*Research Article*


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# DEVELOPMENT AND EVALUATION OF RANITIDINE HYDROCHLORIDE FLOATING MATRIX TABLET

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**Abstract**

Currently floating matrix tablets are one of the important categories of drug delivery systems with gastric retentive behavior. Ranitidine is a $H_2$ blocker and absorbed from the upper part of GIT and hence to develop a dosage form that releases the drug in stomach so that it can be absorbed from upper part of GIT leading to improved bioavailability. Tablets of Ranitidine HCl were prepared by direct compression using different concentrations of HPMC K4M, HPMC K15M Carbopol 940, sodium bicarbonate and citric acid. Sodium bicarbonate and citric acid was incorporated as a gas-generating agent. The formulations were evaluated for pre and post compressional parameters. A combination of sodium bicarbonate (18%) and citric acid (5%) was found to achieve optimum *in vitro* buoyancy. The floating lag time of the prepared formulations was good >13 hours.

**Keywords:** Ranitidine Hydrochloride, Gastroretentive, Floating Drug Delivery, Sustained Release, HPMC.

## Introduction

Ranitidine hydrochloride (RHCl) is a histamine H2-receptor antagonist. It is widely prescribed in active duodenal ulcers, gastric ulcers, Zollinger-Ellison syndrome, gastroesophageal reflux disease, and erosive esophagitis[1]. The recommended adult oral dosage of ranitidine is 150 mg twice daily or 300mg once daily. The effective treatment of erosive esophagitis requires administration of 150 mg of ranitidine 4 times a day. A conventional dose of 150 mg can inhibit gastric acid secretion up to 5 hrs but not up to 10 hours. An alternative dose of 300 mg leads to plasma fluctuations; thus a sustained release dosage form of RHCl is desirable. The short biological half-life of drug (~2.5-3 hrs.) favors development of a sustained release formulation.[1] A conventional oral sustained-release formulation releases most of the drug at the colon; thus, the drug should have an absorption window either in the colon or throughout the gastrointestinal tract. Ranitidine is absorbed in only the initial part of the small

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intestine and has 50% absolute bioavailability.[2] Colonic metabolism of ranitidine is partly responsible for the poor bioavailability of ranitidine from the colon.[3] It has been reported that the oral action of gastric disorders with an H2 receptor antagonist used in grouping with antacids promotes local delivery of these drugs to the receptor of parietal cell wall. Therefore this attitude could be useful for humanizing systemic as well as local delivery of Ranitidine, which would efficiently reduced gastric acid secretion.[4] The gastro retentive drug delivery systems can be retained in the stomach and assist in improving the oral sustained delivery of drugs that have an absorption window in a particular region of the gastrointestinal tract. These systems help in continuously releasing the drug before it reaches the absorption window, thus ensuring optimal bioavailability. Several approaches are currently used to prolong gastric retention time. These include floating drug delivery systems also known as hydrodynamically balanced systems, swelling and expanding systems, polymeric bioadhesive systems, modified-shape systems, high-density systems, and other delayed gastric emptying devices.[5,6] The principle of buoyant preparation offers a simple and practical approach to achieve increased gastric residence time for the dosage form and sustained drug release.[7]

In the current research on floating tablets of ranitidine HCL were prepared by effervescent approach using two different grades of HPMC these were as follow :- HPMC K4 and HPMC K15M and Carbopol 940 as release rate retardant. The aim of the work was to evaluate the effect of gel-forming polymer HPMC and Carbopol 940 on floating property and release individuality of ranitidine tablets.

## Materials and methods

### Materials

Ranitidine hydrochloride was received as a gift sample from Cipla Pharmaceuticals Ltd, Goa, India. Hydroxypropyl methylcellulose (HPMC K4 M), HPMC K15 M, and Carbopol 940 were received as gift samples from Watson Healthcare Ltd, Mumbai, India. Sodium bicarbonate and citric acid anhydrous were purchased from Merck Chemicals, Mumbai, India. All other ingredients were of laboratory grade.

