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# Formulation and evaluation sustained release mucoadhesive gastroretentive pantoprazole sodium sesquihydrate tablets for anti–ulcer

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## ABSTRACT

**Objective:** The objective of this research work is to develop and evaluate the mucoadhesive gastroretentive tablets of an anti – ulcer drug for sustain release. **Materials and Methods:** Mucoadhesive tablets were prepared by direct compression method using Hydroxy propyl methyl cellulose K4M, Carbopol 940 NF and Guar gum in the various drug – polymer ratios. The prepared tablets were evaluated for their pre and post compression parameters. In this study the optimized formulation was obtained within the specified limits. **Results:** The final optimized formulation was showed mucoadhesion time 12 h, mucoadhesive strength of tablets were ready with HPMC K4M, Carbopol 940 NF and gum were found to be 45 g and the extreme proportion of drug release was obtained 97.11% at the completion of 12 h. The drug release mechanism for optimized formulations of pantoprazole mucoadhesive sustain release tablets was observed to be zero order kinetic model. **Conclusion:** The formulation of hydroxy propyl methyl cellulose showed excellent mucoadhesive ability and a suitable drug release pattern.

**Keywords**: Pantoprazole sodium sesquihydrate, Gastroretentive, mucoadhesive polymers

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## INTRODUCTION

Mucoadhesive tablets have an advantage of increasing the residence time and much additional intimate contact with the mucus layer and reduction in frequency of drug administration. Mucoadhesive polymers are water-soluble polymers, which are swellable network, linked by cross linking agents[1]. These polymers have ideal polarity to make that they permit adequate wetting by the mucus and optimal fluidity that permits the mutual absorption and interpenetration of polymer and mucus. The effective study was made to formulate the mucoadhesive tablets of pantoprazole sodium sesquihydrate as a model drug whose half-life is 1hour. Mucoadhesive sustained release systems increase the effectiveness of drug by maintaining the drug concentration in therapeutic level and permitting targeting and localization of medication at specific site. The period of contact and intimacy between polymer-drug particles and tissue layer surface is accrued by mucoadhesion. The pantoprazole could be a proton pump inhibitor, belongs to group of benzimidazole, used for the treatment of gastric and duodenal ulcers [2, 3]. In this research work pantoprazole sodium sesquihydrate mucoadhesive gastroretentive tablets are formulated and evaluated.

## MATERIALS AND METHODS

### Materials

Pantoprazole sodium sesquihydrate was obtained as gift sample from Aurobindo Laboratories Pvt Ltd, Hyderabad. Hydroxy propyl methyl cellulose K4M, Carbopol 940 NF, Guar gum, Avicel PH 102, PVP K30, Magnesium stearate and Aerosol were obtained from Kerry laboratories Pvt Ltd.

### Drugs and excipients compatibility study

Tablet dosage form of the drug is intimate contact with some excipients that could result the stable of the drug. Mixture of drug and excipients were prepared and evaluated.

### Formulation of Pantoprazole sodium sesquihydrate mucoadhesive tablets [4, 5]

The procedure for the preparation was direct compression and different formula was used in the formulation shown in table 2. All ingredients were mixed with various ratios for each formulation for binders, disintegrants. Finally, dye was added together with magnesium stearate and talc, later the powder mixture was punched with rotary punch tableting machine using 12 mm punches.

**Table 1: Formula for making of Pantoprazole sodium sesquihydrate sustain release mucoadhesive tablets**

| Ingredients | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
|---|---|---|---|---|---|---|---|---|---|
| Pantoprazole sodium sesquihydrate(mg) | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 |
| Hydroxypropyl methyl cellulose K4M(mg) | 20 | 30 | 40 | _ | _ | _ | _ | _ | _ |
| Carbopol 940NF(mg) | _ | _ | _ | 20 | 30 | 40 | _ | _ | _ |
| Guar gum(mg) | _ | _ | _ | _ | _ | _ | 20 | 30 | 40 |
| AvicelPH 102/MCC(mg) | 80 | 70 | 60 | 80 | 70 | 60 | 80 | 70 | 60 |
| Poyvinyl pyrrolidone K30(mg) | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 | 55 |
| Magnesium stearate 2%(mg) | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| Aerosil/colloidal silicon dioxide(mg) | Qs | Qs | Qs | Qs | Qs | Qs | Qs | Qs | Qs |
| Total(mg) | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 |

**Micromeritic properties:** [1, 4, 5]

**Bulk density**

Bulk density was measured by presieved drug excipient mixture into a graduated cylinder and measuring the volume (Vo) and weight (M)

Bulk density = M/Vo.

