4th International Conference of Multidisciplinary Approaches (iCMA), 2017
Faculty of Graduate Studies,
University of Sri Jayewardenepura,
Sri Lanka
ISSN: 2386 – 1509

MICROBIAL CONTAMINATION OF SELECTED NON- STERILE PHARMACETICALS IN OPD PHARMACY OF A TEACHING HOSPITAL

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A pharmaceutical product must be effective, safe and should be of good quality to assure their sustainability in the competitive pharmaceutical industry. The quality of the pharmaceutical products can be influenced by the presence of microorganisms (MO). According to British Pharmacopeia (BP) Non-sterile pharmaceuticals (NSP) may contain MOs within a certain limit. If a NSP product exceeds the total viable count of bacteria and fungi or if the presence of the pathogenic species, it is pronounced to be contaminated. Contamination of NSP with microorganisms may cause hazardous effects on human beings as well as change the physical, chemical and organoleptic properties of a drug. Microbial toxins have severe consequences to the patients even when the toxins are produced in very low amounts. All these consequences increase health care cost of a country due to readmission to hospitals. Therefore the objective of this study was to investigate the contamination of MOs of NSPs. The study was carried in an OPD of a teaching hospital, Sri Lanka. The protocol of the study involved random selection of five drug samples out of bulk opened containers. The bulk containers are kept open for days and they are kept in the room temperature. 10g of each drug sample was collected in aseptic manner and they were transported to the laboratory in sealed packs, which were also sterilized with 70% ethanol. Microbial contaminations of these samples were tested according to the method specified in the BP 2013. A dilution series was prepared using the drug samples. The prepared dilution series was inoculated in the specified media in the BP using spread plate method. The Total Aerobic Microbial Count (TAMC) and Total Yeast Mould Count (TYMC) was taken and checked with the specified limits in BP. According to the BP for Non aqueous preparations for oral use the TAMC should be below 103 CFU/g or CFU/ml and TYMC should be below 102 CFU/g or CFU/ml and they should be free from *Escherichia coli*. The contaminated microorganisms were identified using microbial identification methods. The results showed that 1/5 (20%) of the tested samples were contaminated with microorganisms and 4/5 (80%) of the samples were free from contamination. The identified microorganisms were *Aspergillus* species, Gram negative Spore forming Bacilli and *Staphylococcus aureus*. Furthermore the total CFU count did not exceed the maximum CFU limit specified in the BP. Therefore it complies with the standards specified in the BP. This is a preliminary study. For the confirmation of whether there is a risk of getting

contaminated during the handling and storage procedure, it is necessary to conduct further studies comprising of more sample. Also it is needed to identify the source of contamination.

Keywords: *Microbial contaminations, Non Sterile Pharmaceuticals, Teaching Hospital, Sri Lanka, Total Microbial Count*