Clinical follow-up was carried out during Pharmacy and Dermatology visits to assess the response to the treatment.
Results The literature reported several cases of ketamine and amitriptyline gel (KAG) at different concentrations for treating chronic pruritus and EB. The off-label use was approved by the medicines-in-special-situations local committee.

Procedure for 400 grams: In phase 1, dissolve 0.6g of sodium methylparaben in 280mL of water and heat it up to 60–70°C. In phase 2, heat 4g of amitriptyline and 40g of glycerol in a second beaker. Add gradually 4g of carboxymethylcellulose at phase 2 until a homogeneous suspension is obtained. Mix both phases at 70°C and stir vigorously until a whitish gel is obtained. After cooling, add 80g of ketamine vial (50mg/mL) and homogenise it. The gel is homogeneous, fluid, whitish, odourless and has good extensibility.

From the treatment's beginning, the patient showed improvement of the pruritus, good tolerance and satisfaction. After 6 weeks, she was ongoing with KAG and applies it every 3 hours instead.
Conclusion and Relevance In our patient, topical KAG is an effective and safe alternative to consider in the EB treatment. The medium long-term effects will be assessed through follow-up. During the studied period, the formula developed maintains stability.

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

3PC-035 PATCH TESTS WITH HAZARDOUS DRUGS: IS IT POSSIBLE TO ENSURE SAFETY DURING PRODUCTION?

M Fernández-Vázquez Crespo*, V Puebla Garcia, P Pastor Vara, N Sanchez-Ocaña Martín, J Corazon Villanueva, M De La Torre Ortiz, A De Diego Peña, JA Dominguez Chafer, L Ybañez Garcia, E Roson Sanchez, AA García Sacristán. *Hospital Clínico San Carlos, Hospital Pharmacy, Madrid, Spain*

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Background and Importance Epicutaneous Patch Tests (EPTs) are the first type of skin tests performed by Allergology Department to diagnose Type IV hypersensitivity allergic reactions (IVHAR) to drugs. They involve application of ointments for epicutaneous patches containing the active ingredient, prepared by the Pharmacy Department, followed by reading results 48 and 72 hours later. When there is suspicion of an IVHAR to hazardous drugs, compounding process must be adapted to protect the handler.
Aim and Objectives The aim of this study is to describe the design and formulation of EPT with Imatinib and Nilotinib, classified as Hazardous Drugs Group 1 by the National Institute for Occupational Safety and Health (NIOSH).
Material and Methods A request was made to the Pharmacy Department for an EPT for a patient suspected of IVHAR after treatment with Imatinib in order to confirm the diagnosis and consider switching to Nilotinib.

A literature search was conducted to determine the optimal concentration of both drugs within each EPT, as well as the best vehicle. A galenic control was established to evaluate the extensibility and organoleptic properties of the formula. The stability of the formula was determined in accordance with the risk matrix included in the Good Practices Guide for the preparation of medications in Hospital Pharmacy Services.

The handling of these drugs was always performed in a fume hood with HEPA-H14 filter, wearing a cap, glasses, FFP3 mask, gloves, disposable gown, and shoe covers.
Results Imatinib 5% petrolatum (pet.):

- Imatinib tablet 0.4 g
- Liquid pet. 2 g
- Petroleum Jelly q.s. 8 g
- Nilotinib 5% pet.:
- Nilotinib capsule 0.2 g
- Liquid pet. 1 g
- Petroleum Jelly q.s. 4 g

For the preparation of both ointments, the commercial pharmaceutical form was placed in a ZIP-type resealable bag with an ENFit connection. The active ingredients were pulverised using a specific roller-shaped device. Subsequently, liquid Vaseline was introduced using an ENFit syringe through the bag's connection. After homogenisation, Vaseline filante was introduced in the same manner and homogenised again. Finally, it was dosed into individualised 1 mL ENFit syringes.
Conclusion and Relevance The preparation of EPT with hazardous drugs in the Hospital Pharmacy Department is totally feasible as long as the appropriate procedures and equipment are available.

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

3PC-036 RISK ANALYSIS OF THE PHARMACEUTICAL CIRCUIT FOR INJECTABLE CHEMOTHERAPIES AFTER IMPLEMENTATION OF DRUGLOG®

C Vergnaud*, M Delamotte, A Lebreton. *Chu Angers, Maine Et Loire, Angers, France*

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Background and Importance As part of a quality assurance approach, a UV-visible spectrophotometer has been installed in 2021 in the cytotoxic reconstitution unit (CRU), enabling pre-release analytical control of cytotoxic preparations. This new step has led to a new risk analysis using the FMECA method (Failure Modes, Effects and Criticality Analysis).
Aim and Objectives The aim was to evaluate the entire injectable chemotherapy process compared to an initial FMECA carried out in 2016 in order to assess the added value of the DrugLog® tool.
Material and Methods The FMECA was carried out between June and September 2023. Six multidisciplinary working meetings were held, attended by two pharmacists, one intern and one pharmacy technician. The failure modes (FM) identified in 2016 were reassessed for a total of 97 FM in 2023, divided into 10 themes. For each FM, a criticality index (CI) based on frequency (F), severity (S) and detectability (D) was calculated using the formula: $CI=F\times S\times D$. The CIs were divided into three categories: mild ($CI<25$), moderate ($25<CI<50$) and severe ($CI>75$).
Results Of the 97 FMs identified, 94 were of mild criticality (97%), three moderate (3%) and 0 severe. In 2016 and 2023, 70 items were common. The cumulative CIs were similar (806 in 2016 compared with 809 in 2023). A decrease in cumulative CI was observed in the personnel (-58%), validation (-69%) and release (-46%) themes. However, a sharp increase was observed in the premises (+55%), equipment