partially used and perforated with a plastic spike, not PFL at room temperature.

Material and methods The stability study was performed by high performance liquid chromatography coupled to a photodiode array detector. The method was validated according to the International Conference on Harmonisation guideline Q2 (R1). Physical stability was evaluated by visual and subvisual inspection. pH values were measured.

Results PDA solutions PFL in D5W at 3 and 12 mg/mL retained more than 95% of the initial concentration after 7 days at 25°C and after 28 days at 2–8°C. PDA ready to dilute 25 mg/mL solutions PFL retained >95% of the initial concentration after 28 days at 25°C and 2–8°C. PDA solutions in D5W at 3 mg/mL and 12 mg/mL and PDA ready to dilute 25 mg/mL solutions not PFL retained >95% of the initial concentration after 7 days at room temperature. All samples had a pH in the range 8.05–8.77. A very light colouration, described in summary of product characteristics, to a more intense yellow–brown colouration, appeared depending on concentration and time. No precipitate was observed.

Conclusion and relevance According to the manufacturer's specifications (colourless to slightly brown–yellow) and to the chemical stability, defined as >95% of the initial concentration, PDA solutions in D5W at 3 and 12 mg/mL and PDA ready to dilute 25 mg/mL solutions PFL were stable for 7 days at 25°C and for 28 days at 2–8°C. PDA solutions in D5W at 3 and 12 mg/mL and PDA ready to dilute 25 mg/mL solutions not PFL were stable for 7 days at room temperature.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-021

STORAGE OF NIVOLUMAB PEMBROLIZUMAB AND DARATUMUMAB FOR 14 DAYS AFTER COMPOUNDING IN THE HOSPITAL PHARMACY: A MICROBIOLOGICAL STABILITY STUDY

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Background and importance Viable microorganisms and/or endotoxins administered parenterally via contaminated preparations may lead to nosocomial infections, SIRS/sepsis and increased mortality of patients. The pharmacist has the responsibility to ensure that the product is stable in the final administered preparation.

Aim and objectives To verify if monoclonal antibodies such as nivolumab, pembrolizumab and daratumumab are promoters or inhibitors of microbial growth. Moreover, the microbiological stability of dilutions at clinically relevant concentrations were verified over a 14 day period.

Material and methods Samples, reconstituted according to the summary of product characteristics (SPC) in 1 mL syringes, were injected into standardised suspensions of *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans*.¹ At different time points (ie, 0, 1, 3, 5, 24, 48 and 144 hours) an aliquot of 0.01 mL, containing about 100 CFU, was transferred to the trypticase soy agar plate and sabouraud dextrose agar+chloramphenicol plate. After 24 hours of incubation at

37°C, samples were assayed. Moreover, a total of 24 syringes were stored for 1, 3, 6, 7, 10 and 14 days before being incubated to determine microbiological stability according to the EP method.

Results The results showed that 144 hours after inoculation no colony forming units were detected for *the C albicans* and *S aureus* strains. The only microorganism that survived after 5 days was *P aeruginosa*. Comparing the control with the samples analysed, no significant growth or reduction in microorganisms were observed. The samples were all clear after 14 days of incubation.

Conclusion and relevance Compared with the control, no significant growth or reduction in microorganisms were observed, indicating that the monoclonal antibodies investigated cannot be used by the strains as substrates for their survival. It can also be deduced that these monoclonal antibodies have no bactericidal or bacteriostatic actions. Under these conditions, the monoclonal antibodies were microbiologically stable for 14 days. In conclusion, when data on 'in use' stability' are available for a period of 14 days, a new model of patient management in the day hospital and drug preparation in the hospital pharmacy could be organised.

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No conflict of interest.

3PC-022

PARTICULATE QUALITY OF A CONTROLLED ATMOSPHERE AREA. COMPLIANCE WITH GOOD MANUFACTURING PRACTICES AT REST AND DURING ACTIVITY, HIGHLIGHTING FACTORS IMPACTING ON CONTAMINATION

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Background and importance The activity of chemotherapy preparations is constantly evolving:

1. It is increasing (+17% in our centre in 5 years).
2. Particulate quality monitoring is recommended but rarely done in hospital pharmacies.

The pharmacist, who is responsible for this activity, must anticipate these changes.

