CHAPTER I
INTRODUCTION

Conventional dosage forms for delivery of drugs via the oral mucosa include solutions, chewable buccal or sublingual tablets, and capsules. Unfortunately, a major portion of the drug in these systems may be unavailable due to involuntary swallowing and a very short residence time. Because of mastication, speech, etc., the administration of such a dosage form is usually restricted in terms of residence times, and hence sustained release is usually not within the scope of such formulations. In recent years, significant interest has been shown in the development of novel bioadhesive dosage forms for mucosal delivery of drug that attempts to overcome these limitations (Rajesh and Joseph, 1994).

Lidocaine has been widely used for local anesthetic in dentistry since 1948 (Taware, et al., 1997). It blocks the sodium channels on excitable membranes by preventing the generation and condition of nerve impulses and providing analgesic relief (Comer and Lamp, 2000). It usually administered either parentally or topically. Rolier and Ship (1975) designed the study to compare two forms of anesthetic, lidocaine, for oral mucosal biopsies: the traditional injection technique of infiltration with anesthetic solution and a new form of topical application of anesthetic impregnation in a film strip. This study showed that the anesthetic film was easy to administer, producing minimal tissue distortion, and no significant side effects. Most patients liked the film flavoring, and appreciated local anesthesia without needle injection. Brook, et al. (1989) reported that application of lidocaine on the oral mucosa produced soft tissue anesthesia of similar depth and extent to that achieved by infiltration anesthetics (Amess and Mathews, 1995). Recently, it was found that topical application of lidocaine to dentine could block the response of the intradental nerves to the probing and air blast stimuli (Amess and Mathews, 1995 and Amess, et al., 1996). One of the main disadvantage of the topical application is the short retention time of the drug on the application site as most of it leaches into the oral cavity shortly after application. The parenteral route of administration is currently the route of choice for the induction of local dental anesthesia worldwide because of better penetration and rapid onset of action of the drug. This mode of delivery can be

painful, especially to pediatric patients. Moreover the increasing risk of acquired immune deficiency syndrome (AIDS) through the use of contaminated syringes has intensified the search alternative to parenteral administration. Mucoadhesive dosage form is potentially to be chosen for the proper choice in pharmaceutical industries.

The mucoadhesive drug delivery systems for oral mucosal administration have been developed in the number of different dosage forms, include films, gels, ointments and tablets (Kohda, et al., 1997). The mucoadhesive films have clearly defined many advantages over other dosage forms. For instance, the films allow more exact dosing and easier application than gels and ointments. In addition, gels were given the relatively short residence time on the mucosa, which is easily washed away and removed by saliva. Although, the mucoadhesive tablets were given the latter advantages too, mucoadhesive films may preferred over adhesive tablet in terms of flexibility and comfort. Therefore, the mucoadhesive films were given more patients' acceptability and patients' compliance than other mucoadhesive dosage forms.

In objective of this present study was to prepare mucoadhesive patch for oral mucosal administration of lidocaine as a viable alternative dosage form to lidocaine injection dentistry. In this study, the mucoadhesive patch containing 45 mg of lidocaine per patch. The adhesive properties, morphology, physicochemical properties, in vitro release and penetration and stability of the preparations were evaluated and compared with the commercial product (Dentipatch®).