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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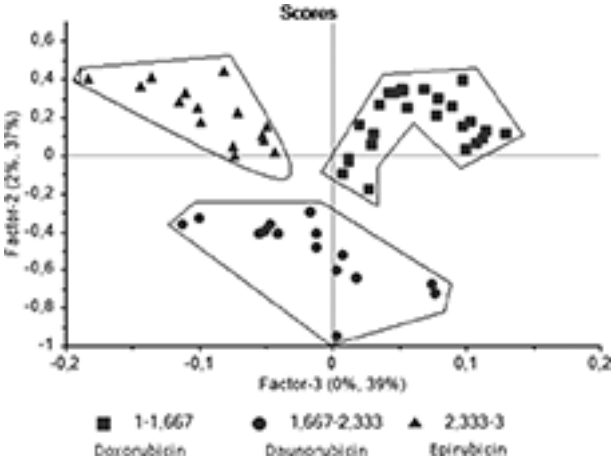
Background and importance Anthracyclines are among the most used anticancer drugs in haematology–oncology, especially in the treatment of solid tumours and leukaemia. High performance liquid chromatography coupled with spectrometry is a well established method in the control of hospital chemotherapy 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 Unscramble X.10.4' performed the chemometric analysis of the data.



Abstract 3PC-023 Figure 1

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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No conflict of interest.

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±3°C, 48 hours) followed by high temperatures (30±2°C with 65±5% relative humidity (RH), 48 hours). Samples were analysed using a variety of validated methods for appearance, pH, protein concentration, container