stability and its capacity to interact with plastic components, due to the presence of Polysorbate 80 as excipient into the formulation. The PVC perfusion system, intact of any chemotherapy administration, was analysed, as a blank sample, corresponding to a NaCl 0.9% bag.

Results HPLC analysis showed that the MS10 tubing (Fresenius Kabi) was plasticised by triethylhexyl trimellitate (TOTM), while the four route link (CAIR LGL) and the Connect-Z link (CAIR LGL) were plasticised by DINCH and TOTM. No trace of plasticiser was found after the 1-hour administration of chemotherapies. No trace of chemotherapy was found in the samples of the perfusion system used for the injection of either Etopophos or etoposide.

Conclusion and relevance No interaction between the PVC perfusion system and the chemotherapies Etopophos and etoposide was found in real-life conditions. However, further analysis, using a larger number of samples, other dosages of chemotherapies or in static conditions, to exacerbate the contact between the drug and the system may be necessary to confirm these results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-012 IMPACT OF PRELIMINARY WIPING OF EQUIPMENT INTRODUCED INTO A CLEANROOM ON THE CONTROL OF THE ENVIRONMENT

[1]F Durieux*, [1]C Nassar, [1,2]D Lannoy, [1,2]P Odou. [1]*Chu Lille, Pharmacy, Lille, France*; [2]*Lille University, ULR7365 Grita, Lille, France*

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Background and importance Parenteral nutrition is a high-risk activity. It is necessary to master and control the preparation environment. Within our parenteral nutrition unit, a decontamination airlock (Malochet) with hydrogen peroxide (H_2O_2) (Clarus, Bioquell) is used to bring the equipment (medical devices, glass nutrient bottles) into the cleanroom. They are introduced directly from an ISO 8 area into the airlock, without systematic wiping.

Aim and objectives The goal was to improve environmental control by studying the impact of preliminary wiping of equipment entering the cleanroom before or after surface decontamination with H_2O_2.

Material and methods The same operator performed surface swabs on medical devices (paper and plastic sides) and glass nutrient bottles. The wiping method was the same for all: 1 pre-impregnated wipe (55% ethanol and quaternary ammonium propionate) per piece of equipment. The airlock was qualified (4 log decontamination, 9-min dwell phase). 6 cycles were performed for 70 samples. For each cycle, before decontamination, 3 swabs were carried out after a prior wiping (on plastic, glass and paper sides) and 4 without wiping (on plastic, glass and two paper sides), then 7 swabs on those pieces of equipment after decontamination. Inoculation on tryptocasein soy agar was performed for each swab. Agar plates were incubated for 3 days at 32°C and 4 days at room temperature. Colony-forming units (CFU) were read on days 3 and 7. Data were collected in an Excel file and analysed with Mann–Whitney and Welch tests.

Results The difference in the number of CFU at 7 days between the groups without wiping and with wiping before decontamination was significant *($p<0.01$)* but not significant after decontamination *($p=0.17$)*. The difference between the groups before decontamination with wiping and after decontamination without wiping was not significant *($p=0.079$)*, but with a strong trend. Most of the contamination found after decontamination was bacteria. A mould was found after decontamination.

Conclusion and relevance This study shows that contamination brought in by equipment is possible. Wiping reduces the risk of contamination when decontamination by H_2O_2 is not possible. It seems important to limit storage inside the cleanroom to avoid a release of contamination into the air.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-013 PHARMACEUTICAL COMPOUNDING IN PAEDIATRIC PATCH TESTING: ARE WE SURE ABOUT THE ACTUAL ACTIVE INGREDIENT CONCENTRATION?

[1]AM Agüí Callejas*, [1]M Cuervas-Mons Vendrell, [2]M Bernaola Abraira, [1]D González Andrés, [1]M Arrieta Loitegui, [1]P Ranz Ortega, [1]MT Pozas Del Río. [1]*Hospital Infantil Niño Jesús, Pharmacy, Madrid, Spain*; [2]*Hospital Infantil Niño Jesús, Allergy, Madrid, Spain*

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Background and importance Large diferences in active ingredient concentrations (AI) in drug patch tests, as a result of the drug source chosen, signify the need for further studies to ensure the quality of the preparations.

Aim and objectives To analyse the variability of the resulting AI concentrations in paediatric patch tests, according to the commercialised forms (CFs) used.

Material and methods A review of the recommendations for drug patch tests preparation was carried out using PubMed.

For the Allergy Department requested compounds, when no pure drug was commercially available, the CFs were used instead. In the latter case, following Spanish Society of Allergy and Clinical Immunology (SEAIC) recommendations, the CF weights were used, rather than their AI content, to obtain the prescribed drug concentration in the compounds. Finally, the actual AI concentration in each compound was calculated.

Results The SEAIC and the European Society of Contact Dermatitis recommendations were followed, whenever possible, using the pure drug, and when this was not available, resorting to the CF. Eight drugs were diluted by the Pharmacy Department at different concentrations in petrolatum. The only drugs whose manufacturers provided the pure drug were amoxicillin and doxycycline. When diluting the content of the capsules of phenoxymethylpenicillin potassium at 10%, the AI concentration obtained was 8%; however, when using the oral powder it was 1.4%. The same thing happened when diluting tablets of cefuroxime at 20%, namely the AI concentration obtained was 11%, while if using the oral powder it was 1.2%. For ampicillin at 5%, using the capsules the AI concentration obtained was 4.25%. When preparing brivaracetam at 30% and rufinamide at 3%, using the available tablets the AI concentrations obtained were 5.34% and 1.63%, respectively. However, when diluting the capsules of ethosuximide at 20%, the AI concentration obtained was 15.8%.

