Chapter 1

Introduction

1.1 INTRODUCTION

Buccal drug delivery has become an important route of drug administration. Various bioadhesive mucosal dosage forms have been developed, which includes adhesive tablets, gels, ointments, patches, and more recently films[1-5]. Recently, the use of polymeric films for buccal delivery has been investigated by Peh and Wong[5]. Here, an attempt was made to prepare the fast dissolving film and fast dissolving tablets of salbutamol sulphate, ondansetron, hydrochloride and lamotrigine containing polyvinyl alcohol for sublingual route.

Fast dissloving film is a thin, drug containing film having area of 4 cm^2 (Dimension: 2 cm × 2 cm). The rapid dissolution in water or saliva is ensured by a special matrix of water soluble polymer and filler. An unpleasant taste can be masked by the addition of flavours and / or sweeteners. The film can be placed below the tongue and the dissolved mass is to be swallowed. The film dissolves quickly which makes the absorption of drug through sublingual mucosa and oesophagus. The sublingual mucosa is a smooth surface, not furred like the top of the tongue, and is free of mucus and undigested food unlike stomach. Furthermore, the sublingual mucosa is relatively permeable due to the thin membrane and large veins. It gives rapid absorption and instant bioavailability of the drugs due to high blood flow and lack of a stratum corneum epidermidis. It can also bypass enzymatic degradation in the gastrointestinal tract and the hepatic first pass effect[6-8]. The proposed film could be useful in the chronic and acute treatment of asthma where quick bioavailability is needed and patient finds difficulty of swallowing the tablets.

Fast dissolving drug delivery systems (FDDS) have started gaining popularity and acceptance as new drug delivery systems, because they are easy to administer and lead to better patient compliance. Some useful techniques to prepare fast dissolving tablets such as freeze drying, spray drying and sublimation[9-11] have been reported. But all these techniques are expensive. Some researchers have developed rapidly disintegrating tablets using freeze dried amorphous sucrose[12] or lactose with various particle sizes[13]. Other

compressed, rapidly disintegrating tablets include one with treated agar[14] and another with camphor as a subliming material[15]. However, the manufacturing methods of all these tablets are more or less complicated. Directly compressible rapidly disintegrating tablets using microcrystalline cellulose (MCC) and low-substituted hydroxypropylcellulose have been reported[16], but taste was unsatisfactory, as expected. Rapidly disintegrating tablets with pleasant taste containing erythritol have been reported[17] but cost of these tablets increased due to costly erythritol. In this study, approach was made to prepare the rapidly disintegrating tablets with a pleasant taste using mannitol which has a negative heat of solution, pleasant taste and low cost.

1.2 AIM OF WORK

This investigation was undertaken with the aim to "prepare and evaluate immediate relese films and tablets of salbutmaol sulphate, ondansetron hydrochloride and lamotrigine" to provide rapid onset of action. Salbutamol sulphate is in asthamatic attack where quick onset of action is desirable. Ondansetron hydrochloride is an antiemetic agent. In emesis, intake of water is even not possible and quick onset of drug action is neeed. Lamotrigine is used in epileptic acttack, the conditions where rapid drug action is required.

1.3 PROPOSED PLAN OF WORK

To review the literature on the subject of immediate release films and tablets and profile of the drugs.

To develop analytical method for the estimation of the drug in dissolution media and in rabbit plasma.

To reiview the article entitled "artificial neural networks (ANNs) modeling in pharmaceutical research: basic concept and application: A review".

To carry out the pH dependent in vitro buccal permeation studies of the drugs through porcine buccal mucosa using Franz diffusion cell and perform the buccal absorption test on human volunteer.

To carry out the parallel artificial membrane permeation assay of the drugs at various pH.

To prepare immediate release films and evaluate them for tensile strength, elastic modulus, elongation, drug release in dissolution study. To perform the stability studies of the prepared films.

To enhance the solubility and dissolution rate of Lamotrigine using artificial neural network modeling.

To prepare immediate release tablets and evaluate them for disintegration time, hardness, friability and drug release in dissolution media. To perform the stability studies of the prepared tablets.

To perform in vivo studies to compare pharmacokinetics for the developed dosage forms and the convetional tablet dosage foms.

1.4 REFERENCES

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