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Design And Development Of Mucoadhesive Buccal Tablet Of Pantoprazole By Using Tamarind Seed Powder

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Abstract: ***Pantoprazole undergoes hepatic first pass metabolism, hence it shows poor bioavailability. The aim of study was to prepare and evaluate mucoadhesive tablet of pantoprazole using tamarind seed powder in combination with HPMC, magnesium oxide, and talc. Tamarind seed powder is used for dissolution enhancer (improve dissolution).***

Method: ***Six Formulations were developed with varying concentration of polymer like HPMC and other excipients like tamarind seed powder, magnesium oxide and lactose.***

Result: ***The formulations were evaluated for hardness, thickness, surface pH, weight variation, content uniformity, and swelling index. The maximum in vitro drug profile was achieved with the formulation F4 which contain drug , tamarind seed powder, HPMC, magnesium oxide and talc in (20, 17, 4, 50, 9) mg concentration respectively. The surface pH and drug content of F4 formulation was found to be 7, 95.56% respectively. The formulation F4 exhibit drug release i.e.95.56% in 6 h.***

Conclusion: ***It is concluded that tamarind powder shows the residence time of pantoprazole for 6 h. The release of F4 batch shows maximum drug release 95.56 %.***

Keywords: ***Pantoprazole, Mucoadhesivebuccal tablet, tamarind seed powder.***

I. INTRODUCTION

Buccal drug delivery is an alternative route for the oral administration of drugs which undergo degradation in the gastrointestinal track or hepatic first pass metabolism oral mucosal surface is rich in blood supply and offers several advantages over both injectable and enteral methods of drug delivery. The absorption rate through oral mucosa is about four times greater than the skin. There are different regions in oral cavity: buccal, rapid onset of action is required the buccal route is more preferable.

Buccal drug delivery offers a safe mode of drug delivery system and dosage form can be removed in case of toxicity. Buccal mucosa has an excellent accessibility, which leads to direct access to systemic circulation through the internal jugular vein which bypasses the drug from hepatic first pass metabolism.

Pantoprazole sodium sesquihydrate [PSS], it is chemically known as sodium-5-(difluoromethoxy) – 2 – [[(3,4-dimethoxy-2- pyridinyl)methyl]sufinyl]-1H-benzimidazole sesquihydrate. It exhibits potent and long –lasting inhibition of gastric acid secretion by selectively interacting with the gastric acid secretion by selectively interacting with the gastric proton pump (K/H–AT Pase) in the parietal cell secretary Membrane. It is used for treatment of erosion and ulceration of the esophagus caused by gastro esophageal reflux disease. However , the bioavailability of pantorazole following oral administration is usually very low, since it degrades very rapidly in the acidic environment of stomach and undergoes hepatic first pass metabolis,. To improve the bioavailability of pantoprazole in particular by preventing gastric degradation, various oral formulations of pantoprazole such as enteric coated granule and tablet have been developed with a

subsequent 40% increase in oral bioavailability of pantoprazole in humans. However, these oral formulations of pantoprazole have been known to have a wide individual variataion of plasma concentration in human subjects. Thus, attempt were made to develop alternative dosage form such as rectal suppository and buccal adhesive tablet, since the gastric degradation and first pass metabolism of pantoprazole may be avoided via these route of administration. In particular, pantoprazole buccal adhesive tablets were developed to be attached to human cheek without collapse and longer residence time and dissolution enhancement in human saliva.

The buccal adhesive tablets were prepared by mixing tamarind powder, hydroxyl propyl methyl cellulose (HPMC), and magnesium oxide. The enhanced dissolution and longer residence time of pantoprazole tablet in human saliva was attributed to tamarind powder. Pantoprazole delivered by the buccal adhesive tablets composed of tamarind powder, HPMC, magnesium oxide, compression method.

II. MATERIALS AND METHODS

MATERIAL

Pantoprazole sodium sesquihydrate (PSS) was a gift sample from Wockhardt Ltd. Aurangabad. Magnesium oxide, lactose, HPMC was taken from Pharmaceutics Laboratory, K.T. Patil college of Pharmacy, Osmanabad and tamarind seed powder was made in home and check for presencee of microorganism and evaluated for solubility, pH, density, powder flow property, etc.

METHODS

PRE FORMULATION STUDY CALIBRATION OF PANTOPRAZOLE

A stock solution of pantoprazole is prepared by dissolving 10 mg drug in 100 ml of 0.1 N HCL and PH 6.8 phosphate buffer. The Xmax of the drug was determined by scanning above solution between 400 and 200 nm using UV –visible spectrophotometer.

- ✓ *In 0.1 N HCL:* Drug is calibrated in 0.1 N HCL by using UV spectrophotometer at determined wavelength.
- ✓ *In PH 6.8 Phosphate buffer:* Drug in calibrated in PH 6.8 Phosphate buffer by using UV-spectrophotometer at determined wavelength.

