

Background and Importance Infusions for epidural analgesia are frequently used in maternity wards to ease pain during childbirth. A standardised concentrate for infusion containing bupivacaine, fentanyl and adrenaline used for general epidural analgesia is produced at the Hospital Pharmacy¹ and diluted in infusion bags by an external compounding unit. Recently, a maternity ward asked the Hospital Pharmacy to prepare a concentrate for infusion more suitable for their patients containing only bupivacaine (in a reduced concentration) and fentanyl, reducing the need for in-house compounded alternatives.

Aim and Objectives To confirm the long-term stability of the newer, more suitable concentrate for infusion through an ongoing stability study.

Material and Methods The concentrate was filled in 50 ml vials and stored at 5°C ± 3°C, protected from light. Samples were assayed by UHPLC as previously described elsewhere,¹ and pH and conductivity were measured. The analytical method is validated for linearity, precision, and specificity. Sterility was tested according to Ph.Eur. 2.6.1.

Results Chemical and microbiological test results during the stability study (mean ±SD, n=3) are summarised in table 1. Concentration of bupivacaine and fentanyl is reported as a percent of release concentration.

Abstract 3PC-029 Table 1

Test	Release	9 months	24 months
Bupivacaine (%)	100.00 (±0.31)	100.88 (±0.09)	101.39 (±0.33)
Fentanyl (%)	100.00 (±0.39)	99.68 (±0.51)	100.68 (±0.53)
pH	4.03 (±0.02)	4.14 (±0.01)	4.30 (±0.04)
Conductivity (mS/cm)	1.696 (±0.001)	1.698 (±0.000)	1.711 (±0.002)
Sterility	No growth	No growth	N/A

Conclusion and Relevance The concentrate for infusion was found stable in terms of drug concentration, conductivity, and sterility. There was a slight increase in pH over time, insignificant to overall stability. Based on the current data, it could be concluded that removing adrenaline from the formulation did not decrease stability, and the shelf life could be set to 9 months similar to the older formulation. Furthermore, the study showed that it might be possible to extend the shelf life to 24 months. Providing the hospital with a ready-to-use product adapted to their needs saves the hospital costs, time, and resources, while increasing quality and patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-031

USABILITY OF SEMI-SOLID EXTRUSION 3D PRINTING IN HOSPITAL PHARMACY SETTINGS TO PRODUCE PERSONALISED ORAL MEDICATIONS FOR PAEDIATRIC PATIENTS

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Background and Importance In paediatric hospitals, the lack of age-appropriate licensed medicines for oral use has traditionally been solved by extemporaneous manufacturing of oral liquids, suspensions, dose powders and capsules in hospital pharmacies, and manual drug manipulation at hospital wards. However, there is still a need for new alternatives to provide personalised child-friendly drug formulations and novel printing technologies may present a solution. Despite the recent progress in the development of 3D printers for pharmaceutical applications, there is a lack of research on their usability in extemporaneous manufacturing in hospital pharmacy settings.

Aim and Objectives The aim of this study was to evaluate the perspectives of hospital pharmacy personnel on the usability of semi-solid extrusion printing.

Material and Methods This qualitative study was conducted as focus group discussions in two university hospitals in two Nordic countries. Pharmacists and pharmacy technicians (n=43) from the hospital pharmacies, working within drug manufacturing, compounding, or quality control, participated. Participants did not have previous experience in using 3D printing. Prior to attending the focus groups, they received a demonstration on a semi-solid extrusion 3D printer (Curify MiniLab, CurifyLabs, Finland) and performed the steps in the manufacturing process. A semi-structured interview guide was used to moderate the discussions, which were audio-recorded and transcribed verbatim. In addition, observations were made during the demonstrations as well as the focus group discussions.

Results Many participants perceived the equipment as easy to use. Suggestions for equipment specific development and process optimisation were brought up in the conversations, such as, use of auxiliary tools, disposable cartridges and nozzles, and printing directly into blisters. Benefits and risks associated with quality perspectives, such as drug accuracy and stability, occupational safety, patient safety, and drug administration were recognised. For example, the 3D printed doses had a pleasant aroma and texture and were easier to produce than dose powders.

Conclusion and Relevance To our knowledge, this is the first study to evaluate the perspectives of hospital pharmacy staff on the usability of semi-solid extrusion printing in drug manufacturing in a hospital environment. Our results show that, despite identified further development needs, the manufacturing process shows great potential.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-032

OPTIMISATION OF AN INSULIN 1 IU/ML EYE DROP FORMULATION FOR THE TREATMENT OF CORNEAL ULCERS

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Background and Importance According to literature, a formulation of regular human insulin (Actrapid®) 1 IU/mL eye drops was elaborated using a solution of artificial tears (Systane Ultra®), in sterile amber glass dropper bottles for the treatment of corneal ulcers. To test the stability, a 30-day galenic