

- Outpatient scheduling
- Training in our actual software, good clinical practice and the compounding process
- Evaluate other programmes that include sterile compounding
- Periodic revision of the processing forms
- Strategic placement or marking active ingredients/excipients susceptible to cause confusion
- More microbiological controls
- Periodic revalidation of technicians
- Reduce technician turnover and less multitasking
- Measures we could prioritise would be those related to technicians training and revalidation.

**Conclusion and Relevance** Several critical points were detected in our process of sterile and non-sterile compounding. We found some measures that could help us to reduce risk of errors, but we think that we should prioritise those related to technicians training and revalidation.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

**Conflict of Interest** No conflict of interest.

#### 3PC-043 INTRAVITREAL PREPARATION OF LIPOSOMAL B AMPHOTERICIN: FROM FORMULATION STUDY TO PREPARATION

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**Background and Importance** Fungal vitreitis is a vitreous body infection that falls within the broader field of endophthalmitis. The therapy for this pathology is the intravitreal injection of antifungal drugs that can be accompanied by topical or intravenous administration of the same antifungal drug. The pharmacy had to respond to a request for intravitreal preparation of liposomal b amphotericin 0.01mg/0.1ml. The rational use of the liposomal formulation has been the elective toxicity in the eye compared to the non-liposomal formulation of which are reported in the literature possible adverse events.

**Aim and Objectives** The purpose of this paper is to describe the process which led to the formulation and compounding of the intravitreal preparation.

**Material and Methods** The existing scientific literature has been analysed in order to identify the correct procedure for setting up the required galenic preparation. The compounding has been studied from bibliographical data and discussed internally by our team of pharmacists, laboratory technicians and nurses.

**Results** For the preparation, carried out with aseptic technique, amphotericin b liposomiale 50 mg powder for parenteral use was used. The drug was reconstituted with 12 ml of water for injectable preparation (APPI) to obtain a concentration of 4 mg/ml. The preparation had to be carefully shaken for about 30 seconds to ensure complete dissolution. 2,5 ml of reconstituted solution were taken and then a 5-micron filter was applied and injected into a 100 ml APPI bottle previously emptied of the same ml. A 0,1 mg/ml concentration solution was obtained. 0,3 ml of the final solution was then transferred to a 1 ml luer lock syringe and closed with a self-sealing device. A second syringe has been prepared for microbiological control.

**Conclusion and Relevance** Clinical galenics has been instrumental in ensuring therapeutic opportunities not available with commercially available medicines for the personalised treatment of a patient with fungal vitreitis associated with chorioretinitis. The pharmacist is essential for the particular knowledge of the drug in the field of formulation of galenic prescriptions magistral and laboratory technicians and nurses for the implementation of the same.

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#### 3PC-044 A PHYSICO-CHEMICAL STABILITY STUDY OF VANCOMYCIN EYE DROPS AFTER DIFFERENT THAWING TIMES

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**Background and Importance** In our establishment, an excursion temperature occurred on our freezer containing the hospital preparation including vancomycin eye drops 25 mg/mL. Due to the lack of data, a quarantine of the eye drops was necessary, resulting in a time interval without eye drops preparation. It was necessary to quickly obtain vancomycin eye drops from the other hospitals. Remember that vancomycin eye drops are indicated for the treatment of bacterial keratitis and corneal abscesses.

**Aim and Objectives** We would like to create four scenarios with different thawing times (0.5h, 2h, 6h and 12h) to imagine different situations can meet users of eye drops to check the stability of the eye drop after 7 days.

**Material and Methods** After total defrosting the eye drop have been put back to the freezer. After an interval time of at least 48h at -20°C the eye drop was thawed and stored in the fridge condition between 2 and 8°C for 7 days to mimic a normal use. The assay of vancomycin and degradation products has been determined by HPLC at the end of the first thawing time (J0) and at day 0, 3 and 7 of the fridge storage for each batch (D0, D3 and D7). One batch per scenario was tested, each batch contained three samples and each sample was assayed in triplicate.

Detection of the analyte was performed by UV and mass spectrometry ( $\lambda=280\text{nm}$  and 725 Da). Likewise, detection of degradation products was carried out by diode array UV and mass spectrometer detector (210 nm to 400 nm and 50–1500 Da).

**Results** With all these scenarios, we demonstrated that vancomycin eye drops is stable at D7 after 12 hours of thawing. The average variation in vancomycin concentration is less than 5%. No degradation products were observed.

