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P40 : EVALUATION OF NON-STERILE PRODUCTS IN PHARMACEUTICAL INDUSTRY IN TERMS OF MICROBIAL LOAD FOR QUALITY CONTROL PURPOSES

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Objective: According to the Good Manufacturing Practices (GMP) guideline, it is mandatory to test for compliance in terms of quality control of every material that are either contained in, or has direct contact with the products manufactured and used in Pharmaceutical Industry. Especially, the materials must be tested microbiologically by using multiple methods according to the guidelines of European Pharmacopeia (EP). For this purpose, it is aimed to determine the compliance of the chosen test and the validation methods related to the structure of the product and their microbiological limits.
Method: Our samples were classified according to EP regulations. Each product was investigated with respect to the compliance of its own specifications. Tests used for this purpose, were applied for the testing of compliance of the specifications, determined for the microbiological quality of raw materials (active pharmaceutical ingredients and excipients), primary packages or medicines. Applied tests for the quantitative counting of mesophilic bacteria and fungi are; membrane filtration method, plate counting method (pour plate and streak plate) and most probable number method. According to EP, the bacteria and fungi species were detected quantitatively and identified by the API identification kits (20E, 20NE, Staph, 50CE, BioMérieux, France).
Results: Bacteria and fungi species that were looked for are; Staphylococcus aureus, Pseudomonas aeruginosa, Escherischia coli, Salmonella sp. and Candida albicans. With respect to the microbiological limits determined by EP according to the product classifications, total aerobic microorganism count (TAMC), total yeast-mold count (TYMC) and specific microorganisms, were calculated as colony forming unit/mL (CFU/mL or CFU/g).
Conclusion: After counting and identification, if the products were determined to be microbiologically appropriate and safe, they will be approved for usage, either for the company's product reliability or the quality and security and public health duty will be provided.

Keywords: Non-sterile products, microbial load, quality control