# Chapter I

## Introduction

Dicyclomine is an anticholinergic drug used for its atropine -like effects on the gastrointestinal tract. It is used in the treatment of irritable colon, spastic constipation, mucous colitis, spastic colitis, pylorospasm and biliary dyskinesia. In the treatment of peptic ulcer it is used to delay gastric emptying. Dicyclomine is used in the form of hydrochloride salt and marketed in the form of a syrup, tablet, capsule and injection.

Several methods for the analysis of dicyclomine hydrochloride in pharmaceutical preparations have been published. Most official methods for dicyclomine analysis[1 - 4] were mainly depended on tritration with sodium lauryl sulfate in a biphasic medium between dilute sulfuric acid and chloroform using methyl yellow as a basic dye indicator. The official titrimetric methods were tedious and time consuming. Moreover, methyl yellow, a carcinogen[5], was also harmful to human body. A spectrophotometric method[6] was recently reported for the analysis of dicyclomine via reaction with chloranil in benzene. This method lacked of sentivity to micro - amounts and was relative time consuming; and the prepared chloranil reagent was not stable. Determination of dicyclomine by gas - liquid chromatography has been previously reported by Rader and Fricke[7,8]. Brownell and Alber[9] recently proposed the gas - liquid chromatographic procedure which

provided a means of computerized automation in which the GLC responses was monitored while the system ran unattended. Although the gas - - liquid chromatographic method gave an accurate and good results for determination of dicyclomine hydrochloride in pharmaceutical preparations; the method was time consuming, required a special technique and availability of certain equipments. This stimulated the need for a satisfactory, simple, rapid and sensitive method for determination of dicyclomine hydrochloride in pharmaceutical preparations.

The proposed of this thesis was to find the best and simple method which could be used in quality control of dicyclomine hydrochloride in pharmaceutical preparations. The method was based on selective complex formation of dicyclomine and bromcresol green. This study described two methods for determining dicyclomine by using bromcresol green. Method 1, dicyclomine free base was extracted from aqueous alkaline solution of its hydrochloride salt with chlorofom and then reacted with bromcresol green. A yellow-colored complex was formed and determined spectrophotometrically. Method 2, dicyclomine hydrochloride was reacted with bromcresol green in aqueous buffered at optimum pH. The yellow-colored complex formed was extracted with chloroform and determined spectrophotometrically. These two methods were compared, and the suitable one was then selected and used to determine dicyclomine hydrochloride in formulations. The results obtained by the proposed method were compared with those obtained by the USP method.