CHAPTER IV

SUMMARY AND CONCLUSION

From the experimental data obtained showed that the secondary amine drugs, ephedrine hydrochloride, pseudoephedrine hydrochloride, phenylephrine hydrochloride, epinephrine bitartrate, propranolol hydrochloride and piperazine citrate could be determined by spectrophotometric method using fluorescamine. The secondary amine drugs used in this study reacted with fluorescamine under appropriate conditions to give the drug-fluorescamine derivatives with high absorbance property.

The effect of various experimental conditions, e.g., pH, time, temperature, concentration of fluorescamine used, linear absorbance-concentration relationship were studied. The absorbance of the fluorescamine derivatives showed maximum absorption at 317 - 325 nm., with optimum reactivity over a pH range from 8-10. Under these conditions the reaction was completed within 2 mintues and was slightly decreased when the time increased, nevertheless the absorbance was measured at 15 minutes after the reaction. The maximum absorption of the derivatives was obtained at room temperature. The drugs required about 2-8 equivalents of fluorescamine for the reaction to go to completion. Fluorescamine concentration of 2×10^{-3}M was chosen which was sufficient for the analytical purposed. The linear absorbance-concentration relationship was obtained. The linear concentration

range, mcg per ml, were 4.04 - 20.20 (0.13 - 2.77% CV), 4.04 - 20.20 (0.27 - 3.27% CV), 4.08 - 24.48 (0.27 - 1.69% CV), 6.66 - 46.62 (0.49 - 4.84% CV), 8.34 - 41.70 (0.42 - 3.90% CV), 5.90 - 29.60 (0.61 - 7.24% CV) and 2.14 - 14.98 (0.26 - 3.56% CV) for ephedrine hydrochloride, pseudoephedrine hydrochloride, phenylephrine hydrochloride, epinephrine bitartrate, metoprolol tartrate, propranolol hydrochloride and piperazine citrate, respectively.

The proposed method was applied to determine propranolol hydrochloride in commercially available pharmaceutical preparations. The results were compared well to the official USP method. The proposed method showed high accuracy and good reproducibility. It was found that, the proposed method provided quantitative results in less time consuming than the official USP method.

It was observed that other excipients and vehicle used in pharmaceutical preparations did not interfere the estimation of propranolol hydrochloride in the dosage form. The present study provided a simple, rapid, sensitive, accurate and no special apparatus required method for quantitative determination of propranolol hydrochloride in pharmaceutical preparations and the secondary amine drugs used in this study. It will be more widely used and may apply for determination of another secondary amine drugs, base of this point of view.