

## **DESIGN AND EVALUATION OF GASTRO RETENTING DRUG DELIVERY SYSTEM CONTAINING FAMOTIDINE AS DRUG MOLECULE**

**K. Senthamizholy\*<sup>1</sup>, Drx. L. Gopi<sup>2</sup>, Dr. V. Kalvimoorthi<sup>3</sup>**

<sup>1</sup>\*B. Pharm Final Year, <sup>2</sup>Assistant Professor Department of Pharmaceutics,

<sup>3</sup>Professor Cum Head

Aadhibhagawan College of Pharmacy, Rantham, Thiruvannamalai, Tamilnadu.

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### **\*Corresponding Author**

**K. Senthamizholy**

B. Pharm Final Year, Aadhibhagawan  
College of Pharmacy, Rantham,  
Thiruvannamalai, Tamilnadu.



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### **ABSTRACT**

The present study focuses on the design, formulation, and evaluation of a gastro-retentive drug delivery system (GRDDS) containing famotidine as the drug molecule. Five different floating tablet formulations (F1–F5) were prepared using direct compression technique with HPMC E50, Carbopol 930, sodium bicarbonate, and other excipients. Pre-compression parameters such as bulk density, Carr's index, angle of repose, and Hausner ratio confirmed good flow characteristics. Post-compression evaluations included weight variation, hardness, friability, drug content, buoyancy studies, swelling index, and in-vitro drug release. FTIR analysis confirmed no significant interaction between famotidine and selected excipients. Among the five formulations, F2, F3, and F4 exhibited excellent buoyancy and sustained drug release over 10 hours, with F2 showing the highest release (96.3%). Overall, the study demonstrates that HPMC–Carbopol-based floating tablets can effectively sustain

famotidine release and prolong gastric residence time, making them suitable for improving the therapeutic efficacy of famotidine in gastric disorders.

**KEYWORDS:** Famotidine, Gastro-retentive drug delivery system, Floating tablets, HPMC E50, Carbopol 930, Buoyancy, Sustained release, FTIR, In-vitro drug release.

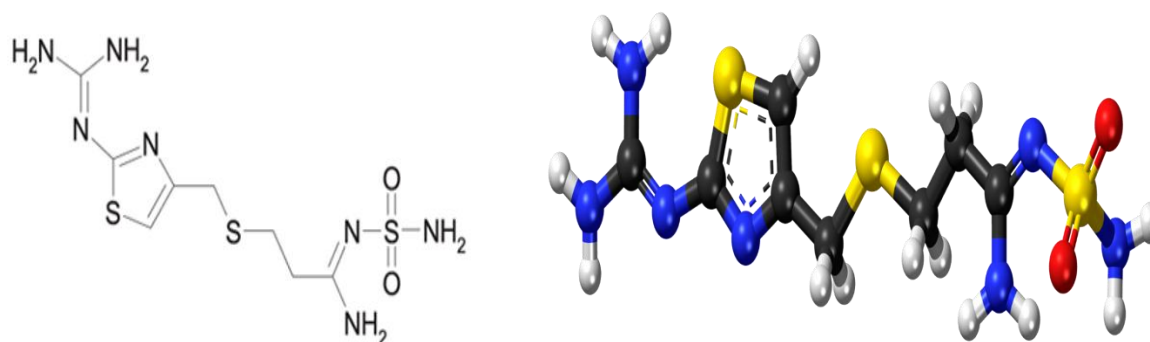
## 1. INTRODUCTION

Gastro-retentive drug delivery systems (GRDDS) are designed to prolong the residence of dosage forms in the stomach, improving the bioavailability of drugs that are preferentially absorbed in the upper gastrointestinal tract or are unstable in intestinal pH. Floating drug delivery systems, in particular, offer advantages such as improved gastric retention, reduced dosing frequency, and enhanced therapeutic performance.

Famotidine, a histamine H<sub>2</sub>-receptor antagonist, is widely used in the treatment of peptic ulcer, GERD, Zollinger-Ellison syndrome, and related gastric disorders. Its short biological half-life (2.5–3.5 hours) and limited oral bioavailability (40–45%) make it an ideal candidate for a sustained release gastro-retentive formulation.

The objective of this study was to develop floating tablets of famotidine using HPMC E50 and Carbopol 930 as release-retarding polymers along with sodium bicarbonate as a gas-generating agent. Five formulations (F1–F5) were prepared by direct compression and evaluated for pre-compression and post-compression characteristics. Drug-excipient compatibility was confirmed using FTIR studies. In-vitro drug release studies were performed to determine the most suitable formulation for sustained gastric retention and controlled drug release.

## 2. DRUG PROFILE: (Famotidine)



**Fig. 1: Structure Of Famotidine.**

- ✚ **Systemic (IUPAC) Name:** (3-[2-(diamino methylene amino)thiazol-4-yl]methyl thio)- N' sulfamoyl propanimidamide)
- ✚ **Formula:** C<sub>8</sub>H<sub>15</sub>N<sub>7</sub>O<sub>2</sub>S<sub>3</sub>
- ✚ **Mol. Mass:** 337.449 g/mol
- ✚ **Bioavailability:** 40-45%(oral)

- ✚ **Protein binding:** 15-20%
- ✚ **Metabolism:** Hepatic- CYP1A2
- ✚ **Half life:** 2.5-3.5 hour
- ✚ **Excretion:** Renal (25-30% unchanged [Oral])
- ✚ **Action and use:** Inhibition of histamine H<sub>2</sub>- receptors and inhibition of gastric acid secretion in the case of Zollinger-Ellisons syndrome and (GERD)
- ