The Investigation of Oral-Gastrointestinal Gels and Suspensions Microbial Limit

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ABSTRACT

Oral-gastrointestinal gels and suspensions are used for the relief of peptic ulcer, inflammation and other stomach and gastrointestinal discomfort. Although these drugs do not need sterilization, their bio-burden are limited by the pharmaceutical and health authority to protect the user's safety and to avoid secondary injury. According to the No.0900058057 announcement of the Department of Health, since 2001, oral-gastrointestinal gels and suspensions are reviewed only when applying for distribution permit. In order to monitor the quality of marketed oral-gastrointestinal gels and suspensions, 20 samples of gels and 64 samples of suspensions were acquired from 25 cities and counties in Taiwan during April to July 2004. The 84 samples were processed with the microbial limit tests, including the total microbial count and the assay for *Escherichia coli* and *Pseudomonas aeruginosa.* The results showed that 2.4% of the samples failed to meet the limit of total microbial count (not more than 100 CFU/mL). The result was lower than the 27.5% in 1994 and 3.0% in 2000. The disqualified samples were from the same domestic pharmaceutical manufacturer. After comparing the result of this investigation with the previous two, we found that the majority of the manufacturers with products that previously failed the test improved the products quality accordingly. Generally speaking, the microbial limit quality of the marketed oral-gastrointestinal gels and suspensions in Taiwan reached a stable and adequate degree.

Key words : oral-gastrointestinal gels, gels, suspensions, microbial limit, total microbial count, *Escherichia coli*, *Pseudomonas aeruginosa*.