Aim and objectives We first demonstrated the compliance of our controlled atmosphere area with the ISO 7 (at rest) and ISO 8 (during activity) criteria. Then we determined the factors significantly impacting on the particle rate in order to design a mathematical model that would predict the number of particles and thus better control the increase in activity.

Material and methods The particle count was carried out according to the requirements of the ISO 7 and ISO 8 standards (particle size, sampling plan, volume, duration and height). We systematically recorded the following factors: date, time, number of people present in the controlled area, temperature, pressure, sampling location, sampling conditions (at rest or during activity) and equipment entering the ZAC mechanically cleaned or not. For the statistical analysis, a grouping of sampling points by critical sector (personnel entry

and exit area, work area itself, material transfer and basket preparation area) was carried out. Data were analysed to perform the multivariate models required for predictive mathematical modelling (significant variables at the $p=0.05$ threshold).

Results All 994 samples (from 16 counting points) in our 80 m² depressed area complied with the ISO 7 and ISO 8 criteria for particulate contamination. Predictive mathematical modelling of the number of particles was based on the significant criteria 'time of day', 'location of sampling' and 'number of people'.

Conclusion and relevance Particulate quality criteria were met at rest and especially during activity (which is rarely evaluated). These results could be related to the technical quality of the air plant (all new air and 25 air changes/hour) and the materials and characteristics of the PPE used (low particle release). By taking into account the factors integrated in the mathematical models, smoothing the number of people over the day and increasing the cleaning of risk areas, it will be possible to guarantee and better understand the particular quality of our areas.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-023 DEVELOPMENT AND VALIDATION OF A DISCRIMINATIVE METHOD FOR ANTHRACYCLINES USED IN ONCOLOGY BY VISIBLE SPECTROMETER

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Background and importance Anthracyclines are among the most used anticancer drugs in haematology-oncology, especially in the treatment of solid tumours and leukaemia. High performance liquid chromatography coupled with spectrometry is a well established method in the control of hospital chemotherapy preparations. However, it remains an expensive method, especially in low income countries. In recent years, UV visible spectrometry associated with partial least square discriminant regression has been used as a method for qualitative and quantitative analysis of drugs in the same therapeutic or physicochemical class.

Aim and objectives The aim of the study was to develop a rapid spectrophotometric method for the discrimination of anthracyclines used in chemotherapy in a paediatric haematology-oncology centre by combining UV visible and partial least square analysis (PLS-DA).

Material and methods Different anthracyclines used routinely (daunorubicin, doxorubicin and epirubicin) were diluted with sodium chloride 0.5% at different concentrations. They were then analysed using a UV vis spectrometer at a wavelength ranging from 300 to 800 nm. Concentrations corresponding to an absorbance of <1 ($A < 1$) were selected for the study. A calibration model was developed by PLS-DA with 25 samples per product. This model was then optimised and validated using three samples per product by projecting them into the space of the latent variables. The statistical software 'the

Abstract 3PC-023 Figure 1

Unscramble X.10.4' performed the chemometric analysis of the data.

Results The model discriminated between the three compounds with a calibration error RMSEC of 0.098 and a regression coefficient of 0.96. Figure 1 shows the factor map of individuals (plot scores) in the 2–3 plane of the PLS-DA result obtained. All validation samples were correctly assigned with 100% accuracy.

Conclusion and relevance This study demonstrated the potential of screw spectrometry associated with the PLS-DA chemometric tool for anthracycline discrimination. It is promising because of its low acquisition cost, speed and ease of use. A calibration range of drug concentrations could allow quantitative control of chemotherapy preparations in the hospital.

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3PC-024 THE EFFECTS OF FREEZE–THAW CYCLING ON THE STABILITY OF THE ADALIMUMAB BIOSIMILAR SB5

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Background and importance Temperature excursions may occur during manufacturing, storage, the distribution process and during clinical trials. Limited data are available to hospital pharmacists to support decision making following temperature excursions.

Aim and objectives To evaluate the stability of SB5 prefilled syringes (PFS) following short term exposure to high and low temperature conditions.

Material and methods SB5 prefilled syringes obtained from a single lot were exposed to three freeze–thaw cycles in their immediate packaging. Each cycle exposed the product to low temperatures ($-5 \pm 3^\circ\text{C}$, 48 hours) followed by high temperatures ($30 \pm 2^\circ\text{C}$ with $65 \pm 5\%$ relative humidity (RH), 48 hours). Samples were analysed using a variety of validated methods for appearance, pH, protein concentration, container