### Methods

**Preparation of Sustained Release Tablet of Ranitidine Hydrochloride**

All the ingredients were passed through 60 mesh sieve separately. Weighed quantity of ranitidine hydrochloride and all the excipients was showed in Table No.1 except lubricants were mixed. Finally magnesium stearate and talc were added and mixed. Tablets were compressed on a Multi station rotary punch tablet compression machine (A-Jaguar, Ahmedabad, India.) using round flat surface punches of 12 mm diameter.[8] The hardness of the tablet was maintained around 5.5 kg/cm$^2$.

**Preparation of Powder Blend of Ranitidine Hydrochloride**

During preliminary studies, total 18 batches were prepared by using different concentration of polymers. This was done to aid in choosing the limits for the ingredients for further evaluation. Pre-optimization investigation containing different concentration of polymers alone or in combination keeping the total tablet weight constant. From above preliminary batches, depending upon floating time and dissolution rate following eight formulations were prepared for further evaluation.

**Table No. 01: Preparation of Powder Blends of Ranitidine Hydrochloride Floating Tablets**

| FC | Drug (mg) | HPMC K4M (%) | HPMC K15M (%) | Carbopol 940P (%) | Sodium bicarbonate(%) | Citric acid (%) |
|---|---|---|---|---|---|---|
| A1 | 336 | 15 | 10 | - | 18 | 5 |
| A2 | 336 | 20 | 10 | - | 18 | 5 |
| A3 | 336 | 20 | 15 | - | 18 | 5 |
| A4 | 336 | 10 | 15 | 15 | 18 | 5 |
| A5 | 336 | 15 | 15 | 15 | 18 | 5 |
| A6 | 336 | 20 | 15 | 15 | 18 | 5 |
| A7 | 336 | 20 | 10 | 15 | 18 | 5 |
| A8 | 336 | 15 | 10 | 15 | 18 | 5 |

(Each tablet formulation contains 18 % w/w sodium bicarbonate, 5% w/w citric acid, 1% w/w of magnesium stearate and 2%w/w talc, Lactose was added to each formulation upto 650 mg.)

**Drug Interaction Study**

**Fourier Transform Infrared (FTIR) Spectroscopy**

Fourier transform infrared (FT-IR) spectrum of drug was obtained using FT-IR Spectrophotometer and the spectrum was recorded in the wavelength region of 4000 to 400 $cm^{-1}$. The sample was mixed with potassium bromide (KBr) in a mortar with the help of pastle. The potassium bromide was previously heated to $110^0$ c for 1 hrs so it become anhydrous to avoid the peaks of water of hydration. The sample was placed in the light path of sample cell and the spectrum was obtained. [9]

**Evaluation of Powder Mixture**

Physical mixture of different formulations was evaluated for pre compressional parameters. Angle of repose (θ) of the powder mixture was determined by. The $\tan^{-1}$ of (height of the pile / radius of its base) give the angle of repose.[10] Powder mixture were poured gently through a glass funnel into a graduated cylinder cut exactly to 10 ml mark. Excess powder mixture was removed using a spatula and the weight of the cylinder with pellets required for filling the cylinder volume was calculated. The cylinder was then tapped from a height of 2.0cm until the time when there was no more decrease in the volume.[11,12] Bulk density (ρb) and tapped density (ρt) were calculated.[13] Carr index (CI) were calculated according to the equation which are follows:- CI= ρt- ρb/ ρt

**Evaluation of Floating Tablet Characteristics**

The thickness of the tablets was determined using a micrometer screw gauge. Three tablets from each type of formulation were used and average values were calculated.[14] The weight variation test was carried out for 20 tablets randomly as per Indian Pharmacopoeia.[14,15] Tablet hardness was calculated by hardness tester and recorded in $kg/cm^2$. Friability of tablet was calculated by using Roach friability tester. Percentage loss should not more than 0.5 to 1.0 % and the % friability was calculated using the formula.[16]

$$\% \text{ Friability} = \frac{W_0 - W}{W_0} \times 100$$

Where,

$W_0$ -Weight of tablet before test,

W - Weight of tablet after test.

