vial at two different storage temperatures over a 28-day period.

Material and Methods Three bevacizumab 25 mg/mL vials (Vegelzma®) each were stored after first opening either light protected at 2–8 °C or at 25 °C for 28 days. Samples were withdrawn on day 0, 1, 7, 14, 21, 28 and analysed with size exclusion chromatography (SEC), ion exchange chromatography (IEC), and dynamic light scattering (DLS). The pH values were measured, and the test vials were visually inspected for visible particles and colour changes at each measuring point.

Results After a 14-day storage period, the quantitative SEC analysis indicated bevacizumab concentrations above 95% of the initial concentration in each test vial. DLS measurements showed no significant variation of the mean hydrodynamic diameter and no appearance of small sized aggregates. IEC analysis revealed no signs of instability. pH values of all samples remained constant, and no visible particles or colour changes were observed.

Conclusion and Relevance Bevacizumab 25 mg/mL concentrate (Vegzelma®) revealed to be physicochemically stable in the original glass vial after first opening for at least 14 days when stored light protected at 2–8 °C or at 25 °C. Investigations are ongoing until day 28 and presented.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest Conflict of interest.

Corporate sponsored research or other substantive relationships:

Research grant by Celltrion Healthcare.

3PC-015 MICROBIOLOGICAL PERFORMANCE QUALIFICATION OF THE ROBOTIC SYSTEMS APOTECASYRINGE AND APOTECAUNIT

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10.1136/ejhpharm-2024-eahp.72

Background and Importance Fully automated aseptic preparation of cytotoxic ready-to-administer (RTA) and ready-to-use (RTU) parenterals is already well established. More recently, innovative robotic systems for the preparation of non-cytotoxic parenterals were brought to the market.

Aim and Objectives The objective of the study was the microbiological performance qualification of the fully automated robotic systems APOTECAsyringe and APOTECAunit (Loccioni, Italy) by media-fill tests and supplemental environmental monitoring in the critical zones.

Material and Methods During the performance qualification phase of the APOTECAsyringe over a 5-day period 500 syringes (10 mL volume) were automatically filled from a bag reservoir containing single-strength tryptic soy broth, capped and labelled. With the APOTECAunit (designed for individual/in series preparation of bags, syringes) over a 10-day period 250 bags and 250 syringes were prepared. Syringes were prepared by dilution of 25 mL of double strength tryptic soy broth with 25 mL of water for injection in 50 mL syringes. Bags were prepared by injection of 50 mL double strength tryptic soy broth into infusion bags prefilled with 50 mL 0.9% sodium chloride solution. Test solutions were incubated at room temperature and visually inspected after 7 and 14 days. Supplemental environmental controls encompassed particle counting, active air sampling (only APOTECAunit), settle plates, contact plates for critical surfaces, and fingerprints. Plates were incubated and colony forming units (cfu) counted.

Results None of the 500 media-fill products prepared by the APOTECAsyringe and 500 products prepared by the APOTECAunit showed turbidity when inspected after 7 and 14 days of incubation, thereby indicating no growth of microorganisms. Particle numbers were below the maximum limits set for cleanroom Grade A, EU-GMP Guide, Annex 1 and cfu counts of the plates met the acceptance criteria.

Conclusion and Relevance APOTECAsyringe and APOTECAunit passed the microbiological performance qualification and allow safe fully automated aseptic preparation of non-cytotoxic RTA and RTU parenterals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-016 PHYSICOCHEMICAL STABILITY OF MOXIFLOXACIN 1 MG/0.2 ML SYRINGES FOR INTRACAMERAL ADMINISTRATION

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10.1136/ejhpharm-2024-eahp.73

Background and Importance Moxifloxacin syringes for intracameral injection are a compounding formula prepared in the Pharmacy Department to prevent endophthalmitis in cataract surgeries.[1] According to the Spanish Good Practice Guides for the preparation of medications in hospital Pharmacy Departments, this compounded formula would have a shelf life of 9 days in the refrigerator (2 °C – 8 °C).[2] This physicochemical stability study is proposed to improve the efficiency in our Pharmacy Service.

Aim and Objectives To characterise the physicochemical stability of intracameral moxifloxacin 1 mg/0.2 ml syringes stored in refrigeration (2 °C – 8 °C) and protected from light for 90 days.

Material and Methods Three 50 ml batches of moxifloxacin were prepared at different concentrations (1, 2, 4, 5, and 7 µg/ml) in a horizontal laminar flow cabinet using water for injection as a solvent, starting from the commercial eye drop Vigamox 5 mg/ml®.

Concentration measurements of moxifloxacin were carried out on days 1, 3, 7, 15, 22, 30, 60, and 90 using a Perkin Elmmer model Lambda 40 UV/visible spectrophotometer at a wavelength of 290 nm (maximum wavelength of moxifloxacin).

