presentation of trastuzumab, which was safe and well tolerated.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest

INDIGO CARMINE SOLUTION AND ADRENALINE IN SUBMUCOSAL CHROMOENDOSCOPY
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Background and Importance Chromoendoscopy involves the injection of dye into the submucosal layer of the intestine wall that enhances the injected area and facilitates the delimitation and marking of areas that are susceptible to endoscopic treatment. The classic technique consists of adding indigo carmine (IC) to the injected solution, colouring the resulting bulge, and ensuring that the injected layer is the submucosa, which reduces the risk of perforation and the feasibility of endoscopic resection. The inclusion of adrenaline in the solution, with a concentration 10 times lower than for haemostatic purposes, reduces the potential risk of haemorrhage and highlights the well-vascularised epithelia. There is no commercialised or standardised preparation for performing this technique.

Aim and Objectives Description and galenic validation of a solution of IC and adrenaline in colloid plasma for use in chromoendoscopy. Establishing the period of validity according to the Guide to Good Preparation Practices (GPP).

Material and Methods The developed formula was made of adrenaline 1 mg, IC 32 mg (4 mL of IC 0.8%) and q.s. ad 100 mL protein-based colloid derived from gelatine. The preparation added to a sterile 100 mL polyolefin bag.

The risk of the final preparation was determined according to the GPP matrix and galenic validation was carried out by evaluating the following parameters: physical stability due to colour change by qualitative assessment on a black and white background by two observers; chemical stability with pH determination by potentiometry; microbiological stability (trypticase soy agar culture). Determinations were made at 0, 15, 30 and 45 days post-preparation.

Results There was no colour change in any sample except at t45, where a marked change in colouration was observed. Regarding the pH, the following results were obtained: t0: 6.65 ± 0.02; t15: 6.83 ± 0.02; t30: 6.57 ± 0.03; t45: 6.70 ± 0.02. There was no microbiological growth in any sample. A medium risk level and a validity period of 14 days between 2–8°C were established according to the GPP.

Conclusion and Relevance The IC solution is physically, chemically and microbiologically stable for 14 days at 2–8°C. The final concentration of IC used and the association with adrenaline allow, in the opinion of the endoscopists, the adequate differentiation of the areas susceptible to endoscopic resection.

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CLOBETASOL PETROLATUM OINTMENT 0.015% FOR THE TREATMENT OF CUTANEOUS GRAFT-VERSUS-HOST DISEASE IN PAEDIATRIC PATIENTS: A CASE REPORT
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Background and Importance Chronic graft-versus-host disease (cGVHD) is an important late complication after allogeneic haematopoietic stem cell transplant (HSCT). The skin is usually the first and most affected organ involved in cGVHD and topical steroids are one of the most commonly used drugs for this affection.1

Aim and Objectives A 3-year-old boy was diagnosed with acute myeloid leukaemia in 2019 and, after HSCT, manifested cutaneous cGVHD. The hospital pharmacy service was asked to develop a paediatric magistral formula of topical ointment based on clobetasol 0.015% in petrolatum.

Material and Methods A scientific literature search was conducted. Galenic development and validation of the formula were described in the monograph ‘Semi-solid preparations for cutaneous application’ of the Official Pharmacopoeia of the Italian Republic.

A topical magistral formula of clobetasol ointment 0.015% in petrolatum was developed, to be administered once daily on lesions. The efficacy of the formulation was evaluated by the physician. Skin therapy also included a moisturising lotion and almond oil.

Results The development was based on a case series of oral cGVHD in which a hydrophilic gel formulation was used successfully. Clobetasol has been shown to have higher potency and the highest level of evidence.

In contrast to the hydrophilic gel, the 0.015% clobetasol ointment preparation was formulated on petrolatum to allow for superior skin permanence, starting with low concentrations of clobetasol as the patient aged. Petrolatum forms an occlusive, hydrophobic layer on the skin, physically blocking transeptal dermal water loss and creating increased skin hydration for more than 4 hours.

A shelf life of 30 days has been established, based on the critical skin injury in this paediatric patient. Odour, colour and phase separation remained stable during the month.

The patient well tolerated the treatment, and the doctor confirmed, after four months of treatment, the improvement of the skin lesion. The paediatric patient, after the described improvement, discontinued the clobetasol ointment.

Conclusion and Relevance Clobetasol ointment 0.015% is a good therapeutic solution in paediatric patient with cGVHD, especially for its pharmaceutical formulation.

REFERENCES

Conflict of Interest No conflict of interest