The uniformity of content was determined as per official procedure. The tablet triturate equivalent to 100 mg of the drug was weighed

accurately, dissolved in pH 1.2 buffer and diluted to 100 ml with the same. Further dilutions were done suitably to get a concentration of 10mcg/ml with simulated gastric fluid pH 1.2. Absorbance was recorded at 322 nm against the blank .The same procedure was repeated for nine tablets[8]. The formula used shown below,

$$\text{Uniformity of Content} = \frac{\text{Absorbance of standard}}{\text{Absorbance of sample}} \times 100$$

**Swelling Characteristics**

To evaluate the water penetration characteristics, the pre-weighted tablets were immersed in 500 ml beaker containing simulated gastric fluid (SGF) and maintained for 12 hrs at 37 ± 0.5$^0$C. Swollen tablets were removed from the solution, immediately wiped with a paper towel to remove surface droplets, and weighed. [17] The % swelling index (Sw) was calculated according the following equation,

$$\% \text{ Swelling index (Sw)} = \frac{W_t - W_0}{W_0} \times 100$$

Where,

$W_0$ - Initial weight of tablet,

$W_t$ - Weight of the swollen tablet at time t.

***In-vitro* Dissolution Study**

The *In-vitro* dissolution study was carried out in USP Dissolution Test Apparatus, Type 2 (paddle type). Simulated gastric fluid 900 ml of pH 1.2 was used as dissolution medium. The temperature of dissolution media was maintained at 37±0.5°C. The paddle rotation speed was kept at 50 rpm. Aliquot 10 ml. of was withdrawn at every 1-hour interval for 12 hours and the same volume was replaced with pre warmed fresh dissolution media. Aliquots were withdrawn from a zone midway between the surface of dissolution medium and the top of rotating paddle not less than 1 cm apart from the vessel wall. The sample withdrawn was diluted to suitable volume with simulated gastric fluid and the absorbance was recorded at 322 nm using UV-VIS spectrophotometer. Cumulative percentage drug release was calculated by using an equation obtained from a standard curve. [18,19]

## Result and discussion

**Physical Parameters of Powder blend of Preliminary Batches of Floating Tablets**

The powder mixtures for all (F1-F18) batches were evaluated for bulk density which ranged from 0.450 to 0.526 (g/ml), tapped density ranged from 0.589 to 0.648 (g/ml), Carr's index ranged from 20.71% to 26.95% and angle of repose ranged from 25.45 to 31.13°.All these results indicated that, the powder mixture possess satisfactory flow and compressibility properties. Diameter of all tablets was found to be 11.95±0.02 mm. The hardness of tablets was found to be 5.1 to 5.6 kg/cm$^2$. The formulations containing Carbopol 940 and HPMC had shown maximum hardness so they shows less % friability and it was found that hardness was increased with increase proportion of polymers. Thicknesses of tablets were found to be in the range of 4.06 - 4.16 mm. Formulations containing Carbopol 940 P were found to be thicker than other formulations as the Carbopol was fluffy in nature. All the tablets shows % friability in the

range of 0.39-0.64 % which was within the limit. All the formulations pass the Weight variation test as all tablets within the range limit for weight variation.

**Table No. 02**: **Evaluation of Powder Mixtures of Floating Tablets**

| Formulations | Parameters | | | | |
|---|---|---|---|---|---|
| | Bulk Density* (± SD) | Tapped Density* (± SD) | Angle of Repose($^0$) | Carr's Index | Hausner's Ratio |
| **A1** | 0.488± 0.16 | 0.592±0.35 | 25.47±0.47 | 17.73±0.22 | 1.22±0.72 |
| **A2** | 0.472 ±0.20 | 0.624±0.38 | 30.87±0.50 | 24.35±0.46 | 1.32±0.51 |
| **A3** | 0.458 ±0.25 | 0.589±0.35 | 28.62±0.65 | 22.10±0.23 | 1.28±0.49 |
| **A4** | 0.516 ±0.45 | 0.617±0.21 | 30.62±0.66 | 16.37±0.61 | 1.20±0.68 |
| **A5** | 0.460±0.21 | 0.627±0.35 | 28.44±0.40 | 26.63±0.24 | 1.36±0.72 |
| **A6** | 0.468 ±0.31 | 0.643±0.56 | 30.82±0.42 | 27.21±0.47 | 1.37±0.67 |
| **A7** | 0.483 ±0.32 | 0.582±0.40 | 29.50±0.55 | 17.01±0.63 | 1.21±0.79 |
| **A8** | 0.473 ±0.35 | 0.597±0.61 | 31.15±0.40 | 20.63±0.48 | 1.26±0.56 |

