Recovery and Detection of Microbial Contaminants

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Description

The presence of microbial contaminants in non-sterile pharmaceutical preparations was not only found to cause spoilage of numerous products but was also proved to be a potential health hazard to the consumer. Accordingly, nonsterile preparations have to pass microbial bioburden tests and tests for the absence of certain specified indicator pathogens. The objective of this study was to test the conditions and challenges for microbial contaminants recovery and detection of specified indicator pathogens in some non-sterile pharmaceutical preparations available in the Egyptian market [1].

Methods and findings

A total of 280 non-sterile pharmaceutical preparations were subjected to microbial limit testing using standard conventional techniques. Method suitability testing was conducted and any antimicrobial property present in the product was neutralized before routine testing. Microbial contaminants could be recovered from 27.6 % of the tested products with oral preparations showing a higher incidence of contamination (33.75%) in comparison to the topical preparations (19.1%). For bacterial counts, six products (3 syrups, 2 tablets and 1 cream) were found to exceed the United States Pharmacopeia (USP) specified limits whilst for fungal counts, three oral preparations (syrups) exceeded the USP specified limits. Regarding the isolates, a total of 60 bacterial and 31 fungal isolates were recovered with gram positive bacilli and molds accounting for the majority of isolates. Eight isolates were USP indicator pathogens; five Staphylococcus aureus isolates were recovered from a cream, a gel, an ointment, a tablet and a syrup; one Pseudomonas aeruginosa isolate was recovered from a capsule; one Escherichia coli isolate and one Candida albicans isolate were recovered from syrups. Conclusion: Testing conditions and challenges could be overcome for recovery and detection of microbial contaminants in collected non sterile pharmaceutical preparations [2].

The microbiological quality of the examined products was, in general, adequate with the exception of few cases. Producers should pay more attention to manufacturing practices and adhere to guidelines given by relevant government authority.

Several measures, including equipment automation, monitoring programs and post-marketing surveillance may be imposed to further reduce the level of microbial contamination of non-sterile pharmaceutical products.

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