PREPARATION OF MUCOADHESIVEBUCCAL TABLET

Mucoadhesivebuccal tablet, each containing 20 mg Pantoprozle sodium sequihydrate (PSS)

Were prepared by direct compression method. Composition of various formulations employing tamarind powder, HPMC, Magnesium oxide and lactose are very important in the formulation. To determine the effect of selected exciplent on the release of pantoprazole six formulations were formed all the batches were prepared which is show in table I.

All the ingredients of tablets were blended in glass mortar with a pestle for 15 min and pass through sieve no 85 to obtain uniform mixture. The blended powder was then compressed into 100 mg tablets on a single stoke, 10 station rotary tablet machine with 6mm round shaped flat punch.

Ingredients (mg)/ Formulations	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**
Pantoprozle sodium sequihydrate	20	20	20	20	20	20
Tamarind powder	15	15	15	17	17	17
HPMC	4	6	8	4	6	8
Magnesium Oxide	50	50	50	50	50	50
Lactose	11	9	7	9	7	5
Total	100	100	100	100	100	100

Table 1

EVALUATION OF MUCOADHEIVE TABLETS OF PANTOPRAZOLE

HARDNESS

Tablets were evaluated for their hardness using Monsanto hardness tester. The experiment was performed in triplicate and average value was calculated.

WEIGHT VARIATION

Ten tablets from each formulation were weighed using an electronic digital balance and the average weight was calculated. The experiment was performed in triplicate and average value was calculated.

THICKNESS

Tablets were evaluated for their thickness using digital Varniercallipers. The experiment was performed in triplicate an average value was calculated.

FRIABILITY

The friability test was done using Roche's Friabilator. Ten tablets were selected and weighed individually. Then the friability test was carried out at 25 rpm for 4 min. There tablets were then again weighed and percentage loss in weight was calculated. The experiment was performed in triplicate and average value was calculated.

% loss = Initial weight - Final weight/ Initial weight ×100

CONTENT UNIFORMITY

The tablet was kept in 100 ml volumetric flask containing phosphate buffer pH 6.8 for 24 h. After the tablet was completely dissolved then solution was centrifuges. The supernatant was taken and the absorbance was measured by using UV at 285. 2 nm. Dilution was done by pH 6.8 buffer, when required. The experiment was performed in triplicate and average value was calculated.

SURFACE pH

The surface pH of the formulations was detained in order to investigate their possible side effects in vivo. An acidic or alkaline formulations will cause irritation of the mucosal membrane and hence it is an important parameter in developing a mucoadhesive dosage form. A combined glass electrode was used for determination of surface pH. The tablets were first allowed to dwell by keeping them in contact with 5 ml phosphate buffer pH 6.8 for 2 hours in 10 ml beakers. Then oH was noted by bringing the electrode near the surface of formulation and allowing equilibrating for 1 min. The experiment was performed in triplicate and average value was calculated.

CALIBRATION OF PANTOPRAZOLE

Calibration of pantoprazole was performed in 0.1 N HCl and pH 6.8 phosphate buffer. The calibration curve obtained is linear.

Concentration	Absorbance
0	0
5	0.194
10	0.34
15	0.53
20	0.707
25	0.869
30	0.013

Table 2: Calibration curve of pantoprazole in 0.1 N HCl

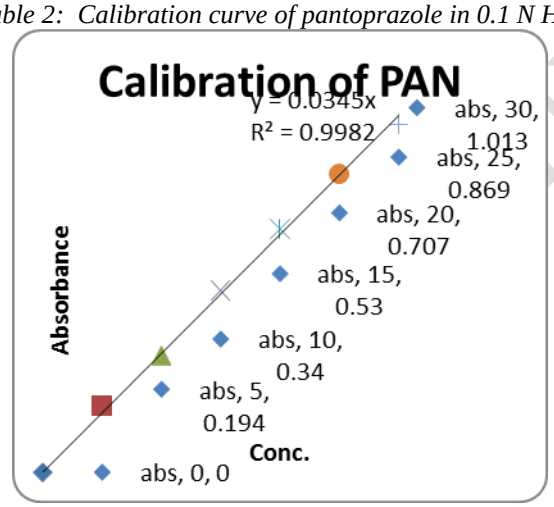

Figure 1: Calibration curve of Pantoprazole in 0.1 N HCl

CALIBRATION OF PANTOPRAZOLE IN PHOSPHATE BUFFER 6.8

Concentration	Absorbance
0	0
5	0.148
10	0.292
15	0.464
20	0.609
25	0.768
30	0.907