**Table No. 03: Physical Parameters of Ranitidine Hydrochloride Floating Tablets**

| Formulations | Parameters | | | |
|---|---|---|---|---|
| | Hardness (kg/cm$^2$)* (± SD) | Thickness (mm)*(± SD) | % Friability | % Wt Variation(mg) |
| **A1** | 5.2± 0.28 | 4.16±0.43 | 0.31±0.24 | 650.1±0.50 |
| **A2** | 5.1± 0.26 | 4.11±0.24 | 0.46±0.59 | 641.3±0.25 |
| **A3** | 5.3± 0.26 | 4.15±0.27 | 0.61±0.65 | 652.5±0.55 |
| **A4** | 5.4± 0.35 | 4.09±0.54 | 0.46±0.53 | 646.6±0.34 |
| **A5** | 5.6± 0.31 | 4.12±0.29 | 0.61±0.58 | 644.2±0.28 |
| **A6** | 5.5± 0.50 | 4.14±0.31 | 0.76±0.51 | 652.1±0.34 |
| **A7** | 5.4± 0.24 | 4.09±0.11 | 0.62±0.25 | 643.8±0.45 |
| **A8** | 5.3± 0.57 | 4.11±0.53 | 0.46±0.22 | 645.6±0.29 |

* n=3: Diameter of all tablets were found to be 11.95±0.02 mm

The floating tablets of Ranitidine HCL were prepared through direct compression technique by means of HPMC (K4, K15M), sodium bicarbonate, citric acid and Carbopol 940P. The magnesium stearate was used as lubricant and talc was used as glidant. The results of the physicochemical characterization are given in Table No. 3. The Hardness of tablets was found in the range of 5.1 to 5.6 kg/cm$^2$. The thickness of tablets was between 4.06 -4.16 mm. All the tablets showed loss of less than 1 % in weight which was considered acceptable. The percentage deviation from average tablet weight 650mg for all the tablet was found to be within the specified limits. Tablets from each batch showed uniformity of content in the range 96.36 ± 0.69 -99.70 ± 0.52 % to 99.70 % which was under pharmacopoeial specifications.

**Swelling Behavior**

Hydrophilic matrices when immersed in water get swells and eventually dissolved. When they are placed in water, swelling starts and the tablet thickness increases. Initially, water diffuses through the polymeric matrix. As the polymer chains become more hydrated and the gel becomes more diluted, the disentanglement concentration may be reached that was the critical polymer concentration below which the

polymer chains disentangle and detach from the gellified matrix. Thus there was a slow diminution of the matrix thickness due to polymer dissolution. The polymer in the matrix undergoes simultaneous swelling, dissolution and diffusion into the bulk medium resulting in erosion of the polymer. [20,21]

The matrices % swelling increases at the beginning attains a maximum and then declines as showed in Figure No. 1. The matrices behavior can be ascribed to a natural hydration process. Hydrophilic matrices in contact with water swell and increase their volume and weight due to water diffusion through the matrix. The polymer chains continue the hydration process and the matrix gain more dissolution medium. The increasing water content dilutes the matrix until a disentanglement concentration was attained. At this point, the polymer molecules are released from the matrix and diffused to the bulk of the dissolution medium. The matrix volume decreases slowly because of polymer dissolution. Polymeric matrices experience simultaneously swelling, polymer dissolution and diffusion. As expected, Floating tablet with increasing polymer proportions showed increased hydration volumes. In floating tablet 336 mg Ranitidine Hydrochloride and a variable quantity of a mixture composed of polymers with 18% sodium bicarbonate. As the matrix polymer proportion increases, the hydration volume increases as well as the time necessary to attain its maximum, while in another case, Floating tablet with high proportion of Carbopol 940P than HPMC K4M & HPMC K15M required more time. The swelling index of marketed preparation was compared with formulated batches, it was found that swelling index of marketed formulation had values nearer to optimized batch A7. The swelling behavior was showed in Table No.4 & Figure No.1.