Results Throughout the entire analysis period, the moxifloxacin concentrations determined by the spectrophotometer remained constant and within the values accepted by the United States Pharmacopeia that ensure its physicochemical stability (± 10%). In addition, linearity was met in all measurements with a determination coefficient (R^2) > 0.999, indicating that the prepared concentrations of moxifloxacin remained stable over time.

Conclusion and Relevance The formulations of intracameral moxifloxacin 1mg/0.2 ml in water for injection are physicochemically stable at least for 3 months when stored in the refrigerator (2 °C – 8 °C) and protected from light. Further investigation would be advisable to continue with the study in order to extend their shelf life.

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Conflict of Interest No conflict of interest.

3PC-017 ELABORATION OF DEFEROXAMINE EMULSION 0.5% FOR HYPERPIGMENTATION DUE TO INTRAVENOUS IRON EXTRAVASATION

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10.1136/ejhpharm-2024-eahp.74

Background and Importance Cutaneous hyperpigmentation due to iron extravasation is a described adverse effect of its intravenous administration.

Aim and Objectives To describe the components and method of preparation of a 0.5% deferoxamine emulsion for the treatment of hyperpigmentation caused by iron extravasation. To describe the efficacy and tolerance of the pharmaceutical compound on a hospitalised patient.

Material and Methods Literature research was carried out in different databases to determine the clinical evidence and experience. (Google Scholar, PubMed, SEFH formulary, Acofarma website).

In order to assess efficacy and tolerance, direct observation of the stain was performed twice a week for 30 days. Possible colour change, and skin irritation were compared with photographs and interviewing the patient.

Results Composition: deferoxamine 0.5g (commercially available lyophilised powder), propylene glycol 20g; NeoPCL self-emulsifier O/W 25g and purified water in sufficient quantity for 100g. In contrast to the available evidence, Beeler base was not used. Instead, NeoPCL was chosen, which allowed the formation of an aqueous external phase emulsion, not very oily, dense, but easy to apply topically.

Methodology

- Deferoxamine-liophilised was reconstituted with purified water.
- Water, propylene glycol and NeoPCL were weighed separately and placed in a waterbath at 60°C.
- NeoPCL was stirred to facilitate the fusion and propylene glycol was gradually added while stirring to form the oleo-aqueous emulsion.
- Deferoxamine solution was added over the previous mixture, stirring constantly until obtaining the oleo-aqueous emulsion.
- It was stirred for 2–3 minutes with an emulsifier.

The final appearance of PhC was a homogeneous white emulsion with no lumps and no characteristic odour. According to the local Guide of Good Practices, a 30-day expiration period was assigned as well as storage conditions of room temperature and proception from light. Galenic validation was performed, and the emulsion did not lose the characteristics described.

Fifteen days after the extravasation, the emulsion was applied every 12 hours for four weeks. A slight improvement was observed. However, there was complete tolerance to emulsion with no adverse reactions reported.

Conclusion and Relevance The development of the emulsion with a self-emulsifying O/W base ensured that the emulsion remained stable throughout the shelf life.

The results did not match with those described in the literature. Time was a limiting factor to have observed better results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-018 GLASS AMPOULE HANDLING PRACTICES IN DUTCH HEALTHCARE: A COMPREHENSIVE ASSESSMENT

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10.1136/ejhpharm-2024-eahp.75

Background and Importance Glass ampoules are extensively used for intravenous administration, pulmonary nebulisation, and oral preparations such as caffeine. Dutch guidelines recommend filter needles or straws when handling glass ampoules,[1] but compliance remains uncertain.

Aim and Objectives This study aimed to evaluate the utilisation of filter needles/straws, the observation of glass particles, and the disposal of ampoules among pharmacy technicians and nurses. Additionally, we examined the handling of glass ampoules during medication procurement in hospital pharmacies.

Material and Methods We employed an observational approach with a questionnaire developed by Utrecht University's UPPER pharmacy practice research section. The questionnaire covered glass particle management and procurement policies. Pharmacy students conducted interviews with pharmacy technicians (both in the pharmacy and on hospital wards) nurses and pharmacists, during their internships from September to November 2022. Descriptive data analysis was used.

Results Data were gathered from 31 Dutch hospitals, comprising six academic, 15 top clinical, and 10 peripheral institutions. Interviews were conducted with 50 pharmacy technicians in the pharmacy, 51 on the wards, and 50 nurses.

Concerning compounding, 14% of hospitals did not employ filtering techniques, except for intrathecal preparations. On hospital wards, 23% of pharmacy technicians did not employ filtering techniques, rising to 50% for nurses (irregular use).

The results revealed that 82% of pharmacy technicians in the pharmacy encountered glass particles during compounding, rising to 92% on wards and 45% for nurses. In terms of ampoule disposal, approximately 16% of pharmacy technicians in the pharmacy reported discarding ampoules due to the presence of glass particles, compared to 19% on wards and 20% among nurses. Only nine hospital pharmacies had established policies aimed at reducing the procurement of glass ampoules.