Results Sample solution meets the assay requirements with assay 92% acceptance criteria is 90–110%. No significant API degradation and related substances were noticed. Samples stored in plastic bottles showed assay increase up to 26% compared to samples in glass bottles where reported growth is up to 5%.

Conclusion and Relevance Clindamycin hydrochloride solution for topical use can be made from oral pharmaceutical forms. Compounding process did not have relevant impact to assay of API. Molecule is stable at least 112 days under mentioned conditions. However, assay increase was noticed in plastic HDPE bottles due to vehiculum evaporation which is more expressed in samples conditioned in elevated temperatures. Container closure system should enable adequate closing between cap and bottle which is a key parameter to be considered.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. James R. Falconer, Kathryn J. Steadman. Extemporaneously compounded medicines. *Australian Prescriber*, 2017;Vol.**40**(1).
2. Hitesh Chavda. In-Use stability guidelines and challenges. *Drug Development and Industrial Pharmacy*, 2021;Vol.**47**(9).
3. European Medicines Agency, Committee for proprietary medicinal products (CPMP), In-use stability testing of human medicinal products – Scientific guideline.

Conflict of Interest No conflict of interest.

3PC-002 STABILITY OF TENECTEPLASE SYRINGES AFTER FRACTIONATION

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Background and Importance Tenecteplase is a recombinant plasminogen activator protein indicated in adults for the thrombolytic treatment of suspected myocardial infarction within 6 hours of symptom onset. The Spanish Agency of Medicines and Health Products reported a shortage of tenecteplase. Therefore, a tenecteplase fractionation protocol was developed in our pharmacy service based on a study that analysed the stability and bioactivity of frozen syringes (-20°C or -70°C) for 1-month[1], admitting up to six freeze/thaw cycles. No studies exploring stability and bioactivity beyond this have been performed.

Aim and Objectives To evaluate the physical and chemical stability of frozen syringes of reconstituted tenecteplase over a 2-month period using proton nuclear magnetic resonance (1H-NMR).

Material and Methods Tenecteplase was reconstituted and fractionated in 5mg/1mL syringes. They were stored at -20°C and evaluated at days 0, 30, 45 and 60. Physical parameters were monitored: turbidity and colour. Chemical stability was evaluated by 1H-NMR spectroscopy. The spectroscopic signals were interpreted and assigned to the chemical structure of tenecteplase and subsequently compared with the spectra at days 30, 45 and 60. All spectra were acquired using a Bruker Avance DRX 500 MHz spectrometer.

Results In terms of physical parameters there appears to be no difference between the syringe at day 0 and at days 30, 45 and 60. Regarding chemical stability, the spectrum resulting from the syringe at day 30 does not show significant differences compared to the reference spectrum. However, when comparing the spectrum of the syringe at day 45 with the reference spectrum, there do appear to be significant changes that call into question the stability and bioactivity of the fractionated reconstituted tenecteplase. Therefore, the study was stopped and the spectrum at day 60 was not compared with the reference spectrum.

Conclusion and Relevance This study seems to confirm the stability (physical and chemical) and bioactivity of tenecteplase syringes frozen at -20°C for a month. However, it does not seem to maintain chemical stability at 45 days, so it is assumed that at 2 months it has no stability.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Semba CP, Weck S, Razavi MK, Tuomi L, Patapoff T. Tenecteplase: stability and bioactivity of thawed or diluted solutions used in peripheral thrombolysis. *J Vasc Interv Radiol.* 2003.Apr;**14**(4):475–9.

Conflict of Interest No conflict of interest.

3PC-003 SUITABILITY OF ELASTOMERIC PUMPS FOR DRUG STORAGE

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Background and Importance Elastomeric pumps (EP) are self-sufficient delivery systems for the continuous intravenous administration of drugs and are mainly used in outpatient settings (e.g. oncology, infectiology).

The product-contacting materials of EP consist of various polymers and additives. In contrast to sterile plastic syringes, data on leachables for EP are only available in individual cases.[1]

Aim and Objectives In order to assess the suitability of the EP for the storage of drug solutions, a transfer of substances from the pump material into the drug solution was investigated.

Furthermore, the weight loss of the pump contents due to the water vapour permeability of the plastic layers was determined, which can lead to an increased concentration of active substances.

Material and Methods Seven different EP devices were examined: 5 to 10 pumps of each device were filled with isotonic sodium chloride solution. At day 1, 7, 28, 90 and 180 the pump contents were quantified to determine the water vapour permeability as well as according to Ph. Eur. 3.3.8 in terms of absorption, acidic or alkaline reacting and reducing substances.

By means of HPLC-MS leachables were identified from a database of 200 substances and recorded semi-quantitatively.[2]

Results Six of seven EP showed weight loss <8% after 180 days (upper limit: 9.0%). One device showed weight loss ≤7.0% at 90 days and ≥11.4% at 180 days.

All seven EP devices met the requirements according to the monograph Ph. Eur. 3.3.8 regarding absorption, acidic or alkaline reacting and reducing substances.

The transfer of up to five antioxidants and plasticisers into the contained isotonic sodium chloride solutions was detected by HPLC-MS for all seven EP devices from day 1.

