CHAPTER IV

SUMMARY

The current official method of assay for mostly antimicrobial agents, include erythromycin, involve the use of microbiological assays. In recent years, HPLC was developed for analysis of erythromycin, however reported HPLC method for erythromycin assay was not practical in any laboratories due to the heat of column oven.

In this investigation, a new HPLC method was developed for analysis of erythromycin in raw material and pharmaceutical dosage forms by using simple routine instrument. A well separation between erythromycin, its related substances, degradation products and internal standard was obtained with no interference from any adjuvants. A phenyl column was used as stationary phase in which the erythromycin was less retained in this column than in C_8 and C_{18} reversed phase column. With the optimal mobile phase of acetonitrile-methanol-0.05M sodium dihydrogen phosphate pH 5.0 (15:38:47, v/v), erythromycin A could be separated from erythromycin B, erythromycin C, anhydroerythromycin A and erythromycin A enol ether at ambient temperature with a good stability at reasonable elution time and was also suitable for column lifetime.

Ultraviolet detection was used by selecting the wavelength at 215 nm which was optimal to detect erythromycin A, its related substances and degradation products.

The developed method had good precision and accuracy, the relationship between erythromycin and peak height ratio was linear in the range of 0.48-1.28 mg/ml of erythromycin. The detection limit was 9.26 ppm which is sufficiently sensitive to detect erythromycin.

The assay content obtained from this HPLC method was not different from microbiological assay significantly at 95% confidential limit, and the low relative standard deviation was noted from the HPLC method.

High-performance liquid chromatographic method is rapid, precise, accurate, specific and stability-indicating. In the future HPLC method may be used as alternative official assay in the quantitative analysis of erythromycin in raw material and pharmaceutical dosage form.