**Table No. 04: Swelling Behavior for Prepared Batches and Marketed Preparation**

| Time hr | A1 | A2 | A3 | A4 | A5 | A6 | A7 | A8 | MP |
|---|---|---|---|---|---|---|---|---|---|
| 00 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 01 | 38.62 ± 0.76 | 51.66 ± 0.68 | 32.66 ± 0.89 | 41.00 ± 0.79 | 63.33 ± 0.85 | 56.66 ± 0.71 | 53.15 ± 0.68 | 44.33 ± 0.77 | 51.18 ± 0.61 |
| 02 | 53.33 ± 0.89 | 77.66 ± 0.79 | 52.33 ± 0.89 | 51.33 ± 0.79 | 77.33 ± 0.89 | 73.00 ± 0.79 | 71.00 ± 0.89 | 61.00 ± 0.79 | 69.00 ± 0.79 |
| 03 | 70.00 ± 0.78 | 103.33 ± 0.89 | 72.66 ± 0.78 | 72.66 ± 0.73 | 97.00 ± 0.84 | 103.00 ± 0.86 | 84.00 ± 0.84 | 80.00 ± 0.77 | 83.00 ± 0.54 |
| 04 | 90.33 ± 0.48 | 116.00 ± 0.89 | 95.66 ± 0.82 | 94.00 ± 0.82 | 115.00 ± 0.91 | 119.66 ± 0.97 | 104.33 ± 0.93 | 100.33 ± 0.61 | 103.65 ± 0.98 |
| 05 | 108.66 ± 0.88 | 131.00 ± 0.61 | 108.33 ± 0.84 | 103.66 ± 0.87 | 133.00 ± 0.64 | 132.66 ± 0.82 | 120.00 ± 0.87 | 119.00 ± 0.68 | 118.00 ± 0.67 |
| 06 | 127.00 ± 0.89 | 149.00 ± 0.89 | 132.00 ± 0.89 | 125.00 ± 0.78 | 154.00 ± 0.61 | 150.66 ± 0.86 | 131.66 ± 0.89 | 131.33 ± 0.75 | 127.26 ± 0.79 |
| 07 | 149.10 ± 0.95 | 162.00 ± 0.85 | 149.00 ± 0.83 | 168.33 ± 0.84 | 172.00 ± 0.94 | 169.33 ± 0.81 | 150.00 ± 0.95 | 143.33 ± 0.94 | 147.30 ± 0.95 |
| 08 | 159.00 ± 0.44 | 194.66 ±0.27 | 171.33 ±0.41 | 172.66 ± 0.37 | 197.66 ± 0.34 | 189.00 ± 0.27 | 161.33 ± 0.67 | 157.33 ± 0.36 | 160.33 ± 0.67 |
| 09 | 192.00 ± 0.37 | 198.66 ± 0.94 | 198.33 ± 0.91 | 189.00 ± 0.86 | 208.00 ± 0.83 | 202.66 ± 0.82 | 202.66 ± 0.95 | 168.33 ± 0.62 | 201.66 ± 0.95 |
| 10 | 204.66 ± 0.82 | 217.33 ± 0.73 | 221.00 ± 0.96 | 209.00 ± 0.85 | 227.33 ± 0.72 | 212.33 ± 0.94 | 207.66 ± 0.93 | 186.33 ± 0.94 | 206.66 ± 0.93 |
| 11 | 223.33 ± 0.81 | 239.00 ± 0.82 | 244.66 ± 0.94 | 218.00 ± 0.87 | 232.66 ± 0.82 | 228.33 ± 0.95 | 228.66 ± 0.82 | 198.33 ± 0.96 | 227.66 ± 0.72 |
| 12 | 229.33 ± 0.93 | 249.33 ± 0.92 | 285.00 ± 0.95 | 243.33 ± 0.94 | 243.00 ± 0.94 | 258.66 ± 0.98 | 245.00 ± 0.91 | 209.33 ± 0.97 | 244.00 ± 0.89 |

