



CHAPTER 4

DISCUSSION

The microbial contamination in oral pharmaceutical preparations were studied by microbial limit tests method of The United States Pharmacopeia 1975 (11). It was shown that liquid preparations have more contamination than tablets (Table 12,13,14). Many aqueous preparations, syrup, and suspension in absence of active preservatives are ideal media for microbial growth. Rather often that pathogenic microorganisms such as Pseudomonas aeruginosa was found from Antacids and Chloramphenicol palmitate syrup.

In order to make gel, raw materials for instance Magnesium hydroxide and Aluminum hydroxide have to be macerated, in this connection Antacids have marked tendency to contaminate. Contamination is oftenly found in a long maceration period, involving poor sanitary process of manufacturing.

In the case of Chloramphenicol palmitate syrup, the antibiotic does not interfere with the test, because it will become active only after it is acid hydrolysed into free Chloramphenicol base. Contamination found in Chloramphenicol palmitate syrup is due to various factors in ingredients, syrups, methods of preparations and containers etc.

The microbial contamination in Antitussis and Expectorants found in these tests were less frequent than in others of preparations (Table 15,16). According to the formula of Antitussis and Expectorants, the main active ingredients consist of tinctures and other self-preserved vehicles, such as chloroform water or diluted alcohol, which are enough to provide an antibacterial activity.

In Thai-native drugs, the total microbial count were very high i.e. $4.6 \times 10^2 - 7.6 \times 10^5$ (95.5%) (Table 11,17). According to these studies, 63 samples of Thai-native drugs from a total 66 samples tested were found to be contaminated, but no pathogenic microorganism was found. The use of previously contaminated raw materials as well as unsanitary practice in the manufacturing processes are the two main factors which cause severe contamination in most of the finished products of Thai-native drugs. Yeasts and molds were not included in these total microbial counts. The reasons are, firstly, because of the results were observed after 24 to 48 hours of incubation. This lapse of time was not long enough for yeast and mold (if present) to give an observable growth. Secondly, the Soybean Casein Digest Medium used in these studies is not assumed as an ideal medium for the growth of yeast and mold.

From the results Pseudomonas aeruginosa is only pathogen

detected by this study, it causes general infection, and may be remained infectious for extended period, and able to grow even in the media containing only traces of nutrient.