**Tapped density**

Tapped density is set by putting a graduate containing comparable form of residue by manual tapping for a set variety of 100 faucets till powder bed volume was touched a minimum.

Tapped density = mass of powder / minimum volume of powder.

**Angle of repose**

This can be the utmost angle attainable between the external of a heap of residue and also the horizontal plane. Adequate amount of mixture of API powder were well-versed a funnel from a specific height (2cm) onto a flat surface till it fashioned a heap, that touched the tip of the funnel. It was measured the heap crest. Angle of repose ($\theta$) = $Tan^{-1}(h/r)$

**Evaluation of Mucoadhesive Tablets** [6, 7]

All formulations were evaluated for various parameters such as hardness, thickness, friability, disintegration time, drug release in vitro dissolution studies, mucoadhesion time and strength, in vitro wash off test and swelling index.

**Thickness**

Vernier callipers was determined the tablets thickness. Every batch 3 tablets were used, and calculated average values. Tablet thickness ought to be controlled at intervals a ± 5th variation of standard worth.

**Hardness**

The prepared tablets were subjected to hardness test.

**Friability**

The friability decided victimisation Roche friabilator stated in %. 20 tablets were weighed and located in chamber. in line with guideline friabilator was started at 100 times for 4 minutes. And tablets were exposed for mutual influence of scrape and shock result of the malleable cavity ringing the tablets drops them at an aloofness of 6 inches with each revolution. The tablets were then dusted and reweighed and also the part of friability was calculated by victimisation the subsequent formula

% Friability =Iinitial weight–final weight/initial weight x100

**Weight variation test**

20 tablets were designated indiscriminately from the heap, weighed on an individual basis and also the average weight was determined. The % deviation of every tablets weight against the typical weight was calculated. The best necessities are met, if no more than 2 of the individual weights deviate from the typical weight by quite fifth and none deviates more than 10%. Weight variation IP limits just in case of consideration of tablets more than 80 mg however less than 250 mg is ± 7.5%.

**Disintegration test(USP)**

The USP device to check disintegration uses 6 glass tubes that are three longs open at the highest and ten mesh screens at the bottom end. to check for disintegration time, one tablet is placed in every tube and also the basket rack is positioned in a very one l beaker of water, 0.1N HCl answer at 37±2°C specified the2.5 cm tablet remains below the surface of liquid on their upward movement and not nearer than 2.5 cm from the underside of the beaker in their downward movement. Passage the basket encompassing the tablets awake and bottom into of 5-6 cm a distance at a frequency of 28 to 32 cycles per minute. Floating of the tablets is prevented by inserting perforated plastic discs on every tablet. According to the test the tablet should disintegrate and every one particle should pass through the 10mesh screen in the time fixed. If any residues remain, it should have a soft mass. Disintegration time for uncoated tablets is 5 - 30 minutes, for coated tablets 1-2 hours.

**Content of drug**

The ready pantoprazole Na sesquihydrate tablets were tested for their drug content

From the prepared tablets of each batch one tablet were taken and it absolutely was dissolved in 100 ml of 0.1N HCl during a 100 ml meter flask and therefore the solution was filtered. 1 ml of the filtrate was more diluted to 10 ml with 0.1N HCl. Absorbance of the ensuing solution was measured by UV- visible spectrophotometer at 282 nm.

**In vitro drug dissolution studies**[7, 8]

The USP dissolution equipment kind II was used to review the in vitro drug unleash from numerous formulations ready. The dissolution medium used was 900 ml of acidic buffer

of hydrogen ion concentration 0.1N HCl for 12 h. the tablet was unbroken in to the basket. Maintained the temperature at 37°C ± 0.5°C and therefore the stirring rate was 50 rpm. At regular time intervals Samples were withdrawn and therefore the same volume was replaced with recent dissolution medium. And performed in vitro dissolution studies of marketed delayed enteric coated pantoprazole sodium, USP, 40 mg. This was additionally performed with the hydrogen ion concentration 0.1NHCl for two hours so placed the hydrogen ion concentration 6.8 phosphate buffer for 10 hours. The samples were measured by ultraviolet light – visible spectrophotometer at 282 nm.

**Swelling index studies**

Swelling of excipients of mucoadhesive dose type involves the absorption of a liquid leading to associate degree increase in weight and volume. Liquid uptake by the particle could also be because of saturation of capillary areas inside the particles or association of molecule. The liquid enters the particles through pores and bind to giant molecule, breaking the chemical bond and leading to the swelling of particle. the extent of swelling is often measured in terms of proportion (%) weight gain by the mucoadhesive dose type. technique the swelling study of various formulations were disbursed mistreatment USP dissolution equipment (rotating paddle) II at 37± 0.5°c rotating at a 50rpm mistreatment 0.1n HCl for 12 hours. The 0.1N
HCl resolution was ready by mistreatment 8.5 millilitre of HCl in a thousand millilitre of water. before the swelling index (wo) in this study individual weight tablet was taken, the tablets were unbroken during a basket, tablet was removed each 1hour interval up to twelve hours, excess water was removed mistreatment filter paper. Reweighed at time 't' the swollen tablets.

$$\text{Swelling index} = (wt. - wo) / wo \times 100$$

where, wo = tablet initial weight, wt. = swollen tablet weight at time 't'.

**In vitro mucoadhesive strength**

The changed physical balance methodology by resolve the mucoadhesive capability of all formulations. The changed double beam physical balance equipment consists of proper pan in lower finish has been connected with copper wire by a glass slide. 3.8 cm diameter a glass vial and a height of two cm was unbroken in a beaker stuffed with media HCl of pH 0.1 N, below right side of the balance that was then placed. model membrane Goat stomach membrane wetting fluid media for pH 0.1N HCl. The abdomen membrane thickness used in between from 1.3 to 2.5 mm. It was to a glass slide abdomen membrane tried and slide was mounted over the protrusion within the 2sided adhesive glass ampule employing a thread. The in an exceedingly glass beaker glass block was then unbroken. The beaker was stuffed with 0.1N HCl up to the side of the goat abdomen membrane to keep up abdomen membrane viability throughout the experiments. The one side of the tablet was connected to the glass slide of the proper arm of the balance so beaker was raised slowly till contact between goat membrane and mucoadhesive pill was established and extra weight, to make the proper side weight equal with left side pan. A preload of five g was placed on the slide for five min between mucoadhesive tablet and goat abdomen membrane. The preload and preload time were unbroken constant for all formulations. Next, water was dropped into the beaker at a speed of 2 ml.min-1 till the tablet. The addition of water was stopped once mucoadhesive tablet containing water was weighed and therefore the minimum detachment force was calculated consequently. The detachment force in gram (g) was transformed into Newton (N, force of adhesion) by employing a factor (1 g = 0.009806N).

$$\text{Adhesion force (N)} = \frac{\text{Strength of Mucoadhesion}}{1000} \times 9.81$$

## RESULTS AND DISCUSSION

**Compatibility study between drug and polymer by FTIR**

The FTIR method was to study the compatibility between the drug and polymer. The pantoprazole sodium sesquihydrate showed characteristic bands at 3484.7 $cm^{-1}$ for N-H stretching, 2996 $cm^{-1}$ for C-H bending, 1377$cm^{-1}$ for C-N stretching, 1037$cm^{-1}$ for C-H bending.

On performed pure drug and drug with polymer mixture all the characteristic peaks of drug were found to be similar IR spectra of drug polymer mixture showed the suitability of the polymers used for the preparation of mucoadhesive tablets. These are shown in figures 1, 2, 3.

