

Background and importance Newly formulated Thiotepa Riemser was approved in 2021 for conditioning treatment before allogeneic or autologous haematopoietic progenitor cell transplantation.

Prior to administration Thiotepa Riemser is reconstituted with water for injection and diluted with 0.9% sodium chloride or 5% glucose (G5) infusion solutions. According to the *Summary of Product Characteristics*, the ready-to-administer (RTA) infusion solutions are physicochemically stable for 24 hours stored at 2–8°C or 4 hours stored at room temperature. To our knowledge, long-term stability data have not yet been published. Of note, physicochemical stability improves when G5 infusion solutions are used as vehicle solutions.

Aim and objectives Due to lack of long-term stability data for newly formulated Thiotepa Riemser RTA solutions, the physicochemical in-use stability of diluted infusion solutions in pre-filled G5 infusion bags was investigated.

Material and methods Thiotepa Riemser 1 mg/mL, 2 mg/mL and 3 mg/mL test solutions were prepared in triplicate using pre-filled 5% glucose polyolefin bags. Test solutions were stored at 2–8°C or 25°C for 14 days. Directly after dilution and on days 1, 3, 5, 7, 14 the test solutions were inspected and samples withdrawn. Thiotepa concentrations were measured by a stability-indicating high-performance liquid chromatography (HPLC) method, adapted from the Thiotepa monographs in the British and US Pharmacopoeias. In parallel, pH and osmolality were measured. Non-visible particles were counted in the test solutions on days 0 and 14.

Results When Thiotepa Riemser test solutions were stored at 2–8°C, thiotepa concentrations remained above 98% of the initial concentration for 14 days. When stored at 25°C, thiotepa concentrations fell below 95% of the initial concentration after 3 days in 1 mg/mL solutions, 5 days in 2 mg/mL solutions and 7 days in 3 mg/mL solutions.

Peaks of unspecified impurities were detected in the chromatograms of all test solutions directly after dilution and degradation peaks increased during the storage time. Particle counts and osmolality remained unchanged in most test solutions. Values of pH increased slightly, especially when test solutions were stored at 25°C.

Conclusion and relevance Thiotepa Riemser infusion solutions diluted with G5 are physicochemically stable for 14 days when refrigerated and depending on the concentration for 3–7 days when stored at 25°C. Evaluation of the amount and relevance of unspecified impurities is ongoing.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest Corporate sponsored research or other substantive relationships: research grant from Riemser Pharma GmbH Germany.

3PC-033

Y-SITE COMPATIBILITY OF INTRAVENOUS NEFOPAM WITH MEDICATIONS COMMONLY USED IN INTENSIVE CARE UNITS

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Background and importance Patients hospitalised in intensive care units (ICUs) often require many drug infusions. Due to limited intravenous (IV) accesses, concomitant administration

of drugs in the same infusion line is usually necessary. Compatibility studies of Y-site administrations are available in the literature, but many data are lacking. Previous work¹ identified a list of Y-site administrations without compatibility data.

Aim and objectives Nefopam, a non-opioid analgesic, is usually administered in critical care units. The aim of this study was to evaluate the physical compatibility of nefopam with other drugs used in ICUs, to secure the Y-site administration of IV drugs.

Material and methods Compatibility of nefopam with nine drugs commonly used in ICUs has been tested (calcium chloride, cefotaxime, hydrocortisone, isosorbide, magnesium, nicardipine, pyridoxine, thiamine, tramadol). These drugs were diluted in different solvents (water for injection, 0.9% sodium chloride (NaCl), 5% dextrose (D5W), 10% dextrose, Isofundine) or used pure, leading to 21 pairs being tested. For each pair, three ratios were evaluated (nefopam 80–160 µg/mL/drug B: 9/1; 1/1; 1/9). Physical compatibility examinations were performed on each mixture after preparation, and after 1-hour and 4-hour storage. This evaluation included a visual examination with the search for precipitation formation, colour change, gas formation, and a subvisual evaluation: absorbance measurements by ultraviolet (UV) spectrophotometry at 350, 410 and 550 nm, and the light obscuration particle count test. pH evaluation was performed at each analysis time point.

Results 20/21 pairs tested were compatible (95%), conforming for all items. The mixture nefopam (160 µg/mL – 0.9% NaCl) with cefotaxime (40 mg/mL – D5W) at a ratio of 1/9 revealed a subvisual incompatibility by particle counting at each time studied, while no visual change was observed.

Conclusion and relevance These laboratory tests demonstrated the compatibility of 20 pairs containing nefopam. The pair with a high concentration of cefotaxime showed particle counting, allowing the incompatibility of nefopam (160 µg/mL – 0.9% NaCl) with cefotaxime (40 mg/mL – D5W) to be concluded. New compatibility data are now available to secure IV administration. These results cannot be extrapolated for mixtures of more than two drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-034

DEVELOPMENT AND VALIDATION OF A METHOD FOR THE DETERMINATION OF VANCOMYCIN EYE DROPS BY ULTRAVIOLET-VISIBLE SPECTROPHOTOMETRY

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Background and importance Vancomycin is used as fortified eye drops for the treatment of bacterial keratitis. Given the absence of an available equivalent speciality, the hospital pharmacy prepares these eye drops under aseptic conditions. Content uniformity is required before each batch is released.

