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Short communication

Galenic formulations as solutions to dosage form problems

Delina Xhafaj*, Sindi Shehaj, Kleva Shpati, Ederina Karriqi, Erjona Sheqeri

Department of Pharmacy, Faculty of Medical Sciences, Albanian University, Blv.Zogu I, 1001 Tirana, Albania

Introduction

Compounding has an important role in the field of pediatric medicine. The United States Pharmacopeia (USP), which sets quality standards for drugs, describes compounding as "the preparation, mixing, assembling, altering, packaging, and labeling of a drug…in accordance with a licensed practitioner's prescription …" (USP, 2014). So, in other words, it is the creation of a medication that is not commercially available (Watson et al., 2021). In the Albanian legislature, the pharmacist can make galenic preparations, but compounding lacks of a national specific regulations. In the Act 3 point 55 in the current Pharmaceutical Law in Albanian legislature there is just a prescription of the galenic preparation (Law No. 105/2014), and some national literature used in academic sector covers some of the specifications of this compounding field (Duressi, 2014).

Galenically prepared drugs are those produced in the galenic laboratory of a pharmacy, according to the procedure provided in pharmacopoeias, various monographs or on the pharmaceutical formularies (FDA, 2015). Galenic (or compounding) represents the most special aspect of the pharmacist profession, but even today, incomplete legislation (national and international) reserves an important and interesting role for study. Galenic preparations (known as compoundings) are essential for patient care as the gap between industry-licensed medicinal products closes and the lack of treatment options for certain groups of patients and individual patients with special medical conditions or needs (EAHP, 2020).

In pediatric or geriatric patients this profiling is a fundamental problem, for example when it comes to amitriptyline (Al-Ruthia et al., 2017), which have a single dose (15 mg tablets) or are shortage on the market. Antidepressants are widely used for chronic pain. 10–40 mg/day of amitriptyline is recommended for adult patients. However, older patients need a lower dose of antidepressants than younger patients to achieve an effective blood level (Suga et al., 2019).

The aim of this study is to compound various syrups dosage forms of Amitriptylline from their original pharmaceutical form of tablet that are available in the market in order to achieve a better and easier dosage for different groups of patients.

Materials and methods

First, the dosage of the principal active ingredient is set in accordance with the protocols of treatment of specific pathologies.

Two types of syrups have been prepared Amitriptyline 20 mg/mL (simplex and CMC-syrup). The syrups were prepared following the literature recommendations (MOH, 2015). All the preparations were packaged in 50 mL amber glass bottle (up to 30 mL). Amitriptyline 20 mg/mL has been analyzed for its principle active ingredient with potenciometric titration with 0.1 N perchloric acid (USP 29).

Results and discussion

The formulations were prepared and analysed at room temperature. The potenciometric titration analysis show principal active ingredient content of Amitriptyline for the simplex syrup 94.5±1.8, whereas the CMC syrup based has a content of 96.3±3.8. The syrups don't show any organoleptic changes during the storage time of 28 days and they flow loosely in any measuring syringe.

Overall, the reconstructed forms of the syrups are relatively easy to be prepared in the pharmacy conditions in a small galenic laboratory. They can be prepared in different concentrations with different kind of flavors.

*d.xhafaj@albanianuniversity.edu.al

Conclusion

The different preparations of amitriptyline syrups (suspensions in simplex and CMC-syrup) are relatively easy to be manipulated starting from their original pharmaceutical form (tablets) to syrups and the reconstructed forms of syrups show good principal active ingredient content during the storage time.

The pharmacist has a key role in preparing these reconstituted pharmaceutical forms when they are needed by specific groups of patients at shortage situations or inappropriate dosage forms.

For the Albanian community and hospital pharmacist, it is needed to development the compounding sector by regulating this sector with specific SubActs in the Pharmaceutical Law. Also, the creation of an official register of formulations provided by the pharmacies of compounding service and official instructions for the specific preparations such as those.

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