Conclusion and Relevance The study highlights the variability in the adoption of filtering techniques for glass ampoules across different hospitals, with hospital pharmacies demonstrating better compliance. Both pharmacy technicians and nurses observed glass particles, leading to ampoule disposal. Future studies should investigate the causes of disparities between pharmacy departments and hospital wards. Additionally, further research is needed to assess potential health consequences of glass particle exposure.

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Conflict of Interest No conflict of interest.

3PC-019 DEVELOPMENT OF A TOPICAL EMULSION FOR THE TREATMENT OF THIRD-DEGREE BURN PATIENT CANDIDATES FOR SKIN GRAFT

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10.1136/ejhpharm-2024-eahp.76

Background and Importance A third-degree burn (TDB) destroys the epidermis and dermis presenting a high risk of infection. These lesions are treated with skin grafts (SK) in the absence of infection.

Aim and Objectives The hospital pharmacist was asked to develop a non-irritating, antibacterial, easily spreadable and removable topical emulsion formula specific to prepare the burned tissue for SK.

The aim is to describe effectiveness and tolerance of topical magistral formula emulsion.

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.

The efficacy of the formulation was evaluated by the physician.

A retrospective observational analysis was performed. Patients with TDB who were eligible for SK in 2022–2023 are being evaluated. The variables collected were: duration of treatment, dosage, clinical response and adverse effects.

Results We have formulated Oil-in-water emulsions. The main components are:

- C15–20–acid-PEG-8–ester-12%, hydrophilic-lipophilic balance 12, emulsifier, non-toxic for skin enzymes, suitable for the most sensitive skin, and the most histophilic of known emulsifiers.
- Squalane-7%, a texturiser, creates a film that protects the skin by delaying the loss of trans- epidermal water and improves the spreadability of the product.
- Sebopessina –2%, active principle for sebaceous secretion problems because burned skin has blisters.
- Silicone oil improves –0.3% the application and absorption of creams. The favourable environment, created by occlusion-hydration, the formation of hypertrophic scars is prevented.
- Cerium nitrate –2% combined with silver sulfadiazine-0.3% to provide broad antibacterial activity, forms a temporary barrier and promotes re-epithelialisation.

A shelf life of 30 days has been established, based on the critical skin lesion. Odour, colour and phase separation remained stable over the month. Spreadability and emulsion removal were excellent. Fifteen patients were treated; 100% responded well to treatment after an average of 2 weeks and a dosing frequency of 3 times a day. The physician confirmed good delimitation and absence of infections in the burnt areas that will receive the SK. No adverse reactions were reported.

Conclusion and Relevance The galenic emulsion described is a good therapeutic solution in patients with TDB who are candidates for SK.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-020 PREVENTION OF INFECTIOUS RISK IN PATIENTS TREATED WITH TUMOUR NECROSIS FACTOR ALPHA INHIBITORS (ANTI-TNFα)

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10.1136/ejhpharm-2024-eahp.77

Background and Importance Tumour necrosis factor alpha inhibitors (anti-TNFα) have become a common treatment in many diseases, but they can increase susceptibility to infectious diseases, including tuberculosis.

Aim and Objectives Evaluate the analysis record and vaccination schedules in patients with anti-TNFα treatment in our hospital.

Material and Methods We have reviewed clinic history of all outpatients of the Pharmacy Service in a regional hospital who are currently administering subcutaneous anti-TNF (adalimumab, certolizumab, golimumab and etanercept). The informatics programs Farho and HCl are used to review if tuberculin test or Quantiferon assay, recommended vaccination schedule by the Prevention Service of the hospital and hepatitis serology have been requested (hepatitis B virus (HBV), hepatitis C virus (HCV) and hepatitis A (HAV)).

Results 147 patients with anti-TNFα have been analysed, with a mean age of 49 years (14–84), of which 53% (n=78) are men. 18.37% (n=27) had rheumatoid arthritis, 15.65% (n=23) psoriasis, 14.97% (n=22) psoriatic arthritis, 10.20% (n=15) ankylosing spondylitis, 19.05% (n=28) other spondyloarthropathies, 1.36% (n=2) juvenile idiopathic arthritis, 17.01% (n=25) inflammatory bowel disease, and 3.40% (n=5) others. Tuberculin/quantiferon testing was completed in 87.07% of patients; 12.50% of them were positive and received isoniazid for 9 months. Serological markers have been recorded in 93.20% and 91.16% of patients for HBV and HCV respectively, all of which were negative. 41.50% of the patients received four doses of HBV vaccine, because they presented anti-HBs <10 mUl/ml. 10.88% of the total patients received two doses of the HAV vaccine with an interval of 6 months. 81.63% of patients were vaccinated with the pneumococcal vaccine. 51.02% of patients have received the flu vaccine annually.

Conclusion and Relevance Regarding the safety guidelines, the recommended screening and vaccination schedules are completed and recorded in the majority of patients (>85% patients). Nevertheless, it would be necessary to reconcile the way of registering data in order to simplify the recording of tests performed and the monitoring of administered vaccines.

