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 laminar flow hood. An alternative method, using terminal sterilization Q2 (R1). Physical stability was evaluated by visual and after a 6 hour, 24 hour and 48 hour storage at room temperature.

Material and methods Chemical stability was assessed 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 (turbidity 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 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.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.
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.

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**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 holomateral 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 acetint, 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 protocol:1 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.

**REFERENCE AND/OR ACKNOWLEDGEMENTS**
No conflict of interest.

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**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 postsurgery 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:

<table>
<thead>
<tr>
<th></th>
<th>Fridge (5°C)</th>
<th>Room temperature (20°C)</th>
<th>Accelerated (40°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>5.66</td>
<td>5.67</td>
<td>5.66</td>
</tr>
<tr>
<td>Osmolarity (mOsm/Kg)</td>
<td>198.35</td>
<td>198.54</td>
<td>200.45</td>
</tr>
</tbody>
</table>

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.

**REFERENCE AND/OR ACKNOWLEDGEMENTS**
No conflict of interest.