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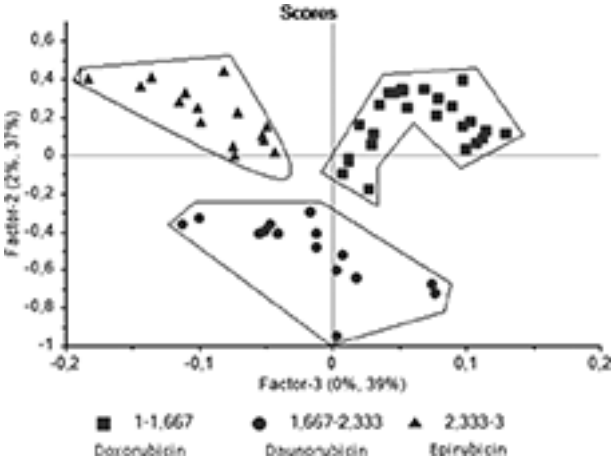
Background and importance Anthracyclines are among the most used anticancer drugs in haematology–oncology, especially in the treatment of solid tumours and leukaemia. High performance liquid chromatography coupled with spectrometry is a well established method in the control of hospital chemotherapy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

REFERENCES AND/OR ACKNOWLEDGEMENTS

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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

Abstract 3PC-024 Table 1 Impact of temperature cycling on SB5 critical quality attributes

Category	Test item	Test method	Baseline (reference) (%)	Following 3 thermal cycles (%)
Purity/ impurities	High molecular weight aggregates	Size exclusion HPLC	0.2	0.2
Purity/ impurities	Total purity	CE-SDS (non-reducing)	96.8	96.6
Biological activity	TNFα binding	Competitive binding assay (FRET)	92	98
Biological activity	TNFα neutralisation	Cell based, NFκB reporter gene assay	94	105

CE-SDS, capillary electrophoresis–sodium dodecyl sulfate; FRET, fluorescence resonance energy transfer; HPLC, high performance liquid chromatography
Other attributes, including charge variants, oxidation and endotoxin levels remained within acceptable limits. Appearance (including colour, clarity and visible particles), pH, protein concentration and particulates showed no significant changes. None of the syringes had signs of container closure breaches.

closure integrity, impurities, charge variants, oxidation, endotoxin, particulates and biological activity.

Results A total of 132 syringes underwent three freeze–thaw cycles, exposing each syringe for a total of 144 hours to 30°C and 144 hours to −5°C. Following exposure, 66 syringes were used for the analysis and 66 were retained. The effects of this thermal cycling on the critical quality attributes of SB5 from baseline is shown in table 1.

Conclusion and relevance SB5 was stable in the immediate pack when exposed to multiple freeze–thaw cycles. These results may help hospital pharmacists assess the impact of temperature excursions during shipment or storage on product quality of SB5.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest Corporate sponsored research or other substantive relationships:

HE is an employee of, and holds stock in Biogen, responsible for the commercialisation of SB5. JK, JY, DP, SJH and SJP are employees of Samsung Bioepis, the marketing authorisation holder of SB5.

3PC-025 MAGISTRAL FORMULATION FOR A PATIENT WITH MULTIPLE FOOD ALLERGY

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Background and importance Multiple food allergy (MFA), in its severe stage, is a pathology with nutritional and pharmacotherapeutic restrictions. Drug intolerance to available medicines and lack of alternatives can lead to magistral formulations.

Aim and objectives To compound oral liquid formulations of iron, zinc and sirolimus by eliminating all preservatives, antioxidants, colourings and flavourings, and evaluate their use in a paediatric patient with MFA.

Material and methods We made a literature review including physicochemical characteristics of the active principles studied and the compounding magistral formulations described. We also compared the composition between these commercialised drugs and simple syrups.

We accomplished all of the controls described in the pharmacopeia for oral liquid forms on days 1 and 30.

Efficacy was evaluated by clinical monitoring from the patient's birth in 2017.

Results According to our bibliographic review, three active principles were formulated with an adjuvant free vehicle: 64% preservative free simple syrup (PFSS).

The final composition was:

Sirolimus 0.5 mg/mL oral suspension: sirolimus in 1% preservative free carboxymethylcellulose and PFSS. It was compounded using as a pattern the formulation of a tacrolimus suspension, based on molecular similarities.

Zinc 5 mg/mL oral solution: zinc acetate dihydrate in sterile water 20% and diluted PFSS, based on existing formulations. We used the best tolerated salt.

Iron 30 mg/mL oral solution: ferrous sulfate heptahydrate in sterile water 20% and diluted PFSS. We chose the salt with the highest absorption and solubility.

Quality controls: the solutions showed clarity and absence of precipitates and the suspension, re- dispersibility and homogeneity after stirring. The organoleptic characteristics were not optimal for the taste. The results for microbiological controls were negative.

Due to the physicochemical and microbiological characteristics, a period of validity of 30 days in refrigerated amber glass was considered.

Zinc and iron deficiency were corrected and blood levels of sirolimus were within the adequate range. Currently the patient continues with treatment and an exhaustive follow-up is being carried out.

Conclusion and relevance Our oral liquid formulation was appropriate for the pathology of our patient and contributed to his growth and health. The comprehensive pharmaceutical care and an individualised compounding for the MFA was essential.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-026 FORMULATION AND GALENIC CHARACTERISATION OF A TACROLIMUS ADHESIVE GEL FOR TREATMENT OF ULCERATIVE PROCTITIS

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Background and importance Ulcerative proctitis is associated with faecal incontinence, pain, itching, bleeding and purulent discharge, and is often managed with topical salicylates or steroids. However, treatment can be refractory in some patients. Rectal administration of tacrolimus may be effective in difficult to treat ulcerative proctitis[1]. Some patients find it difficult to retain rectal pharmaceutical forms, suppositories or enemas, which lead to painful administration and infradosification.

Aim and objectives To develop a tacrolimus adhesive gel and its galenic validation, to improve and extend contact time of tacrolimus with rectal mucosal surfaces.