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FORMULATION, DEVELOPMENT AND EVALUATION APPROACH FOR MUCOADHESIVE TABLETS

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ABSTRACT

The present study has shown that Drug prepared tablets gave promising results in terms of mucoadhesive resistance and in vitro permeation of the dosage form. The present research was planned for the formulation and development of Drug hole-adhesive tablets with 2 factors, namely Moringa gum and Xanthan gum in 3 different levels. For the formulation of hole-adhesive tablets, MG and XG are used in 3 different levels with direct compressible lactose as a diluent. Fixed amount of ethyl Cellulose used as a support layer. The formulation variables include the nature and quantity of polymers and diluents with different physico-chemical properties, mucoadhesive resistance, swelling index studies, in vitro permeability studies and stability. Prestressing parameters such as rest angle, bulk density, shunt density, compressibility index and host ratio within the prescribed limits. The prepared oral adhesive tablets were evaluated for post-compression parameters such as hardness, weight variation, thickness, friability, and swelling index, uniformity of the drug content, surface pH, and mucoadhesive resistance. All prepared oral tablets were found to follow an abnormal non-Fickian release. The formulation was stable with respect to the content of the drug, permeation in vitro during the stability study period.

KEYWORD: Drug, mucoadhesive tablet, mucoadhesive resistance, Moringa gum and Xanthan gum.

INTRODUCTION

Today the interest in the new route of drug delivery is influenced by its ability to improve the bioavailability of a certain class of drugs. Delivery of the drug via the buccal route, using bioadhesive dosage forms, offers such a new path of drug delivery. Oral administration involves administration of the desired drug through the lining of the oral mucosa of the oral cavity. However, the therapeutic potential of the compounds lies in our ability to design and implement effective and stable delivery systems. Based on our current understanding of the biochemical and physiological aspects of the absorption and metabolism of many biotechnologically produced drugs. After oral administration, many drugs undergo a high presystemic clearance in the liver, which often leads to a significant lack of correlation between permeability, absorption and bioavailability of the membrane.[1]

Difficulties associated with parenteral delivery and poor oral availability provided the impetus for exploring alternative routes for the delivery of such drugs. These include routes such as pulmonary, ocular, nasal, rectal, Muccal, sublingual, vaginal, and transdermal. In absence of external stimuli, to facilitate absorption, use of these alternative routes has had limited success. Various strategies have been implemented to promote the bioavailability of these drugs, including supplemental administration of enzyme inhibitors, use of absorption enhancers, novel formulation strategies, and reversible chemical modifications.[2]

Among the various pathways of transmucosa, in the mucosa have good accessibility, an extension of smooth muscle and a relatively immobile mucosa, therefore suitable for the administration of retentive dosage forms. Direct access to the systemic Circulation through the internal jugular vein prevents first-pass liver drugs Metabolism leading to better bioavailability. Other benefits such as low enzymatic activity, suitability for drugs or excipients that damage or irritate the mucosa reversibly and in a reversible way, painless administration, easy removal of drugs, possibility of including permeation enhancer / inhibitor or enzyme modifier or modifier. Not only PH in the formulation but also versatility in design as multidirectional or unidirectional delivery systems for local or systemic actions, etc., opt for oral adhesive drug delivery systems as a promising option for on-going research.[3] However, the effect of salivary sweep and accidental swallowing of the administration scheme; the barrier property of the mucosa is highlighted as the main limitations in the development of adhesive drug delivery systems. Within

the cavity of the oral mucosa, the administration of drugs is classified into three categories.[4]

Experimental Work

- Preformulation studies:

The Preformulation study is an investigation of the physical and chemical properties of a single pharmacological substance and when combined with excipients. It is the first step in the rational development of dosage forms. Preformulation begins when a recently synthesized drug shows sufficient pharmacological responses in animal models to justify human evaluation. Therefore, these studies should focus on the physico-chemical properties of the new compound which could affect the drug's performance and the development of an effective dosage form.

