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

Y Jiménez López, E Pérez Cano, M Merino Almazán, R Claramunt García*, MI Sierra Torres, I Caba Porras. *Hospital Universitario De Jaén, Pharmacy Service, Jaén, Spain*

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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

[1]MF Pérez Almagro*, [1]C Perelló Alomar, [1]MM Santandreu Estelrich, [1]M Ortiz González, [1]M Gómez Zamora, [1]E Rodríguez Campos, [2]B García García, [2]FJ Cámara Aguilera, [1]O Delgado Sánchez. *[1]Hospital Universitario Son Espases, Hospital Pharmacy, Palma De Mallorca, Spain; [2]Hospital Universitario Son Espases, Laboratory Medicine Department, Palma De Mallorca, Spain*

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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.

Material and methods Tacrolimus 0.06% adhesive gel was compounded, in a biological safety cabinet with protection equipment for the manipulator, with tacrolimus 5 mg capsules (Prograf, Astellas Pharma), glycerin (Acofarma) and a lipophilic gel (Excipiente Acofar adhesivo oral, Acofarma). The compounded drug was packed on monodoses of 4.5 g with the aim of administering 2 mg of tacrolimus in 5 mL latex free luer lock syringes (Omnifix, B Braun). Each syringe was supplied with a rectal cannula (José Mestre, SA) for patient administration (1 g of gel is retained in the cannula). Tacrolimus gel was stored at room temperature, in a dry place and protected from light.

Galenic characterisation was carried out, according to good manufacturing practices,[2] testing for homogeneity and appearance, extensibility, pH and monodose mass extraction, weekly over 28 days. Determination of pH was made with pHmeter glp21.

Results For 28 days at room temperature: tacrolimus gel kept the same appearance (granular, translucent and colourless), there were no quite different values for extensibility and pH (5.99) and monodose mass extraction (3.50 g) results differed minimally (<5–10% difference). Currently, one patient is treated in our hospital with this formulation once every 2 days, responding positively, with no adverse effects and good tolerance.

Conclusion and relevance This gel preparation is stable for 28 days at room temperature, maintaining its galenic characteristics and it can be useful in patients with difficult to treat ulcerative proctitis.

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No conflict of interest.

3PC-027 LONG TERM STABILITY OF A READY TO USE TOPICAL ANAESTHETIC GEL KIT

[1]E Dijkers*, [2]H Polonini, [2]A Ferreira, [3]C Zander. *[1]Global Innovation Project Manager, Fagron Bv, Rotterdam, The Netherlands; [2]Ortofarma Analytical Services, Ortofarma Analytical Services, Matias Barbosa, Brazil; [3]Fagron Inc, Fagron Inc, Saint Paul, USA*

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Background and importance Undergoing small surgeries, aesthetic procedures or needle injections can be stressful, especially for paediatric patients. Various local anaesthetics have therefore been developed to numb the skin, including commercially available medications. Unfortunately, shortage of medicines, including for local anaesthesia, remains a widespread and persistent problem. LETS GEL KIT is a ready to use kit developed by Fagron to compound a topical anaesthetic gel. LETS GEL KIT contains lidocaine hydrochloride (4% w/w), epinephrine bitartrate (0.18% w/w), tetracaine hydrochloride (0.5% w/w) and sodium metabisulfite (0.075% w/w). LETS has been shown to be equivalent in providing and maintaining anaesthesia in the treatment of facial lacerations, with up to 10-fold less systemic exposure, compared with a 2.5% lidocaine/2.5% prilocaine solution.

Aim and objectives To evaluate the chemical stability of the LETS GEL KIT when stored in syringes.

Material and methods Samples were stored in plastic syringes (Comar, USA) under controlled refrigeration (2–8°C) and controlled room temperature (20–25°C). Stability was assessed by examining colour, odour and pH, and by measuring the active content at varying time points (0, 30, 60, 90, 120 and 150 days) over a 150 day period. API quantification was performed by validated high performance liquid chromatography (HPLC-UV).

Results Throughout the whole study, no phenomena, such as turbidity, macroscopically visible crystal growth or phase separation, were observed. Colour, odour and pH showed no significant change. Drug content (%) after 150 days were (for refrigerated and room temperature, respectively): lidocaine hydrochloride 94.47±0.25 and 94.86±0.70; epinephrine bitartrate 97.90±0.33 and 98.82±0.20; and tetracaine hydrochloride 102.09±0.70 and 102.18±1.15.

Conclusion and relevance In the current study, LETS GEL KIT showed excellent stability under both controlled refrigerated conditions (2–8°C) and at room temperature (15–25°C) for up to 150 days. Therefore, prefilled compounded syringes using LETS GEL KIT can be a valuable alternative when commercial medication is not suitable or available.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-028 COMPOUNDING AN ORAL LIQUID FORMULATION OF DIAZEPAM ALCOHOL FREE

[1]R Barbosa*, [1]A Capela, [1]C Sampaio, [1]S Fraga, [1]T Soares, [2]J Campos, [2]D Ferreira, [2]P Costa, [3]L Bighinati. *[1]Centro Hospitalar E Universitário São João- Epe, Pharmacy, Oporto, Portugal; [2]Faculdade De Farmácia Da Universidade Do Porto, Ucibio- Requimte-Pharmaceutical Tecnology, Oporto, Portugal; [3]Universitá Degli Studi Di Modena E Reggio Emilia, Chimica E Tecnologia Farmaceutiche, Modena, Italy*

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Background and importance Drug shortages is a common international problem. Pharmaceutical compounding is a viable alternative, especially relevant in paediatrics. An example of such a situation is the oral liquid formulation of diazepam, indicated for epilepsy and seizures. However, only formulations that use ethanol as a cosolvent are described in the scientific bibliographies. This excipient is not recommended in paediatrics, with children's age dependent proposed limits by EMA/FDA/WHO.

Aim and objectives To develop an oral liquid formulation of diazepam that is ethanol free.

Material and methods A compounding vehicle, B9, National Compounding Formulary, formulated with the suspending agent Avicel RC581 polymer was used to prepare an oral suspension of diazepam 0.4 mg/mL. Tablets and bulk material were used as drug sources. The stability of the drug was verified over 90 days under different temperature and storage conditions (ambient and refrigerated) with the inhouse high performance liquid chromatography (HPLC) method using the UltiMate 3000 HPLC (Thermo Fisher Scientific, USA). Particle size was measured using the Mastersizer 300 (Malvern Panalytical, UK).

Results After 7 days, more than 10% of drug loss was observed for the ambient storage preparations, both tablets and bulk, and for the refrigerated bulk preparation. The tablet refrigerated formulation maintained >90% of the drug content until the 60 day mark. No significative changes were