2.1 Aim of present work

Patient convenience and compliance oriented research has resulted in bringing out safer and newer drug delivery systems. Recently Fast dissolving drug delivery systems (FDDSs) have started gaining popularity and acceptance as one such example with increased consumer choice, for the reason of rapid disintegration or dissolution, self administration even without water or chewing. FDDSs includes, fast dissolving tablets (OFT) and fast dissolving films (FDFs) or dissolvable oral thin films (OTFs) have continued to expand in sales and launched as patient compliant, and convenient products efficiently addressing issues for pharmaceuticals as well as nutraceuticals that have been traditionally administered as oral solid dosages. Fast-dissolving films are rapidly gaining interest in the pharmaceutical industry over disintegrating tablet technology because they are handy with patients having difficulties in swallowing or chewing solid dosage forms (Slowson M et al, 1985. Doheny K et al, 1993. Chang R et al, 2000. Seager H et al, 1998).

A recently-released report in “Technology Catalysts” on 'orally disintegrating tablet and film technologies' (3rd Edition), the company identified over fifteen companies actively developing FDFs delivery technologies that enable the shift from a tablet form to a fast-dissolving and highly water-soluble wafer or film. In addition, the report identifies nine launched FDFs pharmaceutical product as well as 47 FDFs product in the pipeline being developed by 12 companies. Technology Catalysts forecasted the market for drug products in oral film formulations to be valued at $500 million in 2007 and could reach at $2 billion by 2010 (Technology Catalysts, 2006, Laxman K et al, 2010).

FDFs have evolved from the confectionery and oral care markets over past decade in the form of breath strips thy have become a novel and widely accepted dosage form by consumers for delivering vitamins and personal care products. Companies’ expertise in formulating polymer coatings for transdermal drug delivery focused on transitioning this technology to FDFs. Today, FDFs are a well proven and globally well accepted technology for the systemic delivery of active pharmaceutical ingredients (APIs) for over-the-counter (OTC) medications and are in the early- to mid-development stages for prescription drugs.
These films are soluble in water at room temperature and will break up within 30 sec and dissolve in one minute. The faster the drug goes into the solution, quicker is its absorption and faster onset of clinical effect. A major claim of the some FDFs is increased bioavailability compared to traditional dosage forms. Because of dispersion in saliva while still in the oral cavity, there can be pre-gastric absorption from some formulations in those cases where the drug dissolves quickly.

Globally, cancer is increasing at an alarming rate. Chemotherapy is the primary treatment for cancer and in some cases the only resort. Most of the chemotherapeutic drugs have been found to cause release of large amounts of serotonin from enterochromaffin cells in the gut. Serotonin acts on 5-HT$_3$ receptors in the gut and brain stem and stimulate vagal affrents to initiate the vomiting reflex. Chemotherapy induced nausea and vomiting (CINV) remains a significant problem for cancer patients, having a long lasting effect on their quality of life. 5-HT$_3$ receptor antagonists or serotonin antagonists suppress nausea and vomiting by inhibiting serotonin binding to the 5-HT$_3$ receptors (Watcha F et al, 1992, Foubert J et al, 2005). Ondansetron is a highly selective serotonin (5-HT$_3$) receptor blocker which inhibits serotonin to bind with serotonin 5-HT$_3$ receptors and hence prevent the vomiting reflex induced by serotonin (Jantunen I et al, 1997, Tortorice P et al 1990).

Allergy is a hypersensitive disorder of the immune system. Allergic reactions occur due to environmental substances known as allergens. Allergy is one of four forms of hypersensitivity and is called type I hypersensitivity. It is characterized by excessive activation of certain white blood cells called as mast cells and basophils by a type of antibody known as IgE, resulting in an extreme inflammatory response. Mild allergies like hay fever are highly prevalent in the human population and cause symptoms such as allergic conjunctivitis, itchiness, and runny nose. A variety of tests now exist to diagnose allergic conditions; these include testing the skin for responses to known allergens or analyzing the blood for the presence and levels of allergen-specific IgE. Treatments for allergies include allergen avoidance, use of anti-histamines, steroids or other oral medications, immunotherapy to desensitize the response to allergen, and targeted therapy (Kay A et al, 2000, Holgate S et al, 1998, Rusznak C et al, 1998).
Levocetirizine is a third-generation non-sedative antihistamine, works by blocking histamine receptors. It does not prevent the actual release of histamine from mast cells, but prevents it binding to its receptors. Levocetirizine prevents the release of other allergic chemicals produced in response to allergens and increased blood supply to the area, and provides relief from the typical symptoms of hay fever (Mahapatra A et al, 2009).

In above mentioned conditions, rapid action of the drug is required. The fast dissolving films fulfill all the requirements of potential solid dosage form for levocetirizine in treating allergic conditions and ondansetron in preventing nausea and vomiting.

**Objectives of Study**

- To select a suitable polymers for the fast dissolving film.
- To select suitable plasticizer for the fast dissolving film.
- To select proper concentration of taste masking agent for the fast dissolving film.
- To select suitable film modifier, sweetener for the fast dissolving film.
- To formulate fast dissolving drug delivery system containing drug.
- Evaluation of prepared films.
- *In-vitro* drug release of prepared films.
- *In vivo* study of optimized films.
- Stability studies of selected films as per ICH guidelines.
- To achieve faster onset of action and improved bioavailability.
- To obtain better patients compliance.
2.2 References