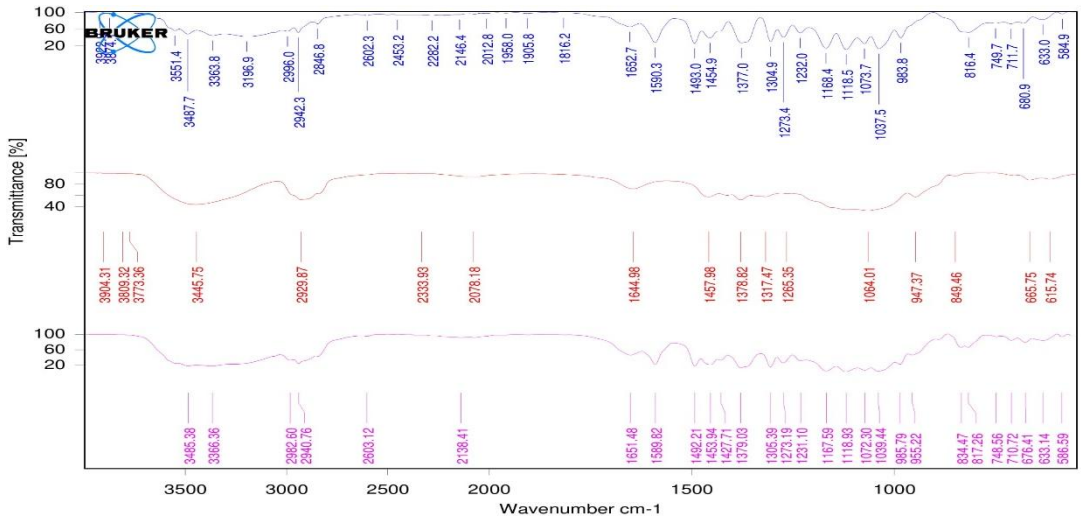


**Figure 1: FTIR Spectrum of Pantoprazole sodium sesquihydrate with HPMC K4M**

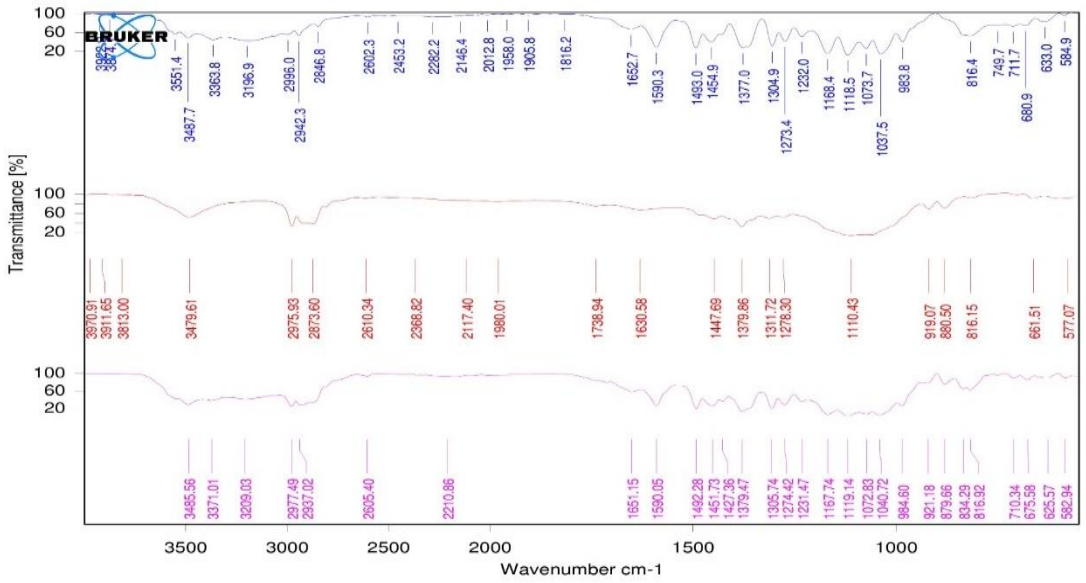


**Figure 2: FTIR Spectrum Pantoprazole sodium sesquihydrate with Carbopol**

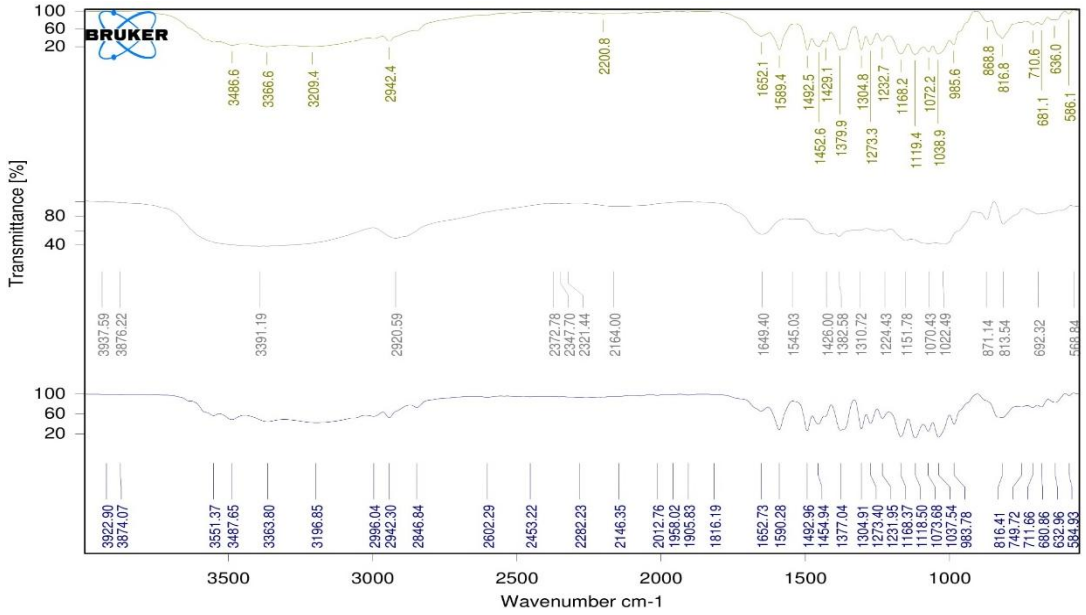


**Figure 3: FTIR spectrum of Pantoprazole sodium sesquihydrate with Guar gum**

**Table 2: physicochemical evaluation of pantoprazole sodium sesquihydrate mucoadhesive tablets.**

All the micromeritic properties are within the IP standards.

| Batch code | Thickness (mm) | Hardness ($kg/cm^2$) | Friability (%) | Weight variation(mg) | Drug content (%) |
|---|---|---|---|---|---|
| **F1** | 0.42 | 4.8±0.28 | 0.13±0.06 | 199±0.14 | 98.75 |
| **F2** | 0.48 | 4.6±0.67 | 0.14±0.05 | 198±0.23 | 98.56 |
| **F3** | 0.46 | 5.3±0.65 | 0.01±0.08 | 197±0.37 | 98.52 |
| **F4** | 1.14 | 4.5±0.53 | 0.51±0.05 | 199±0.65 | 97.95 |
| **F5** | 1.16 | 4.7±0.74 | 0.27±0.75 | 199±0.43 | 96.68 |
| **F6** | 1.24 | 4.9±0.61 | 0.09±0.06 | 198±0.10 | 97.23 |
| **F7** | 1.68 | 4.4±0.53 | 0.07±0.03 | 199±0.38 | 97.69 |
| **F8** | 1.75 | 4.9±0.71 | 0.17±0.08 | 198±0.63 | 99.03 |
| **F9** | 1.56 | 4.9±0.65 | 0.48±0.06 | 197±0.93 | 98.89 |

Mean ±standard deviation (n=3)

**Table 3: Micromeritic properties of Pantoprazole SS powder blend**

| Batch code | Bulk density (gm/ml) | Tapped density(gm/ml) | Carr's index (%) | Hausner's ratio | Angle of repose(θ) |
