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RESEARCH ARTICLE

FORMULATION AND EVALUATION OF COLON TARGETED TABLET OF BUDESONIDE

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ABSTRACT

The main of this study to formulate and evaluate colon targeted tablet by using various proportion of guar gum. Budesonide drug was selected for this research work .The budesonide which is used for treating colonic diseases. The tablet was formulated by using Guar gum, Lactose Starch, Talc and Magnesium Strearate.The tablets were evaluated for thickness, hardness and friability and all this was found to be in within range. The in-vitro dissolution study was carried out by using different PH of phosphate buffer solution as 250 ml HCL buffer PH 1.2 for 2 hr., 250 ml phosphate buffer PH 6.8 for another 3hr.and finally250 ml PBS PH7.4 till the end of 12hr.The drug release of all the formulation was found to be within range of 92.23 to 98.38%.tablet was capable to release drug at colon and protect the tablet from acidic PH.

Keywords: Colon targeted drug delivery, Budesonide, Guar gum, In-vitro Dissolution.

INTRODUCTION

The oral rout is most convenient rout for drug administration .Now a days nearly 50% of the drug delivery systems available in the market are oral drug delivery system. Oral drug delivery system has been more advantages like more patient compliance, better administration[1]. Various approaches are employed for targeting orally administered drugs to the colon include coating with pH-dependent polymers, design of the timed release dosage forms and the utilization of carriers that are degraded exclusively by colonic bacteria[2]. Budesonide which is used in the treatment of ulcerative colitis. Ulcerative colitis is the inflammation of colon, the mucous membrane lining the colon became inflamed and causing bloody diarrhea, pain, gas, bloating, and sometimes hard stools. The ulcerative colitis may be treated by antibiotics, corticosteroids and aminosalicylates[3]. Budesonide is an anti-inflammatory corticosteroid that exhibits potent glucocorticoid activity and weak mineral corticoid activity. It is used in the treatment of inflammation in asthma, Crohn's disease, or ulcerative colitis[4].The aim of the present study was to formulate colon targeted tablets of Budesonide using guar gum as enzyme dependent polymers.

MATERIALS AND METHOD:

Budesonide IP was purchased from Vamsi Lab Pvt.Ltd.Solapur. Guar gum was obtained as a gift sample from Research Lab Chemical Centre, Mumbai. Lactose, starch and magnesium stearate was obtained as a gift sample from Balaji Drugs, Mumbai.

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PREPARATION OF BUDESONIDE MATRIX TABLETS:

Matrix tablets of budesonide were prepared by wet granulation method. Lactose was used as diluent and a mixture of talc–magnesium stearate was used as lubricant. Guar gum was included in the formulations in various proportions. The compositions of different formulations used in the study containing 9mg of budesonide in each case are shown in Table 1. In all the formulations, guar gum was sieved separately and mixed with budesonide. The powders were blended and granulated with starch paste. The wet mass was passed through a mesh and the granules were dried at 60^0C for 2 hr. The dried granules were passed through a mesh and these granules were lubricated with a mixture of talc–magnesium Strearate.The lubricated granules were compressed[1].

Table No. 1: Formulation of Budesonide Colon Targeted Tablet

Ingredients	**Quantity (mg) present per each matrix tablet**			
	F1	**F2**	**F3**	**F4**
Budesonide	9	9	9	9
Guar gum	50	55	60	65
Lactose	105	100	95	90
Starch	40	40	40	40
Talc	36	36	36	36
Magnesium Stearate	10	10	10	10
TOTAL	250	250	250	250

EVALUATION OF TABLETS:

1Physicochemical Parameters

1.1Thickness of Tablets

Tablet thickness is an important characteristic in reproducing appearance. The thickness of tablets was measured by using Vernier calipers [1,5,7].

1.2Hardness of Tablets

Hardness of tablet is defined as the force applied across the diameter of the tablet in order to break the tablet. The resistance of the tablet to chipping, abrasion or breakage under condition of storage transformation and handling before usage depends on its hardness .Hardness of the Tablet was determined by Monsanto Hardness Tester [1,5,6,7].

1.3Friability of Tablets

It is measured of mechanical strength of tablets.Friability of Tablets was performed in a Roche Friabilator. Ten tablets were weighed together and then placed in the chamber. The friabilator was operated for 100 revolutions and the tablets were subjected to the combined effects of

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abrasion and shock because the plastic chamber carrying the tablets drops them at a distance of six inches with every revolution. The tablets are then dusted and re-weighed [8].

1.4 Weight Variation

Twenty tablets were selected randomly for this test and average weight was determined. Then individual tablets were weighed by using weighing balance and the individual weight was compared with the average weight. The percentage deviation was calculated and checked for weight variation. Using this procedure weight variation range of all batches of formulations were determined and recorded [9,10].