* n=3 hr= hours, MP= Marketed Preparation

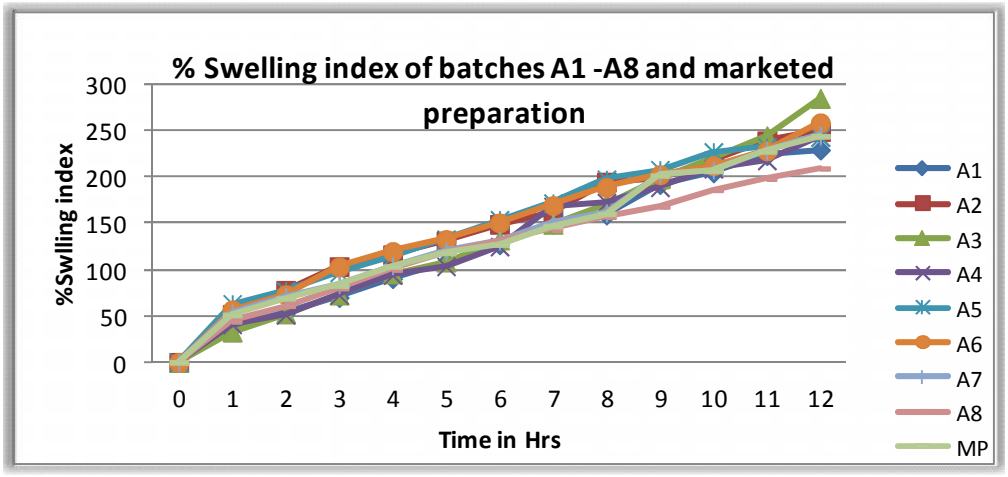


**Figure No. 01: % Swelling Index of Formulations A1 to A8 and Marketed Preparation**

***In- Vitro* Drug Release**

The studies of the formulation Batches from A1-A8 and marketed prparation were carried out to know the in-vitro drug release pattern. The drug release at specified time intervals was determined and calculated to know the release at variable concentration of polymers used. The results obtained were converted in the form of % drug release. The release behavior was compared with marketed preparation. Percent drug release studies were carried out for A1 to A8 batches and were showed in Table No.5 & Figure No.2.

**Table No. 05: *In-Vitro* Dissolution Rate Study of Formulation A1 to A8 and Marketed Preparation**

| Sr. No | Time (hrs) | % Drug Release ± SD | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A1 | A2 | A3 | A4 | A5 | A6 | A7 | A8 | MP |
| 01 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 02 | 01 | 20.89 ±0.23 | 22.49 ±0.41 | 22.34 ±0.58 | 21.54 ±0.23 | 14.47 ±0.44 | 20.89 0.52 | 12.15 ±0.27 | 16.96 ±0.17 | 11.96 ±0.25 |
| 03 | 02 | 33.13 ±0.35 | 34.54 ±0.55 | 34.65 ±0.48 | 35.22 ±0.47 | 20.82 ±0.56 | 29.46 ±0.84 | 21.45 ±0.65 | 29.52 ±0.25 | 20.89 ±0.58 |
| 04 | 03 | 44.70 ±0.62 | 46.39 ±0.70 | 47.10 ±0.46 | 46.30 ±0.59 | 33.05 ±0.84 | 33.76 ±0.35 | 31.80 ±0.71 | 38.45 ±0.48 | 30.90 ±032 |
| 05 | 04 | 51.68 ±0.71 | 51.06 ±0.73 | 52.33 ±0.71 | 53.13 ±0.94 | 44.54 ±0.70 | 41.21 ±0.82 | 44.31 ±0.40 | 45.13 ±0.35 | 43.97 ±0.38 |
| 06 | 05 | 60.73 ±0.48 | 59.82 ±0.67 | 62.09 ±0.70 | 60.73 ±0.59 | 49.55 ±0.49 | 47.40 ±0.59 | 48.94 ±0.94 | 52.74 ±0.59 | 47.79 ±0.92 |
| 07 | 06 | 70.47 ±0.88 | 72.61 ±0.51 | 76.38 ±0.94 | 66.81 ±0.89 | 58.44 ±0.29 | 51.93 0.94 | 57.61 ±0.59 | 60.42 ±0.75 | 56.94 ±0.56 |
| 08 | 07 | 80.03 ±0.59 | 77.97 ±0.58 | 81.39 ±0.48 | 74.54 ±0.84 | 67.26 ±0.59 | 56.93 ±0.65 | 68.01 ±0.34 | 68.16 ±0.88 | 67.44 ±0.31 |
| 09 | 08 | 89.10 ±0.59 | 86.44 ±0.71 | 85.04 ±0.48 | 83.45 ±0.67 | 76.30 ±0.94 | 61.95 ±0.35 | 76.30 ±0.88 | 77.88 ±0.35 | 75.56 ±0.84 |
| 10 | 09 | 96.79 ±0.23 | 91.98 ±0.94 | 91.46 ±0.48 | 89.96 ±0.77 | 84.01 ±0.82 | 64.86 ±0.97 | 83.20 ±0.47 | 85.34 ±0.97 | 82.48 ±0.44 |
| 11 | 10 | - | 98.73 ±0.58 | 95.09 ±0.67 | 97.48 ±0.82 | 89.77 ±0.39 | 68.62 ±0.55 | 87.24 ±0.59 | 92.15 ±0.75 | 86.88 ±0.52 |
| 12 | 11 | - | - | - | - | 95.08 ±0.71 | 74.90 ±0.45 | 93.22 ±0.94 | - | 92.23 ±0.89 |
| 13 | 12 | - | - | - | - | - | 83.05 ±0.94 | 96.42 ±0.55 | - | 95.32 ±0.50 |
| 14 | 13 | - | - | - | - | - | 86.10 ±0.65 | - | - | |