Conclusion and relevance The actual AI concentrations in the compounds vary depending on the CF used.Using the CF with the lowest amount of excipients allows one to obtain AI concentrations closer to those usually proposed by scientific societies. The results obtained demonstrate the need to

establish protocols with the Allergy Department in order to standardise the preparation and thereby assure quality and security in paediatric patch testing.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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3PC-014 EVALUATION OF THE MICROBIOLOGICAL QUALITY OF NON-STERILE DRUGS PREPARED IN A HOSPITAL PHARMACY

S Widmer*, S Deuster. *University Hospital Basel, Hospital Pharmacy, Basel, Switzerland*

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Background and importance Pharmaceutical compounding is an integral part of the services provided by pharmacies for the specific needs of patients. For these pharmaceutical preparations the requirements of the European Pharmacopoeia (EP) regarding the microbiological quality apply, namely that in the manufacture and packaging, as well as during storage and distribution, suitable measures have to be taken to ensure their microbial quality.
Aim and objectives This study evaluated the microbiological quality of non-sterile pharmaceutical preparations of the hospital pharmacy of a University Hospital. A risk-based approach was chosen for the identification of the most microbiologically susceptible non-sterile pharmaceutical preparations.
Material and methods A risk matrix of all 42 non-sterile pharmaceutical stock preparations was created, taking into account the characteristics of the active substance and the formulation, as well as the manufacturing process risk of the individual pharmaceutical dose form. To confirm the microbiological quality, tests were conducted using membrane filtration and the surface-spread method according to EP 2.6.12. Suitability tests were carried out in the presence and absence of the selected products with five American Type Culture Collection (ATCC) test strains.
Results The risk evaluation resulted in seven non-sterile pharmaceuticals of the different pharmaceutical dosage forms with a high microbial risk: calcium glycerophosphate capsules, clobetasol adhesive gel, EEG gel, misoprostol capsules, opium tincture, propranolol solution and sucrose solution, to be tested according to EP 2.6.12. The permitted recovery rate of the test strains of 50% to 200% was fulfilled for all tested products and the chosen method was suitable for the specific products. The seven worst-case products were tested in duplicate and only the opium tincture and the EEG gel showed a microbial growth of one and three colony-forming units (CFU), respectively. These results are fully within the requirements of the pharmacopoeia.
Conclusion and relevance This study demonstrates that non-sterile production of different dosage forms (including packaging and storage) in a hospital pharmacy can guarantee the microbiological quality of pharmaceutical preparations. Only neglectable microbiological growth even of the pharmaceutical preparations with the greatest risk was observed, so that overall the requirements of the pharmacopoeia are fulfilled.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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3PC-016 VANCOMYCIN EYE DROPS AT 50 MG/ML: PHYSICOCHEMICAL STABILITY, IMPACT OF PACKAGING AND STORAGE CONDITIONS

B Gouverneur*, B Gouverneur, M Roche, C Berneron, A Margolle, L Creton, C Nassar, D Lannoy, P Odou. *CHU Lille, Pharmacy Institut, Lille, France*

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Background and importance Vancomycin eyedrops (VED) are unavailable in Europe and are usually compounded as extemporaneous in hospital pharmacies.
Aim and objectives To collect data on VED physicochemical stability in three different containers stored either refrigerated or frozen.
Material and methods VED at 50 mg/ml (10 mL) were aseptically compounded under a laminar flow hood from injectable vancomycin and sterile water for injection (Baxter) and stored in amber glass (n=26; Gravis), classical (n=26; CAT) or innovative Novelia (n=26; Nemera) low-density polyethylene (LDPE) bottles. Assays were performed according to GERPAC-SFPC stability studies guidelines on vials stored either at 2–8°C (analysis at days D1-D3-D7-D15-D40-D60-D90) or frozen at –20°C for 60 days, then thawed (room temperature (RT) or 2–8°C) and refrigerated once thawed (post-thaw analysis at D1-D3-D7-D20). At each time point in the study vancomycin concentration (using a stability-indicating HPLC-UV method), pH and osmolality were determined, and the visual aspect was checked. Sterility and non-visible particle count (by light obscuration particle count test) were performed at the beginning and end of the study. Non-parametric tests were used to compare containers and storage conditions (α=5%).
Results Vancomycin concentration (mean ± standard deviation; expressed as a percentage of the initial value) when stored at 2–8°C from D1 to D60 was between 95.7±1.6% and 107.4±2.1% (except at D7, due to material bias) and 89.5±1.6% and 92.8±1.9% at D90. Vancomycin concentration in vials thawed at RT or 2–8°C was, respectively, between 95.8±1.1% and 102.2±4.3% and 95.3±2.3% and 101.1±4.1% at D7 and between 89.3±1.8% and 93.9±0.6% and 89.9±0.8% and 92.7±1.2% at D20 after thawing. No significant difference was found between packaging (p=0.323) or thawing method (p=0.736). pH and osmolality, respectively, 3.31±0.06 and 46.12±3.61 mOsm/kg, remained stable with no difference between containers (p=0.242 and p=0.414) or thawing methods (p=0.287 and p=0.999). A slight yellow colouration of VED (2–8°C) was perceived after D60. A slight increase in non-visible particles count was observed between D1 and D90 in glass and classic LDPE but values complied with the European Pharmacopoeia 2.9.19 threshold.
Conclusion and relevance VED remained stable for 2 months refrigerated or frozen, and for 7 days after thawing (RT or 2–8°C). These results will allow the preparation of a stock of VED that is available immediately. A microbiological stability study in real conditions of use should complete this work.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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