|---|---|---|---|---|---|
| **F1** | 0.31±0.01 | 0.32±0.03 | 11.03±0.06 | 1.06±0.04 | 25.02±0.13 |
| **F2** | 0.32±0.04 | 0.35±0.01 | 11.21±0.05 | 1.03±0.03 | 25.05±0.16 |
| **F3** | 0.35±0.05 | 0.34±0.04 | 11.35±0.07 | 1.04±0.02 | 25.19±0.21 |
| **F4** | 0.36±0.09 | 0.37±0.09 | 12.04±0.06 | 1.07±0.13 | 26.03±0.01 |
| **F5** | 0.39±0.06 | 0.38±0.17 | 14.05±0.24 | 1.08±0.21 | 26.08±0.04 |
| **F6** | 0.38±0.08 | 0.39±0.21 | 15.09±0.14 | 1.13±0.02 | 27.15±0.08 |
| **F7** | 0.41±0.13 | 0.42±0.34 | 16.13±0.25 | 1.19±0.05 | 28.21±0.37 |
| **F8** | 0.43±0.34 | 0.43±0.18 | 16.34±0.33 | 1.21±0.07 | 28.19±0.28 |
| **F9** | 0.45±0.05 | 0.46±0.35 | 18.31±0.12 | 1.24±0.06 | 30.58±0.32 |

Mean±standard deviation (n=3)

**Ex vivo mucoadhesive strength**

The mucoadhesive strength of different formulations (F1 to F9) were evaluated. Mucoadhesive strength of formulation is depending on the various polymers used and concentration of polymers used and without causing any irritation to the mucosal surface. Tablets of formulation F5 shows least adhesion force than tablets of all other formulations, which might be due to low viscosity of Carbopol (940 NF). The highest adhesion force i.e. highest strength of the mucoadhesive bond was observed with the formulation F3 containing only HPMC, therefore that indicates bio adhesive strength of HPMC is much more than that of the Carbopol.