*n=3 MP= Marketed Preparation

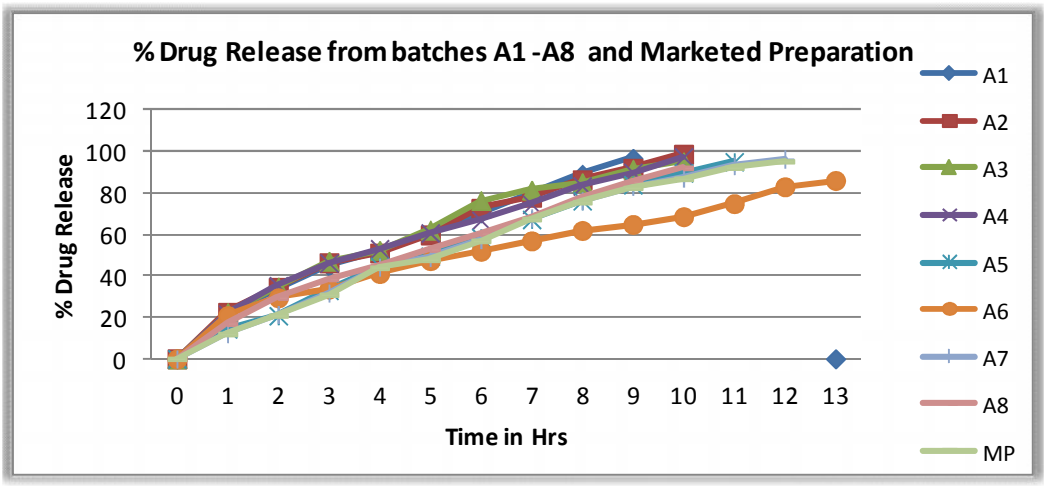


**Figure No. 02: Comparison of % Release of Ranitidine Hydrochloride from Formulation A1and A8 and Marketed Preparation**

From the data (Table No.5) it was found that A1 (15% HPMC K4M & 10% HPMC K15M), A2(20% HPMC K4M & 10% HPMC K15M),A3 ( 20% HPMC K4M &15% HPMC K15M), were unable to sustain drug release for desired time period therefore's not selected for further study. The following Figure No.2 showed the release of Ranitidine hydrochloride from tablets. The tablets (A1) gave complete drug release in 9 hrs and the tablet (A2, A3) gave complete drug release in 10 hrs. Formulation containing Carbopol (A4-A8 ) showed extended drug release as compared to those without Carbopol 940 P (A1- A3 ). As concentration of polymers increases, the drug release found to be decreased. Formulation containing Carbopol 940P showed drug release in between 10-13 Hrs depending on concentration of polymer. Formulation A4 and A5 showed drug release in 10 and 11 Hrs respectively. due to low polymer content. Formulation A7 showed maximum 96.42% drug release in 12 Hrs while formulation A6 had more retardation of release (86.10 % in 13 Hrs). Retardation of concentration of HPMC K15 in formulation A5 caused drug release completed in 11 Hrs. The drug release from the marketed preparation was found to be 95.32 % in 12 hrs and it was nearer to optimized batch A7.