Table 3: Calibration curve of pantoprazole in 0.1 N HCl

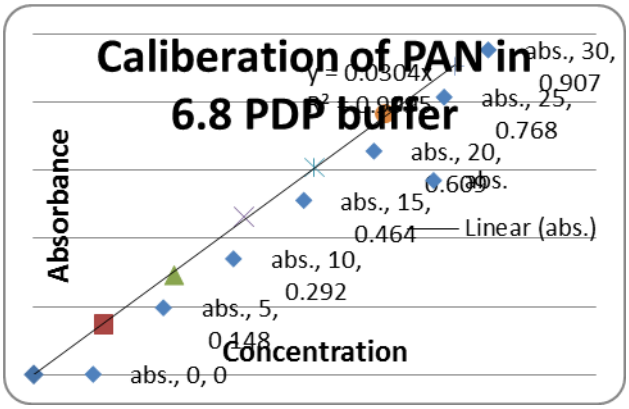

Figure 2

HARDNESS

The hardness of tablets of different formulations (F1 to F6) was determined as per standard procedure. The average hardness of tablets was found to be 5.0 to 5.68 kg/cm2. None of the formulations showed deviation for any of the tablets tested. The result is shown in following table.

THICKNESS

The average thickness of tablets (F1 to F6) determined and results are presented in following table. The maximum and minimum average thickness of tablet was found to 2.26 mm and 2.13 mm. None of the formulation deviated from the standards.

FRIABILITY

Percentage weight loss in friability test was in the range 0.1% to 0.5% in nine batches prepared by direct compression. The experiment was performed in triplicate and average value was calculated.

CONTENT UNIFORMITY

The content uniformity of the entire tablet (F1 to F6) was evaluated and the results are presented in following table. The maximum and minimum percentage of drug content from the different formulations was found to be 95.56 and 91.92 % respectively.

SURFACE pH

The surface pH of tablets of each formulation (F1 to F6) was tested and the results are provided in following table. The maximum and minimum pH value of the formulations were found to be 7.1 to 6.9 respectively. The acceptable pH of saliva is in the range of 5-7 and surface pH of all tablets is within limit. Hence the formulations may not produce any irritation to the buccal mucosa.

WEIGHT VARIATION

Weight variation of tablets of each formulation (F1 to F6) was tested and the results are provided in following table. The

weight variation of each batch of tablet ranged from 99.33 to 101.33

Code	Avg. Thickness (mm)	Hardness (kg/cm2)	% Drug Content	Surface pH	Weight variation
F1	2.26 ± 0.03	5.33 ± 0.02	91.92 ± 0.51	6.9±0.16	99.33 ± 1.24
F2	2.2 ± 0.08	5.63 ± 0.01	92.57±0.28	6.9 ± 0.28	101.33 ±1.69
F3	2.13 ±0.1	5 ± 0.4	95.3 ± 0.29	7.1 ± 0.08	101 ± 0.81
F4	2.2 ± 0.08	5 ±0.4	95.56 ± 0.40	7 ± 0.16	100 ± 0.40
F5	2.19 ± 0	5.5 ± 0.7	93.96 ± 0.12	7.1 ± 0.24	99 ±1.43
F6	2.24 ± 0.02	5.68 ±0.01	93.81 ±0.07	6.9 ±0.21	100.33 ± 1.24

Table: Thickness, Hardness, Drug content, pH and Weight variation

III. DISCUSSION

The main goal of this work was to develop mucoadhesivebuccal tablet of Pantoprazole by using tamarind seed powder. Because of poor bioavailability of Pantoprazole by oral route there is need to increase its bioavailability by formulating it into buccal dosage forms. Tamarind seed powder improve the dissolution.

In the present work mucoadhesivebuccal tablets of Pantoprazole were prepared by using tamarind seed powder, HPMC, magnesium oxide and lactose in each formulation in various concentration by direct compression method.

The prepared tablet was tested for physical parameters like hardness, thickness, weight variation, friability, drug content uniformity and surface pH determination. The results of all these evaluations are given in Table.

Hardness of tablets was found to be in the range of 5 to 5.68 kg/cm^2 and is given in Table. The thickness of tablets was found to be in the range of 2.13 to 2.26mm. Drug content estimation data for all batches are given in Table. It was found to be in the range of 91.92 to 95.56 %. The weight variation of all the prepared tablets was found to be in the range of 99 to 101.33. The surface pH of all batches of tablet found to be in the range of 6.9 to 7.1.

IV. CONCLUSION

From the present study, the following conclusion can be drawn:

Mucoadhesivebuccal tablets of Pantoprazole could be prepared by using Tamarind seed powder in combination with HPMC, magnesium oxide and lactose by direct compression method.

All the prepared tablet formulations were found to be good without capping and chipping.

All the prepared tablets were in acceptable range of weight variation, hardness, thickness, friability, drug content as per pharmacopoeial specification.

The surface pH of prepared buccal tablets was in the range of salivary pH, suggested that prepared tablets could be used without risk of mucosal irritation.

The in vitro release of F4 batch shows maximum drug release 95.56%.

All the tablets showed good residence time of 6 h.

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