(48.8%) were elaborated for non-critical patients and 1085 (51.2%) for the Critical Care Unit.

Concerning glutamine addition, 970 (86.7%) of the bags for non-critical patients were supplemented with glutamine and 446 (41.1%) bags for the Critical Care Unit were supplemented as well.

Without supplementation, the maximum amount of nitrogen available in the dosage regimes is 14 g and, with supplementation, it can rise to 18 g.

Conclusion Since the recommendations of total protein are higher (1.2–2 g nitrogen/kg/day ASPEN2016) than some years' ago (1.3–1.5 g nitrogen/kg/day ESPEN2009) it seems clear that the available regimens of TPN at the pharmacy service are outdated, and glutamine is being used not only as supplementation but also as a source of nitrogen.

In the light of the results, new products high in nitrogen (16 g and 18 g) and new regimens were proposed to limit the use of glutamine only as supplementation and improve the adherence to the Guidelines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-007 IMPLEMENTATION AND QUALITY CONTROL OF A 5% FRUCTOSE AND 10% GLYCEROL STERILE SOLUTION FOR DIGESTIVE ENDOSCOPY

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Background Endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD) are innovative digestive endoscopic approaches allowing 'en bloc' tumour removal – which facilitates histological analysis and lowers the risks of local relapse. To ease complete tumour removal, both techniques require submucosal fluid injections. Nevertheless, no ready-to-use commercial solutions for submucosal injection are available.

Purpose To implement a simple production of a ready-to-use 5% fructose and 10% glycerol sterile solution (FGSS) for submucosal injection and appropriate quality controls.

Material and methods FGSS were aseptically compounded according to good manufacturing practices. Fructose and glycerol were mixed with isotonic sodium chloride in an ISO 5 controlled atmosphere area. The solution was sterile-filtered using rapid flow 0.22 µm filter units (ThermoScientific) and aseptically-filled into glass containers (125 mL) in a vertical laminar flow hood. An alternative method, using terminal sterilisation (121°C for 20 min), was also tested.

Quality controls were performed on three vials (beginning-middle-end of production). Fructose and glycerol concentrations were assessed by colorimetric-enzymatic methods adapted on a chemistry analyser (acceptance limits ±10%). We developed a method of quantifying two fructose degradation products (5-hydroxymethylfurfural (5HMF) and 2-furaldehyde (2FA)) in FGSS, using a high-performance liquid chromatography UV Diode-Array-Detector. Accuracy profile serves for validation (relative acceptance limits: ±10%). Sterility assay and endotoxin testing (kinetic chromogenic method) were performed. Sub-visible particles contamination was assessed using a light-obscuration method (European pharmacopoeia (EP)

2.9.19 threshold: respectively 25 and 3 particles/mL for particles size ≥10 µm and ≥25 µm).

Results Our sterile-filtered compounding method allows the production of a sterile and bacterial-endotoxin-free FGSS. Particle load was 9.99 and 0.37 particles/mL respectively for ≥10 µm and ≥25 µm particles. Fructose and glycerol concentrations (g/L) were respectively at (mean (min-max)) 48.99 (47.04–50.39) and 127.39 (123.4–129.8)). Both 5HMF and 2FA concentrations were below our method's limits of quantification (3.39 and 1.69 ng/mL respectively). When using the moist heat sterilisation method, the solution became light yellow and 5-HMF was 19.61 mg/L (far above EP specification).

Conclusion Our compounding method is simple, limits 5HMF production and can be implemented in any hospital. Produced FGSS complies with the EP quality requirements. We developed the first specific and sensitive method for 5HMF and 2FA concentrations measurement in a FGSS preparation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-008 PHYSICOCHEMICAL STABILITY OF NOREPINEPHRINE BITARTRATE IN POLYPROPYLENE SYRINGES AT HIGH CONCENTRATIONS FOR INTENSIVE CARE UNITS

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Background Norepinephrine is usually used in emergency situations as in intensive care units (ICUs) for the restoration of blood pressure. High doses at 3–5 µg/kg/min can be used in the treatment of septic or hemorrhagic shock.

Purpose The objective was to study the stability of high concentrated solutions of norepinephrine at 0.50 mg/mL and 1.16 mg/mL, diluted in glucose 5% (G5%) in polypropylene syringes, protected or not from light, after the preparation and after a 6 hour, 24 hour and 48 hour storage at room temperature.

Material and methods Chemical stability was analysed by high-performance liquid chromatography coupled to a photodiode array detector at each time of analysis. The method was validated according to the International Conference on Harmonisation Q2 (R1). Physical stability was evaluated by visual and subvisual inspection (turbidimetry by UV spectrophotometry at 350, 410 and 550 nm as recommended by the European Consensus Conference). Three syringes for each condition were prepared. At each time of analysis, three samples were prepared and analysed for each syringe. pH values were evaluated at each moment of the analysis.