From the dissolution data, we can conclude that Carbopol has significant effect on release profile of drug. Formulation without Carbopol showed drug release in 9-11 Hrs.

**Drug Interaction Studies**

**FT-IR Spectroscopy**

IR spectrum of Ranitidine Hydrochloride was compared with standard spectrum in Indian Pharmacopoeia. The FT-IR spectrum of drug shows the peaks which match to the functional groups which was indicated in official FTIR spectra so it confirmed the drug was Ranitidine Hydrochloride as showed in Fig. No.3 - 4.

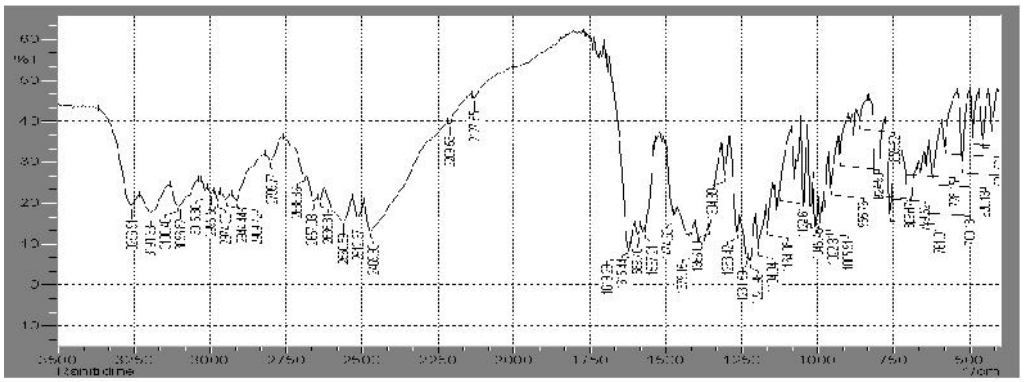

**Figure No. 03:- IR Spectrum of Ranitidine Hydrochloride**

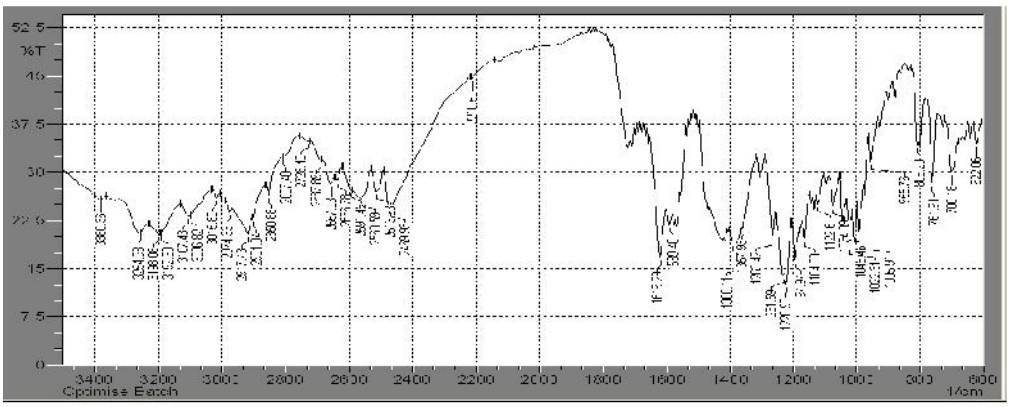

**Figure No.4:- IR Spectrum of Optimized Formulation A7.**

The FT-IR spectrum did not show presence of any additional peaks for new functional groups indicating no chemical interaction between Ranitidine Hydrochloride & the used polymers.

## Conclusion

In conclusion, in the present research, the floating tablet of ranitidine hydrochloride were successfully prepared by using HPMC K4M, HPMC K15M and Carbopol 940 to increase the gastric residence time and hence bioavaibility of ranitidine hydrochloride. The gas-generating agent sodium bicarbonate along with citric acid was essential to achieve *in-vitro* buoyancy. The drug release from the tablets was sufficiently controlled.

## Acknowledgment

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