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Stability studies of the compounding suspension from stomatitis

Lesia Savchenko*, Anna Materiienko, Victoriya Georgiyants
National University of Pharmacy, Kharkiv, Ukraine
**Corresponding author: savchenkolesia@gmail.com*

The stability of the preparations means their ability to preserve the physico-chemical properties and pharmacological activity required by the requirements of the pharmacopoeia and other regulatory documents during the prescribed shelf life. Composition of compounding preparations doesn't contain any preservatives. Given this, the question of the possibility of long-term storage of such medicines arises. The State Pharmacopoeia of Ukraine (SPhU) sets a single expiration date for most of them – 10 days [1]. To increase it, it is necessary to carry out the medicines stability tests.

The aim of our work was chemical stability studies of the compounding suspension from stomatitis: benzocaine 1.72, nystatin 0.23, riboflavin 0.05, sunflower oil 50 ml in relation to the benzocaine and riboflavin quantitative content.

For the chemical stability studies of two components we chose the method of visible absorption spectrophotometry. The extraction of substances from the suspension base was performed by the solution of 0.1 M hydrochloric acid. The advantage of its using is the simultaneous extraction of both substances during the sample preparation.

Quantitative determination of riboflavin during the stability studies was performed by straight spectrophotometry at the wavelength 440 nm in the first extract obtained. For the quantitative determination of benzocaine to the first extract solutions of 0.1 M sodii nitratis, sulfaminic acid and N-naphtilethilendiamine were added. Absorbance was measured at the wavelength 545 nm. The stability parameter was estimated for both methods. It has been proved that the solutions remain stable for an hour.

We have been measured quantity of benzocaine and riboflavin during four months. Based on the physico-chemical properties of the suspension components, it was stored at two different regimes during the stability studies. The first series of suspension was stored in refrigerator (temperature 2-8 ^{o}C, humidity 60-65 %) and the second series of suspension was stored in regular conditions (temperature 25-27 ^{o}C, humidity 60-65 %).

The quantitative content of the suspension components was measured every 10 days in the first month of storage and after every one month of storage. The percentage deviation in the content was determined for each component. According to the SPhU requirements permissible deviation in quantitative content for components of compounding medicines is 10 %.

The obtained results indicate that the optimum conditions for storage of the suspension are the room temperature. Average quantitative content of benzocaine in percent after fourth month of storage was 90.12 %, and of riboflavin – 91.37 %. Suspension under refrigerator conditions of storage lost its quality on the second month of storage (deviation of benzocaine and riboflavin quantitative content was more than 10 %).

References:

1. State Pharmacopoeia of Ukraine: at 3 volumes. 2014. Kharkiv: State enterprise "Ukrainian scientific pharmacopoeial center of medicines quality", 2-nd ed., Vol. 3. , 732 p.