**Conclusion and Relevance** This physico-chemical study could be reproduced for our other hospital eye drop preparation (ceftazidime and amikacine) which are also used for corneal infections. Then, a microbiological study could be done in the same condition to prove sterility of eye drops after a thawing cycle. These first promising results will permit to avoid quarantine after unintentionally thawing of frozen eye drop preparations.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-045

### RETROSPECTIVE STUDY OVER 6 YEARS OF THE TREND IN FUNGAL CONTAMINATION OF CONTROLLED ATMOSPHERE AREAS WITHIN A CELL THERAPY UNIT

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**Background and Importance** Moulds are aerobic eukaryotic organisms naturally present in the environment. According to regulations, no mould should be present in a controlled-atmosphere zone (ZAC).

According to the literature, fungal spores can reach significant quantities, up to several 10, 000's of particles/m<sup>3</sup> of ambient air. The highest concentrations are found during the summer-autumn period in Europe. *Cladosporium spp* is the predominant species in most studies, with concentrations of over 4,000 CFU/m<sup>3</sup> of ambient air.

The trend in outdoor air contamination is well known, but few articles deal with the trend in fungal contamination in ZACs.

**Aim and Objectives** The primary objective of this study was to determine whether there is a seasonal trend in contamination in ZACs. The secondary objectives were to determine the most frequent moulds and the effect of factors such as air conditioning, hygrometry and temperature on fungal contamination in ZACs.

**Material and Methods** Based on microbiological surveillance register of the ZACs at the Saint-Ismier cell therapy and engineering unit, we collected the contaminated samples without counting the number of CFUs contained in this contamination. When available, identification was provided. The variables of temperature, hygrometry and air conditioning were collected using centralised technical management software for equipment and premises. All the data collected was recorded manually in a Microsoft Excel spreadsheet, with data double-checked at the time of collection. Statistical tests were performed on this table.

**Results** The results of the trend analysis showed a significant difference between fungal contamination frequencies in ZACs depending on the season. Autumn and summer are the seasons with the highest risk of fungal contamination. The main species in our study were *Cladosporium, spp* and *Penicillium, spp*.

**Conclusion and Relevance** These results show that the evolution of fungal contamination in ZACs reflects that of external environment. Indeed, although ZAC air treatment systems are capable of filtering large quantities of fungal spores, factors such as personnel, materials and consumables are potential vectors for microbial transfer.

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3PC-046

### RISK OF PERSONNEL EXPOSURE TO HAZARDOUS DRUGS IN ROBOTIC COMPOUNDING

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**Background and Importance** Continuous occupational exposure to hazardous drugs (HD) poses significant risks to healthcare personnel. Robotic compounding systems have been introduced in pharmacies to enhance patient and staff safety. These systems operate within enclosed ISO Class 5 environments with negative pressure, which effectively minimising personnel exposure to HD during critical operations. However, there is a concern that surfaces in the compounding area may get contaminated, potentially exposing hospital personnel to these hazardous substances.

**Aim and Objectives** The primary objective of this study was to evaluate the risk of occupational exposure to HD when utilising robotic compounding systems for the preparation of anti-neoplastic sterile medications. Specifically, we aim to assess the levels of HDs present on the surfaces of ready-to-use preparations and on the gloves worn by personnel involved in the compounding process.

**Material and Methods** This study was conducted over a period of 3 days during routine production at KIRO Oncology (Kiro Grifols, Mondragon, Spain). Each day, we collected wipe samples from the surfaces of 20 HD preparations and from the gloves of the operator engaged in the compounding process using Cytoxlab sampling kits (CYTOXLab, Geneva, Switzerland). Our analysis included the detection and quantification of 25 anticancer molecules commonly used in hospital pharmacies.

**Results** Throughout the study, 19 different drugs were compounded by the robot, including 5-fluorouracil, bevacizumab, carboplatin, cisplatin, cyclophosphamide, docetaxel, doxorubicin, eribulin, etoposide, gemcitabine, irinotecan, nivolumab, oxaliplatin, paclitaxel, panitumumab, pembrolizumab, pemetrexed, trastuzumab, and vinorelbine. We observed only a negligible amount of gemcitabine, which fell below the quantification limit (<0.005 ng/cm<sup>2</sup>), on the surfaces of two out of the 20 bags and on two of the operator's gloves.

**Conclusion and Relevance** The results of this study demonstrate that levels of HD surface contamination in robotic compounding are exceedingly low and, in most cases, undetectable. Occupational exposure to HD remains consistently below 0.1 ng/cm<sup>2</sup>, a threshold deemed 'safe' according to certain studies. This finding assures the safety of the compounding personnel and other hospital staff members involved in cancer treatment.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-047

### PAEDIATRIC IV ANTIFUNGAL ADMIXTURES: CENTRALISATION'S ECONOMIC CONSEQUENCES

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