**Table 4: Mucoadhesive study of pantoprazole mucoadhesive formulations (F1 to F9)**

| Formulation code | Mucoadhesive strength(g) | Mucoadhesive force (N) |
|---|---|---|
| **F1** | 45 | 0.44 |
| **F2** | 42 | 0.41 |
| **F3** | 46 | 0.45 |
| **F4** | 25 | 0.24 |
| **F5** | 24 | 0.23 |
| **F6** | 25 | 0.24 |
| **F7** | 30 | 0.29 |
| **F8** | 34 | 0.33 |
| **F9** | 35 | 0.32 |

**Swelling index studies**

Swelling index of all formulations is shown in Table 6. swelling index was calculated with respect to time. Bio adhesion and drug release profile are reliant on the swelling nature of the tablets. Swelling index increased as the weight improvement by the tablets increased proportionally with the rate of hydration as shown in figure 3. The highest hydration (swelling) i.e. 97.47% was observed with the formulation F3 HPMC3. This indicates that the rapid hydration of polymer used (HPMC K4M). The swelling rate of tablets increased as the concentration of polymer in the tablet increased. It was detected that HPMC K4M was able to give the higher swelling index than the Carbopol 940 and guar gum.

**Table 5: Swelling index of different formulations (F1toF9) of pantoprazole sodium sesquihydrate mucoadhesive sustain release table.**

| Time (hrs) | F1 HPMC1 | F2 HPMC2 | F3 HPMC3 | F4 CARB1 | F5 CARB2 | F6 CARB3 | F7 GG1 | F8 GG2 | F9 GG3 |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1 | 47.25 | 51.75 | 53.17 | 70.21 | 69.75 | 66.15 | 60.72 | 63.26 | 65.25 |
| 2 | 51.67 | 53.01 | 57 | 78.04 | 73.39 | 70.19 | 64.13 | 65.43 | 68.17 |
| 3 | 54 | 55.34 | 61.45 | 79.56 | 76.47 | 76.25 | 66.24 | 67.09 | 70.02 |
| 4 | 57.3 | 56 | 67.5 | 80.14 | 79.05 | 79.36 | 69.43 | 69.45 | 73.42 |
| 5 | 58.12 | 57.45 | 71.63 | 83.44 | 81.08 | 81.62 | 70.45 | 71.63 | 75 |
| 6 | 60.1 | 62.1 | 75.38 | 86.67 | 84 | 84.23 | 72.58 | 75.41 | 78.05 |
| 7 | 61.32 | 65.13 | 78.58 | 89.43 | 87.09 | 87.58 | 75.29 | 78.28 | 81.21 |
| 8 | 64 | 68.45 | 84.69 | 91.39 | 90.62 | 90.62 | 78.49 | 81.56 | 84.19 |
| 9 | 68 | 70.37 | 95.39 | 92.37 | 92.85 | 92.79 | 81.62 | 84.29 | 87.57 |
| 10 | 78 | 88.05 | 97.47 | 94.51 | 95.16 | 96.91 | 85.57 | 88.38 | 91.39 |

Mean±standard deviation (n=3)

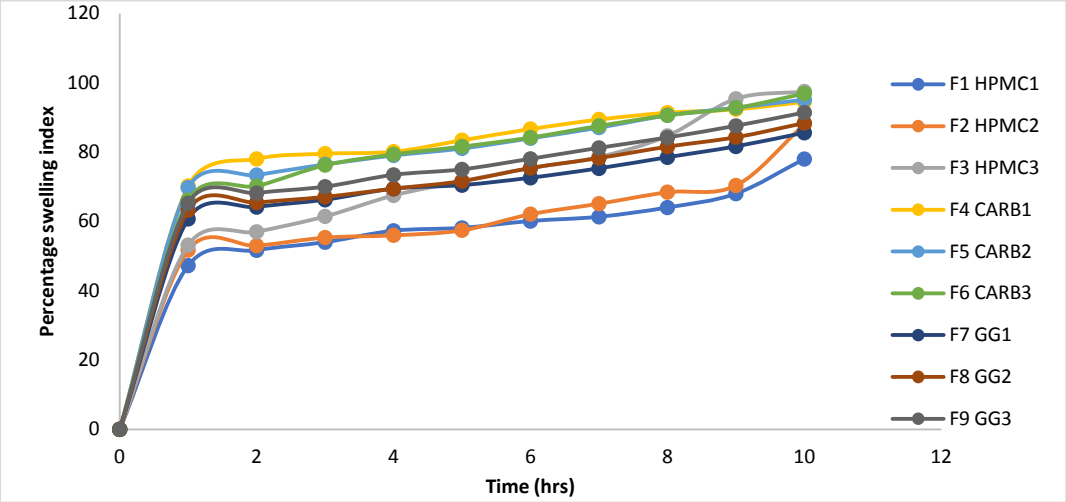


**Figure 4: Swelling index of various formulations (F1 to F9) of mucoadhesive pantoprazole sodium sesquihydrate tablets.**

