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What was the background of this work?

Robotic-compounding-systems (RCS) ensure parental medications thanks to a fully automated system controlled by a software. In order to reduce the working area's contaminations and medication errors during pediatric manipulations, in 2021 a new RCS was located into our Hospital-Pharmacy's Centralized-Intravenous-Additive-Service (CIVAS). ApotecaPed is able to compound standard-dose/personalized pediatric medications into appropriate final containers (syringes/bags); all equipment used is carried out into the clean-room through a barcode-system. It also guarantees an aseptic process thanks to HEPA filters and a controlled environment.



What was the aim of this work?

With this work we would like to evaluate ApotecaPed's productivity (total compounding time and dose accuracy) in a production batch of 10 Pantoprazole 4 mg/ml 10 ml and 10 Cefotaxime 50 mg/ml 20 ml syringes; we also evaluated drug's sterility at time 0, 7, 14 and endotoxins' quantification.

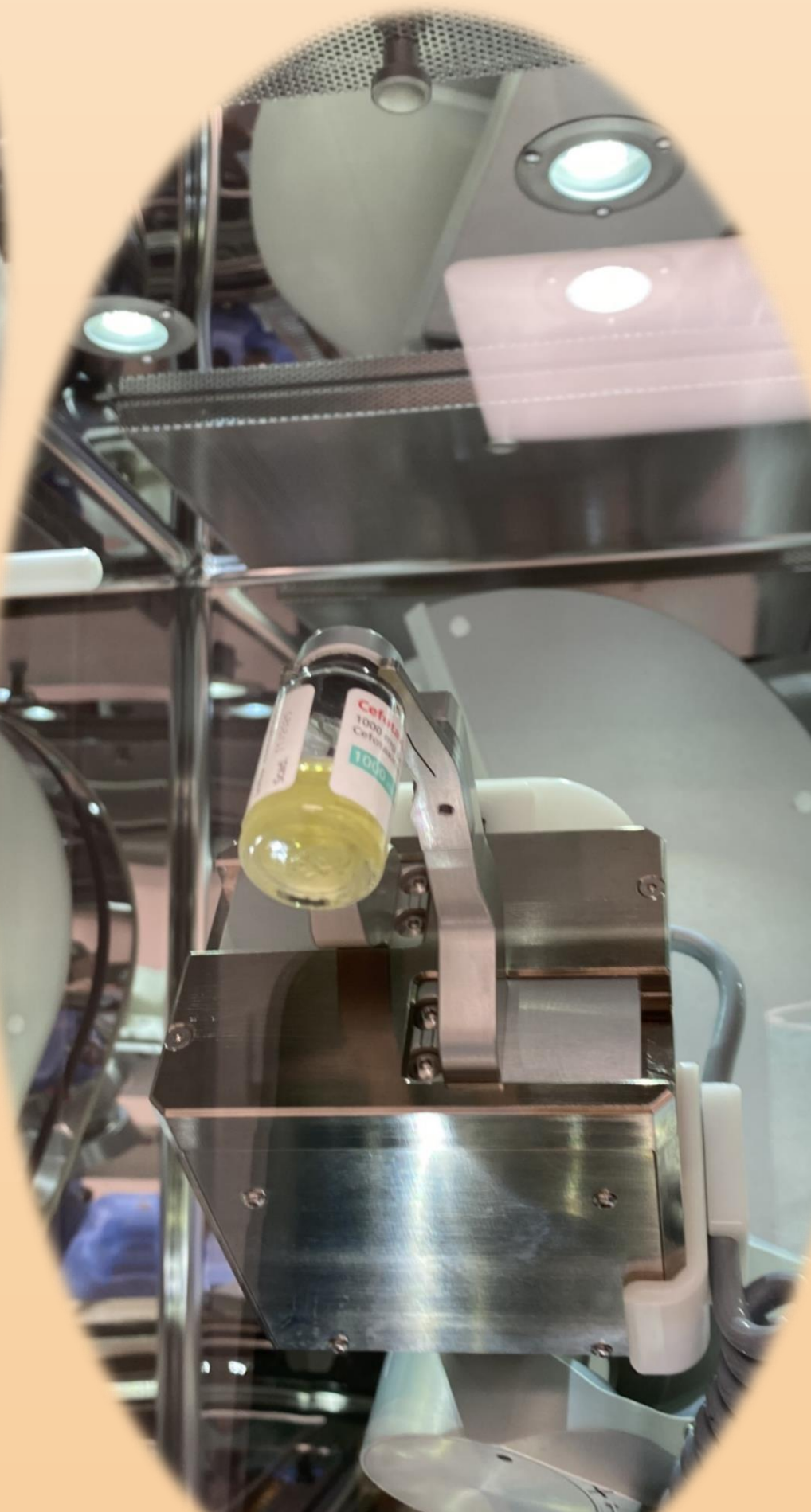
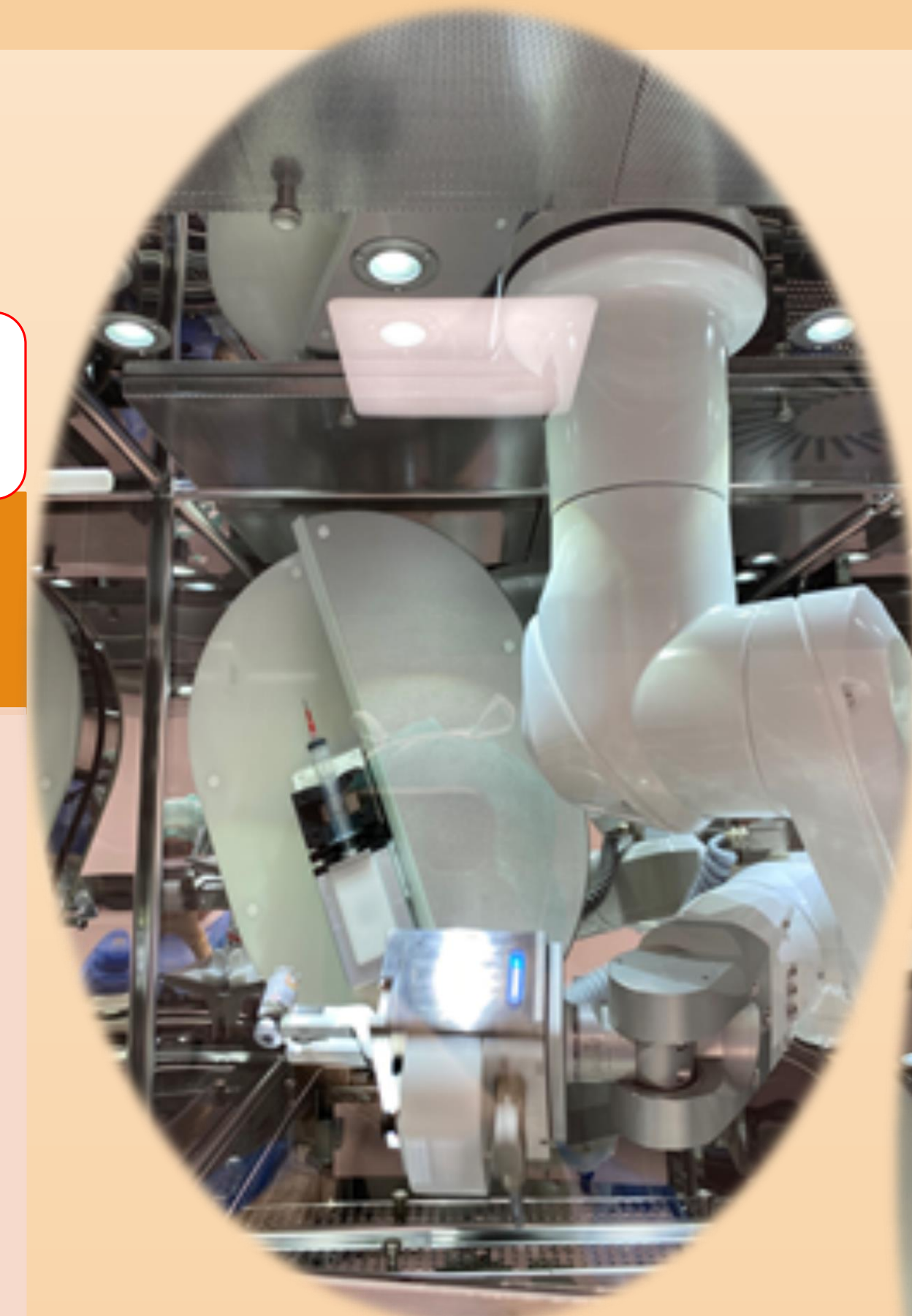
Which methods did we use for this work?

To evaluate dose accuracy and productivity

- Data collection started from ApotecaPed's final reports;
- Dose accuracy was evaluated through gravimetric controls.

