short period (2 months) and the PIs refused were not collected.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-029 STUDY OF PSMA11-68GA ADSORPTION ON MEDICAL DEVICES USED FOR RADIOSYNTHESIS AND MEDIA FILL TEST

[1]F Durieux*, [1,2]B Dekyndt, [1,2]JF Legrand, [2]F Semah. [1]*CHU de Lille, Institut de Pharmacie, Lille, France*; [2]*CHU de Lille, Hôpital Roger Salengro, Service de Médecine Nucléaire, Lille, France*

10.1136/ejhpharm-2022-eahp.52

Background and importance PSMA-11 labelled with gallium-68 (PSMA11-68Ga) is a diagnostic radiopharmaceutical. Labelling is performed in a Trasis Mini all-in-one synthesiser. Sterile excipients, solvents and devices are necessary to produce a sterile and pyrogen-free injectable solution.

Aim and objectives The aim of this study was device evaluation. Two aspects were investigated: the sterility of the final preparation and the absorption of PSMA11-68Ga on the device.

Material and methods Device adsorption evaluation: radioactivity was measured with an ISOMED 2010 activity meter. PSMA11-68Ga labelling was performed and five syringes of 5 mL were filled with 1 mL from the preparation vial every 30 min after the end of the preparation. The weight activity (MBq/mg) of the preparation vial and syringes was calculated, measuring the activity and weight of each of them. At the end of the labelling process, the PSMA11-Ga68 preparation was totally filled in the preparation vial. The residual activity of different parts of the device were measured: the elution vial, the five syringes, the extraction cartridge, the synthesiser garbage, the vented filter, and three additional syringes were measured after three rinses with sodium chloride within 1 hour to 5 hours after elution. Finally, the activity of the elution vial at the end of the elution step and the activity of the final preparation vial at the end of the labelling process were compared on nine syntheses.

Final preparation sterility: media fill tests (MFT) were performed on three syntheses, replacing the excipients and solvents with tryptone-casein-soybean solution. A fertility test was performed with concentrated bacterial strains in accordance with the European Pharmacopoeia.

Results The weight activity difference between the final preparation vial and the five syringes were between 4% and 7%. Residual activities in the syringes, the vented filter, the waste garbage, the extraction cartridge and the three additional syringes were between 0.2% and 5% of the elution activity. The activity variation between the elution and final preparation vials were between –4% and +5%. The MFT did not show microbiological contamination after 14 days of incubation at 37°C. The fertility test was positive after 24 hours of incubation.

Conclusion and relevance These results show that the adsorption of PSMA11-68Ga on medical devices used for synthesis appeared to be limited. The MFT performed show that the manufacturing process was aseptic.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-030 DIFFERENT SUBSTRATES FOR ORODISPERSIBLE FILMS: YOU HAVE THE CHOICE!

S Sauer*, AN Weber, T Hoppe-Tichy. *University Hospital Heidelberg, Pharmacy Department, Heidelberg, Germany*

10.1136/ejhpharm-2022-eahp.53

Background and importance Orodispersible films (ODF) are thin layers of a polymer that can be loaded with an active ingredient (API). This could be realised during the film-forming process or afterwards. Different polymers produce different film properties (eg, dissolution behaviour). So, you have the choice!

Aim and objectives Films of different compositions and heights were produced and investigated. The aim was to estimate whether the resulting films are appropriate candidates for further processing.

Material and methods Four formulations were chosen based on: (1) polyvinyl alcohol (PVA), (2) hydroxypropylmethylcellulose (HPMC), (3) HPMC with microcrystalline cellulose (MCC) and (4) starch.

The ODF based on starch was a commercial product, an 'edible paper'. ODF were produced with solvent casting and different heights. After drying, pieces were investigated for appearance, residual moisture and dissolution time.

Results The dried films differed in resulting thickness. Edible paper was the thickest followed by the mixture of HPMC and MCC, then PVA and finally HPMC. The very thin films of HPMC were difficult to handle.

All the films look different: PVA is white and very flexible. HPMC is colourless and flexible also. It becomes sticky when it comes into contact with water. When MCC is mixed with HPMC the films are white and too brittle to handle. Edible paper is green (colourant added) and also brittle, but is easy to handle.

Residual moisture depends especially on the formulation. PVA has ~1%–2%, HPMC MCC ~5%, starch ~7% and HPMC ~7%–10%.

Dissolution time depends on both the formulation and the height of the films. Starch takes more than 15 min and HPMC up to 3 min. Both formulations become sticky when they come into contact with water. The others predominantly show times under 1 min.

Conclusion and relevance Investigations revealed the different characteristics of the resulting films. The stickiness and prolonged dissolution time could be useful for mucoadhesial formulations. Mixture with MCC shortens the dissolution time but increases the brittleness. This formulation could be optimised. PVA and starch exhibit the easiest handling.

Incorporation of API should be possible for all formulations that were casted when API is dissolved. If the API is to be loaded after film production (eg, via inkjet printing) PVA and starch are promising candidates.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-031 PHYSICOCHEMICAL STABILITY OF DILUTED 'THIOTEPA RIEMSER' INFUSION SOLUTIONS IN PREFILLED 5% GLUCOSE INFUSION BAGS

H Linxweiler*, J Thiesen, I Krämer. *University Medical Center Johannes Gutenberg University Mainz, Pharmacy Department, Mainz, Germany*

10.1136/ejhpharm-2022-eahp.54

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 prefilled 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 prefilled 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

[1]G Ayari*, [1,2]E D'Huart, [1,2]J Vigneron, [1,2,3]B Demore. *[1]Centre Hospitalier Universitaire Hôpital Brabois Adultes, Pharmacy Department, Vandœuvre-lès-Nancy, France; [2]Infostab (Non-Profit Association), Heillecourt, France; [3]Lorraine University, Nancy, France*

10.1136/ejhpharm-2022-eahp.55

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 work[1] 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.

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Conflict of interest No conflict of interest

3PC-034 DEVELOPMENT AND VALIDATION OF A METHOD FOR THE DETERMINATION OF VANCOMYCIN EYE DROPS BY ULTRAVIOLET-VISIBLE SPECTROPHOTOMETRY

[1]B Mathat*, [1]C Delaunay, [1]E Olivier, [2]C Herrenknecht, [1]N Cormier. *[1]CHU Nantes Hôtel Dieu, Pharmacotechnics, Nantes, France; [2]University of Pharmacy, Analytical Chemistry, Nantes, France*

10.1136/ejhpharm-2022-eahp.56

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.