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Non-sterile Generic Drug Materials Pathogens Characteristics

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DESCRIPTION

Pharmaceutical products are classified as either sterile or non-sterile in terms of microbiology. Non-sterile drugs must meet the microbiological purity criteria outlined in pharmacopoeial monographs. Pharmacopoeial studies are designed to ensure that the medicinal product is both therapeutically effective and safe for the patient. The results of microbiological purity tests performed prior to product marketing were included in the analysis. A total of 1285 samples of non-sterile drugs manufactured by various pharmaceutical plants in Poland were studied. The microbiological quality of drugs was evaluated using criteria from the European Pharmacopoeia (EP). An examination of the test results revealed that the percentage of non-compliant samples was 1.87%. The groups of drugs that did not meet EP requirements the most frequently were those containing natural raw materials (5.7%). The studied drug samples did not meet the EP criteria, exceeded the maximum allowable microbiological count limits, and contained microbes whose presence is prohibited. Excessive levels of the maximum acceptable fungal count (n=12) and the maximum acceptable aerobic microbial count (n=10) were the most common non-compliances.

A manufacturing authorization holder must ensure that drugs are fit for their intended use, meet the requirements of the Marketing Authorization, and do not endanger patients due to inadequate safety, quality, or efficacy. To achieve the quality goal, it is necessary to control all stages of drugs, which includes all matters that influence the quality of a product individually or collectively, such as raw materials, the manufacturing process, and the evaluation of finished product. One of the control stages is the evaluation of medicinal products' microbiological quality. The European Pharmacopoeia (EP) consecutive editions are useful tools in quality assessment because they define the microbiological specifications, criteria, and methods for microbial examination of non-sterile products.

The methods used and the results obtained must adhere to the specifications and criteria outlined in the relevant pharmacopoeia. Microbial enumeration tests for Total Aerobic Microbial Counts (TAMC) and Total Yeast and Mould Counts (TYMC) are performed on raw materials and finished products, as well as tests for the following specified microorganisms: *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Salmonella* spp., and *Candida albicans*. Because microbial contamination can reduce or even eliminate the therapeutic effect of drugs or cause drug-induced infections, microbiological testing of non-sterile products is especially important. Microbes in drugs not only make them infectious, but they can also change the chemical, physical, and organoleptic properties of the drugs, as well as the active ingredient content. Furthermore, microorganisms have the ability to convert drugs into toxic byproducts. Even a low level of pathogenic microorganisms, higher levels of opportunistic pathogens, or bacterial toxic metabolites that persist after the primary contaminants die can render the product ineffective.

Not only is the presence of microorganisms, which cause undesirable bacterial infections, harmful, but the presence of metabolites/toxins, even in small amounts, can cause negative symptoms. Toxin-related diseases include diarrhea, acute gastroenteritis, and abdominal pain. Symptoms range from mild distress to stomach death, depending on the individual's sensitivity to the toxin, the amount of toxin consumed, and the victim's overall health. *Klebsiella* spp. and *Bacillus* spp. have been linked to severe infections in immunocompromised people. *Klebsiella* spp. is also linked to a number of hospital-acquired and outpatient-acquired infections, particularly pneumonia. Reports of infections caused by microbial drug contamination prompted the establishment, in the second half of the twentieth century, of a special committee at the International Pharmaceutical Federation (FIP) tasked with developing guidelines governing drug production. The efforts resulted in the creation of Good Manufacturing Practice (GMP) guidelines. They are not a static concept, but rather a dynamically developing system that allows for further process improvement. GMP principles were established to ensure high-quality pharmaceutical products and to protect patients' lives and health.

Furthermore, microbiological purity criteria were established, as was the requirement for final microbiological control. A set of rules was also proposed to govern the issue of maintaining environmental hygiene, preventing potential contaminants from entering manufacturing sites, and ensuring proper storage conditions for raw materials used in manufacturing processes. Given the pharmaceutical sector's rapid growth, rules of conduct for the manufacturing process were established to ensure that appropriate quality of finished products is maintained. The guidelines are organized into Good Manufacturing Practice codes. GPM refers to practices that "ensure that the medicinal products are manufactured and controlled adequately to their intended use and in compliance with the requirements included in their specification," according to the Act on Pharmaceutical Law, which was passed on September 6, 2001, and documents constituting a basis for issuing a permit for medicinal product marketing authorization. The study's goal was to examine the results of microbiological purity tests of non-sterile drugs performed by various pharmaceutical companies in the province of Poland. The study's goal was to present different types of inconsistencies that occurred in the drug groups studied. The obtained results, which are presented below, have the potential to improve pharmaceutical plant production quality, inform/awareness about the importance of microbiological control in the manufacturing process of each drug series, and thus improve the safety and quality of medicines.