A thorough understanding of these properties can ultimately provide a rationale for the design of the formulation or support the need for molecular changes.[5]

- Pre-compression parameter:
- Angle of Repose

The angle of repose is the maximum angle of a stable slope determined by friction, cohesion and the shapes of the particles. When bulk granular materials are poured onto a horizontal surface, a conical pile will form. The internal angle between the surface of the pile and the horizontal surface is known as the angle of repose and is related to the density, surface area, and coefficient of friction of the material, particle size and shape. Material with a low angle of repose forms flatter piles than material with a high angle of repose. In other words, the angle of repose is the angle a pile forms with the horizontal plane. Angle of repose was determined using funnel method. The height of the funnel was adjusted in such a way that the tip of the funnel just touches the heap of the blends. Accurately weighed blend was allowed to pass through the funnel freely on to the surface. The height and diameter of the powder cone was measured and angle of repose was calculated using the following equation.[5]

$\theta = \tan^{-1}(h/r)$

Where, h = Height of pile, r = Radius of pile, and θ = Angle of repose

- Determination of Bulk Density and Tapped Density

It is the ratio between a given mass of a powder and its bulk volume.

- Carr's Compressibility Index

Compressibility index was determined by placing the dried granules in a measuring cylinder and the volume was noticed before tapping, after 100 tappings again volume was noticed.[6]

- Hausner's Ratio

Hausner's Ratio indicates the flow properties of the powder and it's the ratio of tapped density and bulk density. Hausner found that this ratio was related to interparticle friction and, as such, could be used to predict powder flow properties. Generally a value less than 1.25 indicates good flow properties, which is equivalent to 20 % of Carr's index.[6]

- Evaluation of Tablets

All the prepared Mucoadhesive tablets were evaluated for the following official and unofficial tests described in pharmacopoeia or in standard text books or research articles.[7]

- Appearance

The tablets were identified visually by checking the difference in colour against contrast backgrounds.[7]

- Thickness and Diameter

Twenty tablets were randomly selected from formulations thickness and diameter was measured individually by using a vernier caliper. It was expressed in millimeter and average was calculated.[7]

- Hardness

Hardness indicates the ability of a tablet to withstand mechanical shocks while handling and during transportation. The hardness of the tablets was determined by using Monsanto type hardness tester. It was expressed in Kilogram per centimeter square (kg/cm2). 3 tablets were randomly selected from each formulation and hardness of the same was determined. The average value was also calculated.[7]

- Friability

Twenty tablets were weighed as per IP and placed in the Roche friabilator and apparatus was rotated at 25 rpm for 4 minutes. After revolutions, the tablets were dedusted and weighed again. The difference in weight not is more than 0.8 %. The percentage friability was computed using formula.[5]

$\% F = \{(Wi-Wf) / Wi\} \times 100$

Where,

% F = Friability in percentage. Wi = Initial weight of tablets.

Wf = Weight of tablets after revolution.

- Weight variation

The weight variation test was performed by weighing 20 tablets individually, the average weight was calculated and the weight of the single tablet was compared with the average weight. Calculating the average weight, comparing the individual weight of the tablet with the average weight. The tablets comply with the IP 2014 test if no tablet differs by more than double the percentage deviation or if no more than two of the individual weights must deviate from the average weight by a deviation of 7.5%.[8]

- Drug content uniformity

This test is used to monitor the batch-to-batch variation

in drug content. The active substance requires uniform distribution throughout the tablet formulation. Five tablets of each formulation were weighed and pulverized. The amount of powder equivalent to 8 mg of medicine. The equivalent weight drug was transferred to a standard 100 ml volumetric flask and using a buffer solution at pH 6.8 as the extraction solvent. The drug was extracted with intermittent shaking for 24 hours and the samples were analyzed by spectrophotometry (Jasco) at 310 nm. The drug content was estimated to triplicate.[9]

CONCLUSION

In the present work, we have attempted to formulate and evaluate Drug hole-adhesive tablets with 2 factors, i.e. MG and XG at 3 different levels. The following conclusions were drawn from the study: the Drug buccal formulations in hole-adhesive tablets were developed to a satisfactory level, in terms of drug release, mucoadhesive resistance, uniformity of content, swelling index, surface pH, friability, hardness and weight variation. Drug preformulation studies confirm the published values of the literature.

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