### In vitro drug release studies

At 10th hr the cumulative percent drug release for HF1, HF2 and HF3formulations was found to be 85.72%, 87.18%. 97.29% respectively. For CF4, CF5, CF6 formulations, the percentage cumulative drug release was in the order of 86.42%, 84.49%, 81.67% respectively and for GF7, GF8, F9 formulations, the percentage cumulative drug release was in the order of 86.53%, 88.45%, 89. 43% respectively. Among all the formulations (HF1 to HF3) hydroxy propyl methyl cellulose tablets showed increased and sustained drug release. HF3 showed increased amount of percentage drug release due to increased drug polymer ratio and the swelling and diffusion.

The percentage drug release for Carbopol was less than HPMC tablets of pantoprazole sodium sesquihydrate may be due to its high viscous and mucoadhesive nature. The percentage cumulative drug release for Guar gum tablets was less than HPMC tablets but greater than Carbopol tablets due to its high mucoadhesion nature.

Therefore, among all the formulations, HF3 was chosen for further study due to its increased drug release.

**Table 6: In vitro drug release of pantoprazole SS from formulation (F1 to F9).**

| Time (hrs) | HF1 | HF2 | HF3 | CF4 | CF5 | CF6 | GF7 | GF8 | GF9 |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1 | 11.12 ±0.06 | 14.15 ±0.08 | 20.05 ±0.29 | 23.05 ±0.02 | 25.55 ±0.78 | 27.19 ±0.10 | 10.65 ±0.37 | 9.43 ±0.24 | 17.65 ±0.37 |
| 2 | 20.34 ±0.19 | 23.12 ±0.06 | 27.09 ±0.05 | 34.25 ±0.14 | 35.62 ±0.14 | 31.75 ±0.43 | 17.69 ±0.39 | 20.56 ±0.32 | 31.67 ±0.38 |
| 3 | 34.45 ±0.25 | 34.24 ±0.13 | 35.65 ±0.37 | 39.56 ±0.32 | 47.29 ±0.16 | 37.47 ±0.27 | 34.67 ±0.84 | 35.34 ±0.19 | 42.72 ±0.41 |
| 4 | 45.67 ±0.38 | 38.72 ±0.41 | 43.36 ±0.20 | 45.65 ±0.37 | 52.49 ±0.28 | 41.29 ±0.16 | 38.75 ±0.43 | 39.67 ±0.38 | 54.67 ±0.38 |
| 5 | 56.12 ±0.06 | 46.67 ±0.38 | 49.68 ±0.39 | 57.43 ±0.24 | 63.75 ±0.43 | 47.43 ±0.73 | 46.43 ±0.24 | 42.47 ±0.27 | 67.35 ±0.20 |
| 6 | 62.42 ±0.24 | 58.12 ±0.05 | 69.09 ±0.05 | 66.75 ±0.43 | 68.58 ±0.33 | 53.59 ±0.80 | 62.45 ±0.25 | 48.29 ±0.16 | 73.65 ±0.37 |
| 7 | 68.16 ±0.09 | 69.71 ±0.40 | 78.04 ±0.02 | 72.46 ±0.26 | 70.54 ±0.31 | 58.55 ±0.78 | 73.65 ±0.37 | 59.42 ±0.24 | 78.57 ±0.32 |
| 8 | 75.72 ±0.41 | 76.52 ±0.30 | 87.25 ±0.14 | 77.37 ±0.21 | 74.86 ±0.49 | 65.47 ±0.27 | 81.64 ±0.39 | 70.48 ±0.27 | 80.44 ±0.25 |
| 9 | 78.56 ±0.32 | 81.82 ±0.47 | 95.05 ±0.02 | 81.33 ±0.19 | 78.43 ±0.24 | 77.19 ±0.63 | 83.48 ±0.27 | 78.56 ±0.32 | 84.39 ±0.22 |
| 10 | 85.72 ±0.41 | 87.18 ±0.10 | 97.29 ±0.16 | 86.42 ±1.71 | 84.49 ±0.28 | 81.67 ±0.38 | 86.53 ±0.30 | 88.45 ±0.25 | 89.34 ±0.19 |

