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Editorial

Pharmaceutical Microbiological Quality

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PHARMACEUTICAL PRODUCTS

Pharmaceutical items are classified as either sterile or non-sterile in terms of microbiology. Non-sterile medications must meet the microbiological purity criteria outlined in pharmacopoeial monographs. Pharmacopoeial investigations are designed to ensure that the medical product is both therapeutically effective and safe for the patient. The findings of microbiological purity tests done prior to product marketing were included in the analysis. Total of 1285 samples of non-sterile drugs manufactured by different pharmaceutical plants in Polish were taken into study (Wessels 2011). A manufacturing authorization holder must guarantee that medications are fit for their intended use, meet the requirements of the Marketing Authorization, and do not endanger patients owing to insufficient safety, quality, or efficacy. To accomplish the quality goal, it is required to manage all stages of pharmaceuticals, which includes all factors that influence the quality of a product individually or collectively, such as raw materials, the production process, and the evaluation of finished product. The methods utilised and the findings obtained should adhere to the specifications and criteria established in the relevant pharmacopoeia (Wenzel et al., 2006). Testing on both raw materials and finished products includes microbial enumeration tests for total aerobic microbial counts (TAMC) and total yeast and mould counts (TYMC), as well as tests for the following microorganisms: Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Salmonella spp., and Candida albicans. Because microbial contamination can weaken or even eliminate the therapeutic benefit of pharmaceuticals or cause drug-induced illnesses, microbiological testing of non-sterile items is very important. Microbes in medications not only make them contagious, but they can also modify the chemical, physical, and organoleptic aspects of the drugs, as well as the active component concentration (Wilson 2010). Furthermore, microorganisms can convert drugs to toxic products. Not only is the presence of microorganisms, which produce undesired bacterial infections, hazardous, but the presence of metabolites/toxins, even in little levels, may create negative symptoms. Toxin-related diseases can cause diarrhoea, acute gastroenteritis, or abdominal pain. Symptoms range from slight discomfort to gastrointestinal death, depending on the individual's susceptibility to the toxin, the amount of poison consumed, and the victim's overall condition. Klebsiella and Bacillus spp. have been linked to severe illnesses in immunocompromised persons. Klebsiella spp. is also responsible for a number of hospital-acquired and outpatient-acquired illnesses, particularly pneumonia (Bauer et al., 1966). In the second part of the twentieth century, reports of diseases caused by microbial drug contamination prompted the International Pharmaceutical Federation (FIP) to form a special committee tasked with developing criteria governing drug manufacture. The study culminated in the creation of Good Manufacturing Practice (GMP) guidelines. They are not a static notion, but rather a dynamically developing system that allows for future improvement of the manufacturing process. GMP principles were established to assure high-quality pharmaceutical products while also protecting patients' lives and health. The findings of microbiological purity tests done prior to product marketing were included in the analysis. A total of 1285 samples of non-sterile medications manufactured in Poland by various pharmaceutical facilities were studied. Between 2011 and 2013, a cross-sectional study was done at the Department of Genetics and Pharmaceutical Microbiology. More than one non-compliance was observed in two tested samples at the same time (first sample: exceeded count of aerobic bacteria, moulds and bacteria from family Enterobacteriaceae, second sample: exceeded count of aerobic bacteria and Enterobacteriaceae bacteria). Drugs that do not require sterility, regardless of dose form or route of administration, must meet the microbiological purity criteria outlined in an appropriate edition of the EP. Control of pharmaceutical items is a preventative technique

aimed at preventing the release of dangerous products onto the consumer market (Van et al., 2006). Many infections, or more precisely, the metabolites they create, have the ability to either break down or inactivate the medicinal substance. Furthermore, because medications are used by patients with impaired immune systems, successive editions of the Pharmacopoeia put limits on microbiological contamination in order to prevent drug-induced illnesses. In general, drug-induced infections occur infrequently; nevertheless, they can occasionally manifest as hospital acquired infections (HAI) of pandemic proportions. Several incidences of diseases caused by tainted pharmaceuticals have been described in the scientific literature. The first case of drug-induced infection was recorded in 1907, when the bubonic plague vaccination was discovered to be tetanus bacilli infected. Salmonella infections induced by tyroidine tablets and pancreatine powder; Pseudomonas cepacia found in iodated povidone; and ocular infections produced by P. aeruginosa in hydrocortisone ointment were all recognised cases. The findings of our study revealed that the percentage of EP-non-compliant samples before market was 1.87%, implying that: (1) the drugs' microbiological control in accordance with GMP and EP is required at each stage of production, particularly at the stage of the final product prior to release; and (2) each series of produced drugs must be subjected to control. Quality control of pharmaceutical products is vital not only for standard compliance, but also for reducing risk to the end user, and thus to the manufacturer.

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