REASEARCH OF ANTIBACTERIAL ACTION NEW TOPICAL GRUG

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One of the parameters that characterize the quality of medical means is resistant to microbial contamination. The level of microbial contamination depending from the majority of factors: the nature of the raw material, water contenting, the type of packaging materials or disorder drug manufacturing sanitary norms.

It is known that the conditions for the spread of microorganisms in mild topical means more favorable than solid. High level of microbial contamination of drugs is very dangerous for the stability of the drug and to human health.

Achievement the microbial purity of non-sterile means, which include soft means, carried out in two main directions: production according the full compliance with GMP requirements and/or the appending of antimicrobial substances, which, depending from the medical form, is added to kill microorganisms (bactericidal effect), or for the reproduction (bacteriostatic effect) preventing.

The GMP observance is guaranteed the high level cleanness of the prepared of the finished product will be always attained. Even with a threat of microbial contamination or other discrepancies at any stage of the production cycle of a procedure for all technological processes allows time to take appropriate action, so the risk of bad-quality drug release is virtually nonexistent.

It should be noted that conservation does not preclude observance of sanitary requirements of the production process and according to the State Pharmacopoeia of Ukraine 1 edition should not be used as an alternative to GMP. Long-term using of preserving agents is able to break the skin and microbiocenosis, to show allergenic, carcinogenic, mutagenic effect or embryotoxic effect.

During the development of medical forms' composition is obligatory to addressing issues related to adequate protection from the adverse effects preparation, which may be as results from its microbial contamination or reproduction of microorganisms in it during storing and using.

In a state institution "V. Danilevsky Institute for Endocrine Pathology Problems National Academy of Medical Sciences of Ukraine" being developed to create a topical treatment for skin lesions, which are caused by the abnormal various complications endocrinopathies.

Local drug therapy have a key role due to the relatively simplicity of using

available, and its selection depends from on the damage. Now gelatinous formulations for the treatment of damaged skin and tissue surface are preferring, because they have better absorptive capacity and the pasty consistence.

Most of soft drug using to treat skin diseases of various etiologies have antimicrobial activity to include in their composition solvents or other components of the framework, promoting a potentiation of the action.

Decide on the use of preserving agent in a new vehicle for topical treatment of skin lesions, which are caused by complications of different flow endocrinopathies, performed according to the method SPU 1 species (5.1.3. The effectiveness of antimicrobial preservatives).

Soft drugs inoculated test organisms: Pseudomonas aeruginosa - ATCC 9027; Staphylococcus aureus - ATCC 6538; Candida albicans - ATCC 10231; Aspergillus niger - ATCC 16404 and conducted research to study the number of viable microorganisms within 28 days.

Verification of the effectiveness of the antimicrobial preservative action is carried out on the second, seventh, eighth, fourteenth and twenty-eighth days. From each sample one gram sample is collected; calculate the number of microorganisms by seeding on plates or by membrane filtration.

Preservative effectiveness is evaluated by the reduction factor (RF) - the logarithm of the number of microorganisms included (N_1), to the remaining number (N_2). Reduction factor should be at least 3 for the bacteria and at least two of fungi. The preservative should reduce the number of bacteria and fungi at least 1000 and 100 times, respectively. At day 28, increase and growth of microorganisms in ointments should not be detected.

The effectiveness of the drug considered satisfactory if at the conditions of the test, at the storage of the inoculated samples at a setting the temperature during these periods the number of microorganisms significantly decrease or doesn’t increase, depending on the requirements of the finished product. Criteria of evaluation are showing reduce the number of microorganisms over time, depending on the desired degree of protection of medicines.

Today at the Department of Biotechnology of National University of Pharmacy together with the State institution "V. Danilevsky Institute for Endocrine Pathology Problems National Academy of Medical Sciences of Ukraine” research into the effectiveness of antimicrobial preservatives in soft dosage form with expected reparative activity is conducted.