To evaluate drug's sterility

- Bacteria (aerobia and anaerobia) and fungi's contamination was evaluated by the Hospital Hygiene Department after inoculation into TSB broth solutions and incubation for 7 days;
- Endotoxins' quantification was done by the Hospital-Pharmacist using a chromogenic kinetik LAL-test method



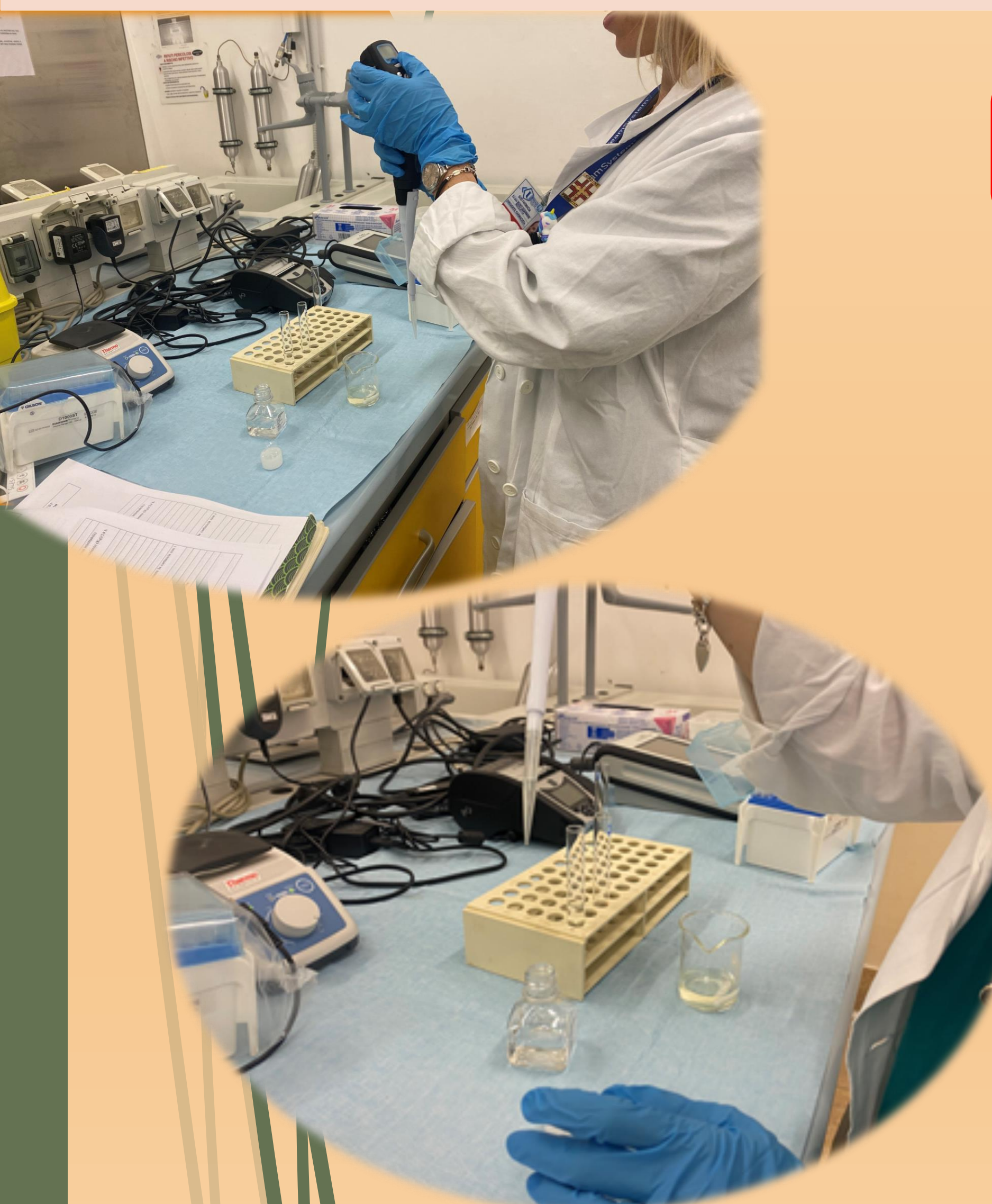
...and the results?

To evaluate dose accuracy and productivity

- Total time to make Pantoprazole's production batch was 57 mminutes (approximately 5 minutes/syringe)(the mean of dose error was - 3,87);
- Total time to make Cefotaxime's production batch was 88 mminutes (approximately 8 minutes/syringe)(the mean of dose error was - 2,12);

To evaluate drug's sterility

- Microbiological tests demonstrated the absence of bacteria and fungi's growth at time 0, 7, 14;
- LAL-test demonstrated that the endotoxins' quantification was under the EL.



Which were the conclusions?

With this study we demonstrated that ApotecaPed guarantees dose accuracy and drug sterility during the compounding. Even if the total robotic preparation time was longer than manual, RCS could reduce humans' errors and increase drugs' safety