40. VARIATION OF THE PH OF COMBINED ANTIFUNGAL EAR DROPS IN CONDITIONS OF HIGH HUMIDITY

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Introduction. The pH of the external auditory canal in healthy people ranges from 5,0 to 7,8, while the pH of the external auditory canal affected by otitis is higher, ranging from 7,1 to 7,8. Recent studies show local changes in the pH of the external ear canal from acidic to alkaline in patients with chronic external otitis, demonstrating that the acidic pH of the external ear canal plays a protective role against infection. Thus, this parameter is extremely important for otologic pharmaceutical forms, and maintaining stable pH in the process of using ear drops is a condition for successful treatment. Hydrolytic stress through exposure to increased humidity is one of the parameters determining stability under accelerated conditions.

Aim of study. To study the influence of humidity on the pH values of ear drops combined with econazole, ciprofloxacin and volatile basil oil.

Methods and materials. pH meter Consort C 861, Belgium, was used for the determinations. The open pack pharmaceutical form was stored in an exicator over water for 48 hours at 250C.

Results. Most ototopic preparations have a pH of 3-4, because bacterial growth is inhibited at this level. Pharmacopoeial requirements stipulate limits between 5,0 and 7,0 for ear drops. In the investigated pharmaceutical form, pH corrector was used: phosphate buffer solution containing monosodium phosphate/disodium phosphate, pH=6,0. The results obtained after exposure to humidity for 48 hours, determined in triplicate, show that the pH of the formulation does not tend to major oscillations from the initial value (5,3), being equal to 5,35; 5,29 and 5,34.

Conclusion. It was determined that humidity does not influence the pH of the combined ear drops, which demonstrates that the buffer system has the ability to maintain the constant value of the medium to ensure the optimal effect.