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

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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

Conflict of interest Corporate sponsored research or other substantive relationships:

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

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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