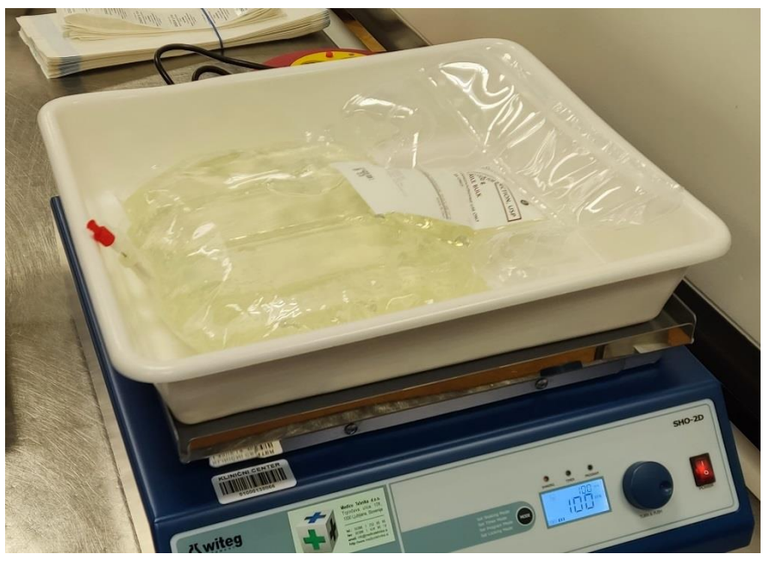
- ✓ Establish a semi-automatic aseptic preparation process, ensure the production of final products that meet quality standards, develop analytical methodologies for in-process and final product quality control, ensure the reliability and validity of test results, and conduct a stability study to confirm long-term storage.

2.**WHY** WAS IT DONE?

- ✓ Cefazolin injection 100 mg/mL is a sterile pharmaceutical formulation comprising cefazolin sodium and water for injections. Traditionally, cefazolin injections were prepared on hospital wards by reconstituting cefazolin sodium powder for injections with water for injections and subsequent dilution before intravenous administration.

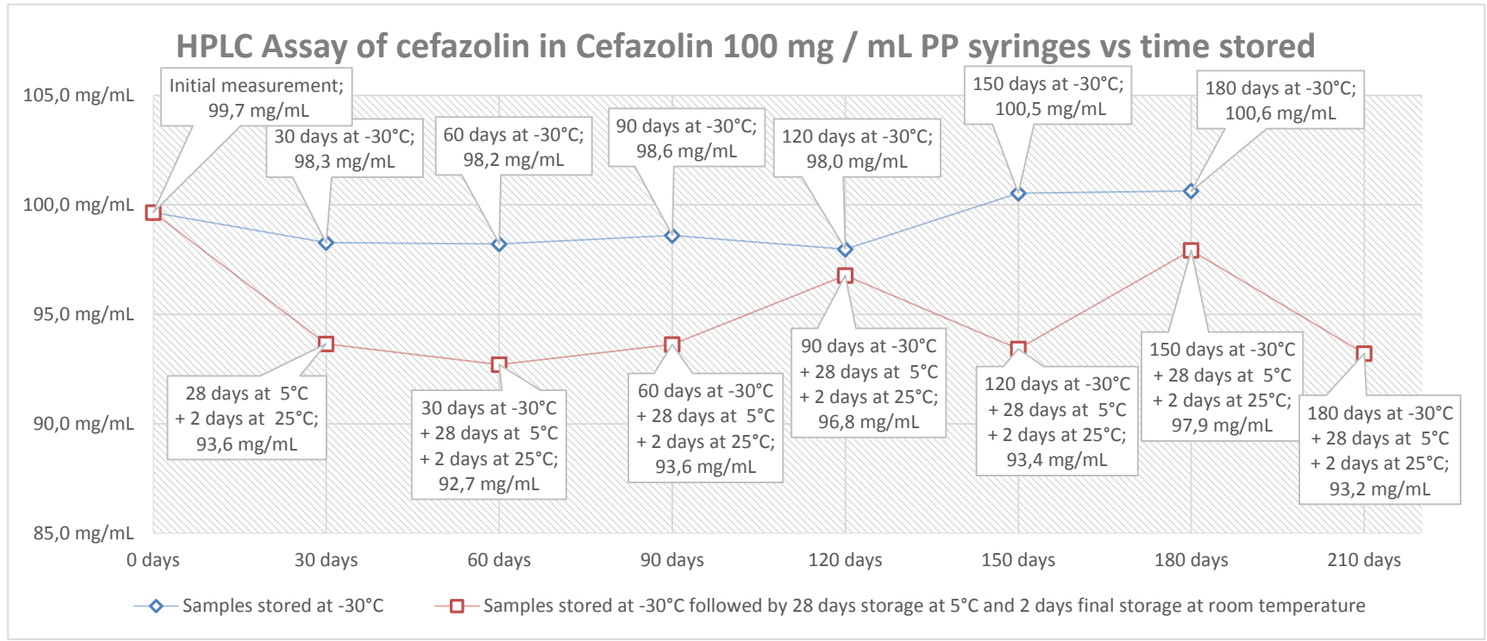
3.**HOW** WAS IT DONE?

- ✓ Product materials include: **Pharmacy Bulk Package** of Cefazolin for Injection, USP, water for injections, Luer Lock 20 mL sterile polypropylene syringes, steribags. Product is prepared with **aseptic technique within a laminar flow unit** situated in a pharmaceutical **cleanroom**.
- ✓ Bulk package is connected to a dispensing device, followed by **reconstitution with water for injections**. In-process samples are collected and volume-adjusted based on density. Following the preparation and dispensing, syringes undergo labeling and packaging into steribags. They are then promptly stored **at -30°C within 4 hours**.
- ✓ Final product samples are obtained and analysed (**pH value, cefazolin content, endotoxins, sterility**) prior to product release.



4.**WHAT** HAS BEEN ACHIEVED?

- ✓ Preparation of **cefazolin sodium injections** in a controlled, aseptic environment utilizing **pre-prepared bags** has successfully addressed critical concerns surrounding the **safety, efficacy, and quality** of these pharmaceuticals when administered on hospital wards.
- ✓ Challenges related to stability and shelf life have been addressed with the storage approach **at -30°C within the pharmacy** for **up to 6 months**, followed by a carefully monitored transition to **ward storage at 5°C** for **up to 28 days**, and subsequent **patient administration at room temperature within 2 days**. The combined shelf life has been confirmed by a ICH compliant stability study (HPLC stability indicating assay, pH, polarimetric analysis, spectrofotometric analysis).



5.**WHAT** NEXT?

- ✓ This approach not only streamlines the process but also safeguards the well-being of patients, marking a significant advancement in pharmaceutical preparation within our healthcare setting.