Conclusion and Relevance Regarding water vapour permeability and the adapted requirements from Ph. Eur. 3.3.8 six EP devices are suitable for 180 days and one for 90 days for the storage of drug solutions.

The effects of the identified leachables on the human organism are the subject of current investigations and cannot be assessed conclusively at present.[3]

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Trittler R, Hauk A, Hug MJ. *Krankenhauspharmazie*. 2016;**37**:479–84.
2. Bello W, Pezzatti J, Berger-Gryllakia M, Rudaz S, Sadeghipour S. *J. Pharm. Biomed. Anal.* **236**(2023):115640.
3. https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/[cited: 04.09.2023].

Conflict of Interest No conflict of interest.

3PC-004 DRUG WASTE OF READY-TO-ADMINISTER SYRINGES IN THE INTENSIVE CARE UNIT: ASEPTICALLY PREPARED SYRINGES VERSUS PREFILLED STERILISED SYRINGES

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Background and Importance The availability of ready-to-administer (RTA) syringes for intravenous drugs facilitates rapid and safe administration in emergency and intensive care situations. However, the preparation of these syringes in hospital pharmacies via aseptic batchwise filling results in significant drug waste due to excess production and their limited microbiological shelf-life of 31 days, which contributes to considerable environmental pollution. RTA sterilised syringes have much longer shelf-lives (up to 36 months) than aseptically prepared RTA syringes and might contribute to reducing drug waste.
Aim and Objectives This study aimed to evaluate the difference in drug waste between RTA syringes that were prepared through aseptic batchwise filling in the hospital pharmacy and RTA sterilised syringes (produced in a large-scale compounding pharmacy) in the Intensive Care Unit (ICU).
Material and Methods In a 32-bed mixed medical-surgical ICU, drug waste of RTA syringes was measured over an 8-year period from August 2015 to May 2023. An intervention group of three drug products that were replaced by RTA sterilised syringes (potassium chloride 60 mmol = 60 ml, midazolam 50 mg = 50 ml and morphine 50 mg = 50 ml) was compared to a control group of five drug products that were not replaced by sterilised syringes during the study period. Statistical analysis included a Kruskall-Wallis test along with two interrupted time series (ITS) analyses to assess and visualise the effect of different study periods on waste percentages.
Results A total of 319,621 RTA syringes were dispensed by our hospital pharmacy during the study period. Introduction of RTA sterilised syringes significantly decreased drug waste of RTA syringes irrespective of drug type in the intervention group, from 31% before introduction to only 5% after introduction ($p<0.001$). The control group showed no significant decrease in drug waste over the same time periods (from 20% to 16%; $p = 0.726$). The ITS model of the intervention group showed a direct decrease of 17.7% in waste percentage after the introduction of the RTA sterilised syringes ($p = 0.083$).
Conclusion and Relevance RTA sterilised syringes can significantly reduce drug waste in the ICU, supporting hospitals to enhance environmental sustainability.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

Conflict of Interest No conflict of interest.

3PC-005 PREPARATION OF EPICUTANEOUS TESTS WITH MINOXIDIL AT 2% AND 5%

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Background and Importance Topical minoxidil solution is a safe and effective treatment for alopecia. However, some patients present pruritus and scalping. Patients suffering from allergic contact dermatitis may benefit from patch testing to determine the causative allergen. In the few reported cases of suspected hypersensitivity to topical minoxidil, propyleneglycol triggered the allergic response in the majority of cases.
Aim and Objectives Describe the design, preparation and results of patch tests and prick tests for minoxidil.
Material and Methods The allergology department requested to perform minoxidil patch tests and prick tests for a patient with suspected type IV hypersensitivity.

The pharmacy department proposed carrying out a battery of epicutaneous tests, both for minoxidil and the excipients present in the commercial drug the patient used.

For patch tests two different vehicles were used in the compounding: Vaseline (usual excipient for patch tests) and dimethyl sulfoxide (DMSO) since it has been described for its involvement in increasing the skin penetration of the accompanying active ingredient.
Results As the commercial drug the patient used had alcohol and propyleneglycol as excipients, the following battery of epicutaneous syringe tests for minoxidil patch test was designed:

- Minoxidil 2 and 5% in liquid Vaseline (compounded as 20 mg and 50 mg in 1 mL).
- Minoxidil 2 and 5% in DMSO (compounded as 20 mg and 50 mg in 1 mL).
- 1 mL of liquid Vaseline.
- 1 mL of DMSO.
- 1 mL of propyleneglycol 10, 50 and 100%.
- 1 mL 70° alcohol.

Additionally, the pharmacy prepared the following syringes for prick tests:

- Sterile minoxidil 2 and 5% in sodium chloride 0.9% (compounded as 20 mg and 50 mg in 1 mL).
- Propyleneglycol prick test was obtained commercially.

The compounding was prepared ready to use.

Results after exposure were negative in the immediate readings, as well as at 48 and 96 hours, ruling out this drug and its excipients as causing the hypersensitivity.
Conclusion and Relevance The design and preparation of patch tests and prick tests are key when it comes to dismiss