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

3PC-021 FORMULATION OF VORICONAZOLE OVULES AND EFFICACY IN VULVOVAGINAL CCANDIDIASIS BY CANDIDA GLABRATA: A CASE REPORT

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10.1136/ejhpharm-2024-eahp.78

Background and Importance *Candida glabrata* is a vaginal coloniser causing vulvovaginal candidiasis (VVC), usually asymptomatic. Typical first-line therapies, boric acid or nystatin ovules, are not effective due to their inherent resistance. Flucytosine, amphotericin B or voriconazole would be the treatment of choice.
Aim and Objectives To formulate voriconazole ovules (VO) and describe our clinical experience in the treatment of VVC by *C.glabrata*.
Material and Methods The patient was a 52-year-old woman with VVC by *C.glabrata* who presented vulvar pain, irritation, and burning. She was treated with oral fluconazole, oral voriconazole, topical amphotericin B, boric acid ovules and combined therapy by fluconazole-amphotericin B, but her symptoms did not resolve and the culture remained positive.

A bibliographic search was carried out (Pharmacopoeia, UpToDate and PubMed) about VO formulation and its solubility in polyethylene glycol (PEG) was confirmed. Other magistral formulations of ovules containing PEG as an excipient were used as a reference for formulation design. Galenic validation included organoleptic controls and physical tests, mass uniformity and dissolution time.

Finally, treatment efficacy was assessed by symptom resolution and negativisation of the vaginal exudate culture.
Results Modus operandi for 30 units VO 15 mg with an excess of 20%:

1. Melt: 81.36 g PEG 400 and 54.72 g PEG 4.000.
2. Crush 11 tablets of voriconazole 50 mg in a mortar and pestle. Work in biological safety cabinet type I if there is reproductive risk, otherwise Personal Protective Equipment (PPE).
3. Add powder to the melted mass and homogenise.
4. Pour mixture into 3 g ovule moulds and allow to cool.
5. Unmould, package and label.

Regarding galenic validation, the surface of VO was shiny, smooth and without cracks. All were within the weight range (±5) and took 34 minutes to dissolve. The given expiry date was 6 months.

The patient started treatment with daily VO and after 3 months of treatment, complete resolution of symptoms and negative cultures were achieved. The frequency of administration increased to every 48 hours and then every 72 hours until 6 months of treatment, without reactivation of the infection.
Conclusion and Relevance The magistral formulation was validated and proved to be effective in the treatment of VVC by *C.glabrata*.

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

3PC-022 DESIGN AND STABILITY STUDY OF AN ISONIAZID AND PYRIDOXINE ORAL LIQUID FORMULATION

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10.1136/ejhpharm-2024-eahp.79

Background and Importance Infant tuberculosis treatment is a combined therapy, which entails two main issues: commercialised paediatric presentations scarcity and inadequate adherence. Isoniazid is indicated as a front-line treatment. In order to prevent isoniazid's induced peripheral neuropathy, pyridoxine should be supplemented.
Aim and Objectives The aim of this study was to develop and study the physicochemical and microbiological stability of a combined isoniazid+pyridoxine oral liquid formulation.
Material and Methods Literature search was performed to study isoniazid + pyridoxine formulation stability. As there were no published data in this field, the active pharmaceutical ingredients physicochemical proprieties and quality conditions were checked in Pharmacopeia and scientific literature. Stability-indicating methods were conducted and validated according to the Methodological Guidelines for non-sterile products.

- Physical study: organoleptic characters (colour, odour, flavour); clarity and degree of opalescence; and pH. The pH-goal of combined doses to avoid any possible active ingredient degradation was settled at 5.
- Microbiological study: total aerobic microbial count <103 UFC/ml; total combined yeasts/moulds count <102 UFC/ml; and absence of Escherichia coli/ml.
- Chemical study: high-performance liquid chromatography (HPLC) analysis and method validation to quantify isoniazid +pyridoxine recommended acceptable purity limit (90–110%).

Results Isoniazid 50 mg/ml + pyridoxine 8,3 mg/ml oral liquid formulation was compounded using aqua conservans and 70% liquid sorbitol. Samples were stored at aliquots, light and non-light-exposed, at room and refrigerated temperature, for 28 days. Each sample was analysed at 0, 7, 14, 21 and 28 days.

Refrigerated samples stayed physically stable and pH measure was 4,8±0,15. Room temperature samples got darker, bitter and slightly acidified. The concentration of isoniazid and pyridoxine was found to be at day-28 50,6±0,6 + 8,2±0,2 at room temperature and 51,3±0,6 + 8,3±0,1 at refrigerated temperature, respectively. Moreover, all samples maintained microbiological stability.

The validated method proved to be selective and linear. It exhibited an adequate repeatability and intermediate precision with variation coefficient lower than 2%, and a recovery higher than 98%.