Aim and objectives The objective of this study was the development and validation of a method for vancomycin eye drops dosage by ultraviolet-visible spectrophotometry.

Material and methods Analyses were performed at 280 nm. The method was validated according to the International Conference on Harmonisation (ICH) Q2(R1): specificity, linearity, repeatability, intermediate precision, accuracy, limit of detection, limit of quantification. Memory effect, vial equivalence and background noise were studied. Five standard solutions were performed from 0.1 to 0.4 mg/mL and a 200th dilution to analyse the samples. A relative standard deviation (RSD) of 5% was accepted for each of the criteria.

Results The method was specific. The equivalence of vials was demonstrated with a variation of 0.58%. The background noise measured variations up to 0.00097 mg/mL. Linearity was established with the equation $y=4.6489x-0.0256$ and $R^2=0.9975$. RSD were 1.91% for repeatability and 4.65% for intermediate precision. The recovery rates varied between 98.5% and 101.9%. The limit of detection was 0.007 mg/mL and the limit of quantification was 0.021 mg/mL.

Conclusion and relevance When measuring accuracy, the prepared eye drops had a vancomycin concentration of 45 mg/mL and not 50 mg/mL as expected. After questioning our manufacturing protocol we questioned our supplier. The powder vials contained a quantity of vancomycin base equivalent to an antimicrobiological activity of 1 000 000 UI/vial. Legislation requires presentation in milligrams and UI. The amount of vancomycin base in a vial therefore varied between 850 mg and 950 mg depending on the initial content of active ingredient and was not 1 g as indicated.

The analytical method was validated. The method is suitable for routine use due to its speed and accuracy allowing a control before release of each batch of our eye drops.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-035 MINIMISING WASTE IN ONCOLOGY

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Background and importance The rise of promising new cancer therapies and their costs represents a colossal challenge for health systems. In addition, we face daily restrictions on the supply of cytotoxic drugs, while the number of patients is increasing. The Cytotoxic Centralised Units (CCUs) allow the optimised use of cytotoxics and monoclonal antibodies vials between treatments. There is, however, a significant waste of drugs, due to the impossibility to reuse the vials if they lose the sterility conditions provided by the biosafety chamber, at the end of the working day. Closed system transfer devices (CSTDs) were initially developed to minimise occupational exposure during cytotoxic preparation. They represent an important additional resource providing safety for the technician and facilitating work operations in the chamber. Recent data supporting the extent of the physical and chemical stability of drugs and the sterility provided by the CSTD in an aseptic environment allow the remaining amounts of each vial to be stored and reused.

Aim and objectives Assess the profitability of the use of CSTDs in the CCU.

Material and methods Several models of CSTDs were analysed concerning their safety performance and ergonomic design. The Tevadaptor model was the one selected. During 2020,

the daily records of wastes and savings of each oncologic drug vial were compared, as well as the comparison between the saving on opening new vials versus the annual cost for the acquisition of the CSTDs.

Results The increase in the annual budget reached the amount of € 14 934. The analysis of the number of vials that were spared with the reuse of the waste of each day resulted in a total annual savings of € 205 665.05. The balance is clearly positive for the institution, with an economic outcome of € 190 731.

Conclusion and relevance The innovation cost in oncology, combined with a context of frequent shortages, offers constant challenges to hospital budgets and makes it imperative to reduce daily waste with drugs. The use of CSTDs is a strategy that entails additional costs but allows maximisation of the use of the vial, always respecting the physical-chemical and microbiological stability of each drug, offering additional security in the working area and decreasing the risk of occupational exposure.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Section 4: Clinical pharmacy services

4CPS-002 COVID-19 HOSPITAL VACCINATION CENTRE: PATIENT AND NURSE SATISFACTION

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Background and importance The COVID-19 pandemic has challenged all countries in a race against infection and the emergence of variants. Vaccination campaigns were the answer to this public health crisis.

In our university hospital, a multidisciplinary team was mobilised for the opening of two vaccination centres (VCs): for health professionals and for patients with high risk of severe COVID-19 illness according to national health authority guidelines.

Aim and objectives The aims of our study were to collect patient and nurse satisfaction regarding these VCs and to identify adverse events (AEs) related to vial manipulation.

Material and methods This prospective study was conducted from April to May 2021. Two satisfaction questionnaires for patients and nurses were created, each containing 13 questions subdivided into four items. Patient items were: organisation of vaccination, care, service and quality of care. Nurse items were: VC organisation, handling of vials and syringes and interprofessionalism. Responses were rated from 'poor' to 'very good'.

Results Over 1 month, 51 patient questionnaires and 4 nurse questionnaires were collected.

Regarding patient satisfaction, 82% of respondents expressed 'very good' satisfaction with their medical care. VC location and the convenience of the vaccination boxes received 61% and 65% of 'very good' ratings. Some patients mentioned low confidentiality measures.

The nurses' general satisfaction was 100% 'very good', as well as the cooperation with the pharmacy department. As for the information technology (IT) service, 50% answered 'rather bad'. The impact of the media on their activity was perceived as 'bad' for half of them and 'average' for the other half.