Results Solutions of norepinephrine at 0.50 and 1.16 mg/mL, diluted in G5%, with or without protection from light, retained more than 95% of the initial concentration after 48 hours of storage at 20°C–25°C. Solutions remained clear, without change of colour or precipitation during the study. Concerning turbidity assays, values of absorbance remained inferior to 0.010 AU. No degradation product appeared during stressed degradation was observed during the study, but an additional peak with a retention time at 3.8 min was observed and constant. This peak was equally observed on chromatograms of the G5% solution. A solution of 5-hydroxymethylfurfural (5-HMF), a degradation product of glucose, was prepared and analysed by HPLC. The retention time was also

3.8 min and the spectrum was identical. This additional peak was identified as 5-HMF.

Conclusion Norepinephrine diluted in G5% at 0.50 mg/mL and 1.16 mg/mL were physically and chemically stable over a period of 48 hours at room temperature. These stability data of highly concentrated solutions provide additional knowledge to assist ICUs in daily practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-009 SUCCESSFUL TREATMENT OF HAMARTOMA IN CHILD SYNDROME AFTER 30 MONTHS WITH TOPICAL ADMINISTRATION OF SIMVASTATIN/CHOLESTEROL CREAM: A CASE REPORT

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Background Congenital hemidysplasia with ichthyosiform erythroderma and limb defects syndrome (CHILD) syndrome is a rare X-linked dominant disorder of cholesterol metabolism that clinically expresses as an epidermal hamartoma. Using co-application of topical formulation of simvastatin and cholesterol (TFSC) on skin lesions after previous failures has recently been reported.¹

Purpose To describe protocol of use, efficacy and safety of TFSC.

Material and methods A woman, born in 1988, presented at birth with an extensive epidermal hamartoma due to CHILD syndrome. The cutaneous presentation was ichthyosiform erythroderma with sharp midline demarcation involving the right side of the body and a homolateral lower limb. She had skeletal malformations of her upper and lower limbs. Partial lower limb amputation was necessary when she was 2 years' old. In February 2016, since skin lesions did not improve with acitretine, topical corticoid and various types of dressings, TFSC was began after obtaining informed consent.

We developed an original ethanol-free formulation with simvastatin, cholesterol in Excipial Lipocreme (Galderma). The preparation consists of incorporating simvastatin in powder and triturated ground powder of cholesterol with Excipial: physical stability was satisfactory for at least 30 days. We used the following protocol¹: in the first month, 0.5% simvastatin and cholesterol in Excipial Lipocreme, twice per day on a limited area to test tolerance; then afterwards at 2%, twice per day on a wider area. Efficacy was clinically assessed (aspect and extension of the skin lesion) and tolerance was clinically and biologically assessed.

Results TFSC was started in February 2016. Erythema whitened after 10 months and totally disappeared after 18 months. After 24 months, improvement began on the papillomatous aspect of the stump. After 30 months, whitening areas were stable, with persisting papillomatosis in the stump and flexion areas.

A 2 month supply disruption of simvastatin powder during the first year led to the reappearance of erythema. When TFSC resumed, the lesions improved again.

The main reported side effect was the skin's dryness on application, leading to emollient use. Complete blood counts, electrolytes, urea, triglycerides, cholesterol, CPK and liver function remained normal.

Conclusion This case shows the interest and safety of TFSC in hamartoma lesions, indicating a potential interest in other types of hamartoma.

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No conflict of interest.

3PC-010 STABILITY OF CHLORHEXIDINE 0.05% EYE DROPS COMPOUNDING DRUG

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Background Chlorhexidine has been used as a surgical prophylaxis in patients allergic to povidone in order to reduce post-surgery infections.¹

Purpose To develop a 0.05% chlorhexidine ophthalmic formulation and study its stability in different storage conditions: in fridge (5°C), at room temperature (20°C) and accelerated (40°C).

Material and methods Chlorhexidine 0.05% ophthalmic formulation was compounded in the pharmacy service by an aseptic technique, as starting products, chlorhexidine digluconate 20% (Acofarma), glacial acetic acid (Fagron), anhydride sodium acetate (Fagron) and water for injection (Braun) were used. The compounded drug was packed into a high-density polyethylene eye dropper.

The pH and osmolarity of the samples were subsequently checked. The determination of pH was made with pHmeter Hanna HI5221 and the osmolarity was made with Fiske Model 210.

Stability was determined by HPLC, Agilent 1260series HPLC System with a PAD detector.

Each sample was taken twice for each condition.

Results The organoleptic properties of the three formulas were acceptable. The pH and osmolarity results differed minimally between 0 and 6 months, less than a 5% difference in pH and less than a 10% difference in osmolarity. The values were:

Abstract 3PC-010 Table 1

	Fridge (5°C)	Room temperature (20°C)	Accelerated (40°C)
pH	5.66	5.67	5.66
Osmolarity (mOsm/Kg)	198.35	198.54	200.45

The concentration fell below 10% at month 6.

Conclusion Chlorhexidine 0.05% eye drops can be compounded in the pharmacy service for allergic surgical patients. The drug meets the galenic requirements for ophthalmic preparations and can be stored at room temperature as well as in the fridge for a period of 3 months unopened.

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No conflict of interest.