Mean±standard deviation (n=3)

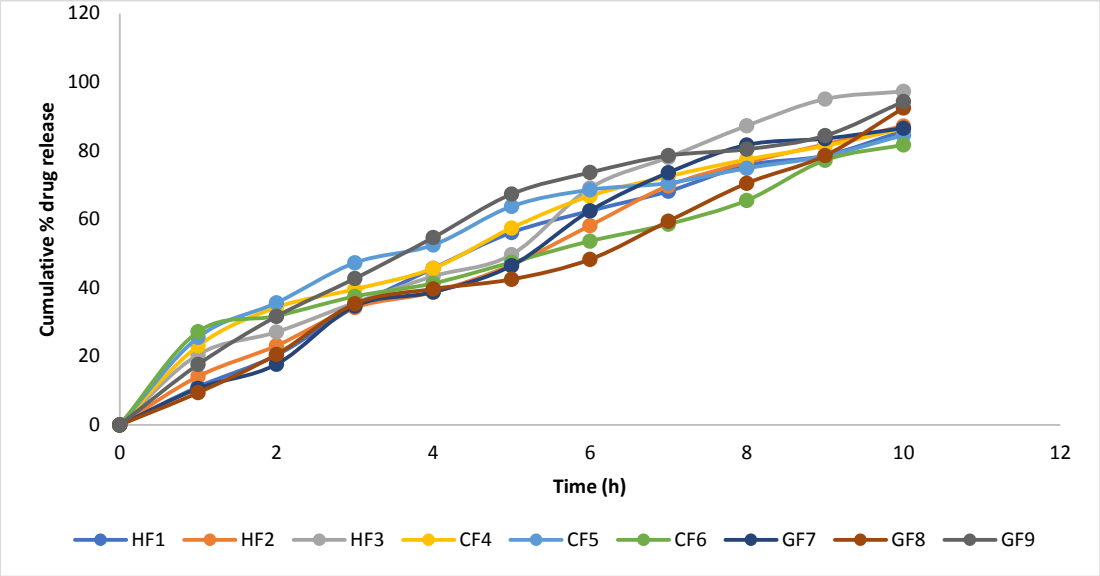


**Figure 5: Cumulative percentage drug release for mucoadhesive tablets of pantoprazole sodium sesquihydrate (F1 to F9).**

**Table 7: Drug release kinetics data for mucoadhesive tablets of pantoprazole sodium sesquihydrate (F3)**

| Formulation code | Zero order $R^2$ | First order $R^2$ | Higuchi diffusion kinetics $R^2$ | Korsmeyer peppas $R^2$ |
|---|---|---|---|---|
| F3 | 0.984 | 0.869 | 0.936 | 0.959 |

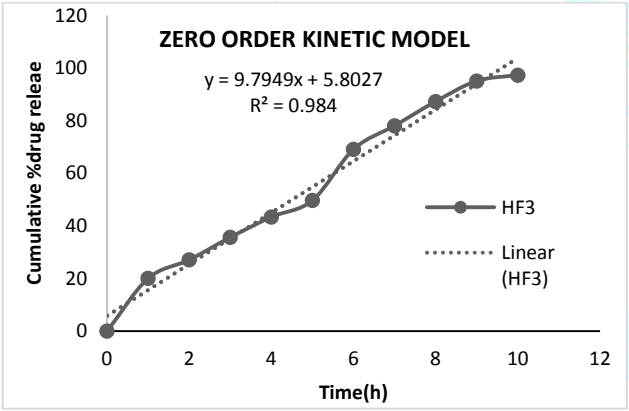


**Figure 6: Zero order Equation for mucoadhesive tablets of pantoprazole sodium sesquihydrate (HF3)**

## CONCLUSION

The present work was concluded to develop a mucoadhesive drug delivery system using three different grades of polymers of hydroxy propyl methyl cellulose K4M, Carbopol 940 NF and Guar gum, in different concentrations. The optimized formulation F3 showed excellent mucoadhesive ability and a suitable sustained drug release pattern. The developed gastroretentive drug delivery system provides advantages of ease of preparation and sustained drug release.

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