Chapter V

Summary and Conclusion

From the experimental data obtained showed that dicyclomine hydrochloride could be determined by using acid dye, bromcresol green, method. The development of complex between dicyclomine and bromcresol green has been investigated in two ways. Method 1, dicyclomine free base was extracted from aqueous alkaline solution with chloroform. Bromcresol green in chloroform was then added to the combined chloroform extracts to produce a yellow - colored complex with a maximum absorption at 415 nm. Method 2, dicyclomine hydrochloride was treated with bromcresol green in aqueous buffer pH 2 and the yellow - colored complex formed was extracted with chloroform. The complex showed maximum absorption at the same wavelength as mentioned in the first method.

The effects of various factors were studied and compared in both methods such as stability of the complex, concentration of dye used, mole ratio of complex formed and linear absorbance - concentration relationship. It was found that in both methods, the mole ratio of complex formed was 1 : 1 and concentration of dye used was four times of drug. The complex formed was stable to time and temperature. The linear absorbance - concentration range in first method was 1.38 - 16.51 mcg/ml with coefficient of variation of 0.75 - 6.67 % , while in the second method linear absorbance - concentration range was 1.37 - 16.46

mcg/ml with coefficient of variation of 0.69 - 11.76 % . The results obtained showed that the first method was more sensitive and suitable for quantitative determination of dicyclomine hydrochloride.

The suggested method was applied to determine dicyclomine hydrochloride in commercially available pharmaceutical preparations. The results obtained were compared to those obtained from the USP method. The proposed method showed high accuracy and good reproducibility as that of the USP. However, the USP method has the disadvantage for preparation containing color which interferes with the end point color. Furthermore, it is time consuming since restandardization is always required before use, for sodium lauryl sulfate precipitates upon standing.

It was observed that other common excipients used in pharmaceutical preparations did not interfere in the estimation of dicyclomine hydrochloride. Because of its simplicity, sensitivity and accuracy, this method was suited for routine analysis of pharmaceutical preparations of dicyclomine hydrochloride.

The results obtained from the study of the new method could be summarized as followed.

1. The suggested method was simple and rapid in contrast to the tedious and time consuming USP method. Their accuracy and reproducibility were comparable.

2. The procedure was very sensitive to micro - amount of

dicyclomine hydrochloride in formulations and could be applied to various dosage forms, e.g., syrup, tablet and capsule.

3. The required reagent was bromcresol green which was available commercially. The prepared reagent was non - toxic and could be stored for a long period of time without appreciable change.

4. Interferences by common excipients were found to be negligible.

Cautions of this procedures were : -

1. The presence of traces detergent could react with bromcresol green and cause large error in analysis. Therefore, the glassware used might be scrupulously cleaned with the special attention paid to ground - glass surfaces. It was recommended to wash all glassware with 0.1 N hydrochloric acid, follow by distilled water.

2. Most substances with tertiary amine group, or quaternary ammonium salts could form complexes with bromcresol green. Since the common encountered formulation of dicyclomine hydrochloride in this experiment did not contain any of the above mentioned drug and therefore, no such interferences were expected. If these substances present in the formulations it was suggested that preliminary chromatographic separation might be performed before running the proposed procedure.