1.5 In-Vitro dissolution Studies:

Budesonide release from the Matrix tablets was evaluated by dissolution testing using the USP XXIII tablet dissolution test apparatus-II (rotating basket) at a rotation speed of 50 rpm maintained at 37.0±0.5°C . The release study was performed in 250 ml HCl buffer pH 1.2 for 2 h, followed by 250 ml PBS pH 6.8 for another 3 h, and finally 250 ml PBS pH 7.4 till the end of the 12h to simulate the pHs pertaining to the stomach, proximal and middle small intestine (duodenum and jejunum), and distal small intestine (ileum), respectively. 1 ml of dissolution medium was withdrawn at 1 h interval up to 12h and replaced with an equal volume of media. The collected media was filtered through 0.45 µm membrane and analyzed spectrophotometrically at 247.5 nm [4,11].

Table No.2: Evaluation Parameter of Colon Targeted Tablet of Budesonide

Formulation Code	Thickness in mm	Hardness in Kg/cm^2	Friability in %w/w	Weight Variation	Drug Release %
F1	**4.16±0.04**	**7.4±0.02**	**0.55±0.07**	**251±0.04**	**92.23**
F2	**4.13±0.06**	**8.2±0.01**	**0.52±0.06**	**253±0.06**	**96.46**
F3	**4.10±0.09**	**7.1±0.05**	**0.50±0.02**	**250±0.01**	**98.38**
F4	**4.12±0.10**	**8.5±0.06**	**0.53±0.01**	**254±0.03**	**97.52**

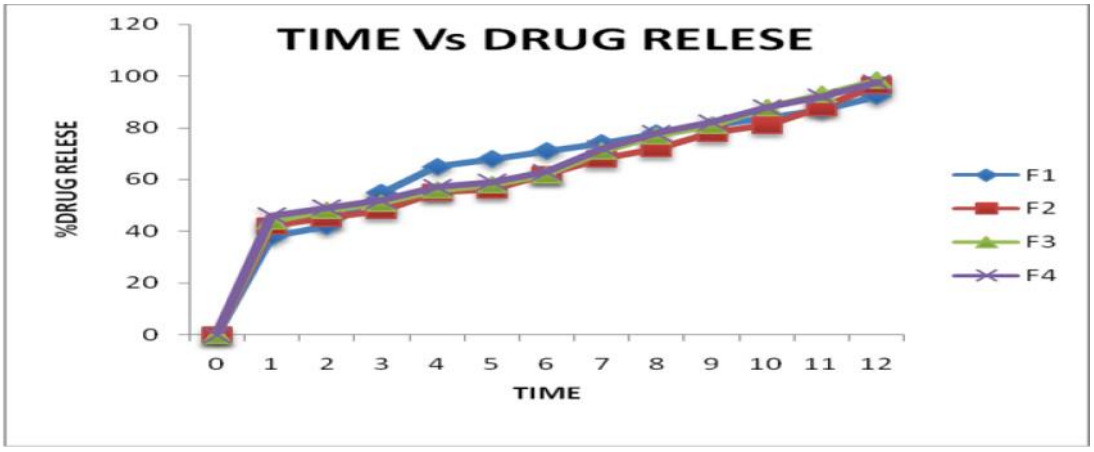

Figure 1. : Time Verses Drug Release Graph

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RESULT AND DISCUSSION:

Thickness of all the formulations was acceptable; it ranged from 4.10 mm to 4.16 mm. The hardness of all the tablet formulations ranged from 7.1 to8.5 kg/cm2. The average friability of all the formulations lies around 0.52%. Average weight of the tablet was 252 mg. All the colon targeted matrix tablet formulations of Budesonide were evaluated for in vitro dissolution studies by using different P^H of phosphate buffer solution as 250 ml HCL buffer P^H 1.2 for 2 hr., 250 ml phosphate buffer P^H 6.8 for another 3hr.and finally250 ml PBS P^H7.4 till the end of 12hr .The highest in-vitro dissolution profile at the end of 12 hr was shown by F3 (98.38) . From the in-vitro dissolution studies it can be discussed that the colon targeted matrix tablet containing 60 mg guar gum was the best formulation to target the Budesonide to the colon.

CONCLUSION:

All the physical characteristics of the formulations like thickness, hardness, weight variation, friability and in vitro dissolution study were found to be well within the limits and official standards. From the in-vitro dissolution studies it was found to be that formulation having low content of guar gum shows less drug release, the optimum concentration of guar gum was found to be 60 mg shows 98.38% drug release at colonic site because it exhibits the best overall general appearance, hardness of 7.1±0.05 Kg/cm^2, friability and a maximum percentage drug release of 98.38% at the end of 24 hr in in-vitro dissolution studies. In the present study, the matrix formulation containing guar gum is most likely to target drug to colon without being released significantly in stomach and small intestine.

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