CHAPTER I

INTRODUCTION

Recently, much attention has been focused on quality of pharmaceutical product during distribution. Once it is leave the processing stage, it is keeping properties and extent to which it will retain it is intended attributes are a function of the environment inside and outside the package. The important parameters are gas composition, relative humidity, pressure or mechanical stresses, light and temperature. Changes in external conditions cause a change inside the package, with subsequent effects on the quality

The quality of any medicine product and its useful shelf life is strongly dependent on its temperature exposure history. A tightly monitored temperature exposure during distribution and an optimized stock rotation in the retail level based on the temperature of each product, instead of an often meaningless expiration date, can lead to better control of quality. Time-temperature indicators (TTIs) can serve of tools for achieving these goals. TTIs are small, inexpensive devices that show a time-temperature dependent, easily measurable and irreversible change that can be correlated to changes of quality of a medicine undergoing the same variable temperature expose. (Taoukis and Labuza, 1989).

A systematic approach that allows the correlation of the response of a Times-Temperature indicator to the consumed and remains shelf life of pharmaceutical product exposed to the same variable temperature condition was developed by design of Smart polymeric materials with edibles indicator. Thus, considerable research effort is now being made to thermally control the release of indicator to reaction.

Smart polymeric materials such as poly-N-isopropylacrylamide (PNIAAM) respond to small changes in their environment with dramatic changes in their physical properties. Environmental stimuli include temperature, pH, chemicals, and light. The

research aims to bring together the exciting design of these materials and the ever-expanding range of their uses by focusing on thermo sensitive systems with a specific temperature-dependent solubility or swelling behavior .In these systems, temperature variation triggers alteration of polymer configurations, leading to change of release rate of compounds incorporated in the system. (Ichikawa and Fukumori, 2000)

Studies related to edible pH indicators are few, especially involving natural and edible components However there are patents reporting pH indicators based on food compounds such as carotenoids and anthocyanins (Bamore et al., 2003). They were proposed for a conventional non biodegradable package cooking procedure and for laboratory indicators, respectively. In this study demonstrated that red cabbage dry could be used as a pH indicator in Pharmaceutical formulations. This water-soluble color is also found in red cabbage, apple skin, red onion skin, plums, poppies, blueberries, cornflowers, and grapes. Red cabbage contains an indicator color molecule called flavin, which is one type of molecule called an anthocyanin. Acidic solutions will turn anthocyanin a red color. Neutral solutions result in a purplish color. Basic solutions appear in greenish-yellow. Therefore, it is possible to determine the pH of a solution based on the color it turns the anthocyanin pigments in red cabbage juice.

The present study was designed to use of red cabbage extract as a source of pH indicators (anthocyanin) on the color change of a hydroxypropyl methylcellulose and poly-n-isoproplyacrylamide thin films. The purpose of this study was formulated thin films were use as tablet degradation detector of two model drugs, glibenclamide and aspirin commercial tablets. Glibenclamide was characterized for solid state transformation by X-ray powder diffraction (XRD), differential scanning calorimetry (DSC) and it effect on solubility. Aspirin was evaluated chemical degradation, salicylic acid. The thin films as degradation indicator was evaluated the color parameters and physical properties of each film formulations.

Objectives of the study

1. To develop formulation of thin films as a drug degradation indicator.

2. To study the factors effecting the efficiency of thin film as indicator to detect drug degradation.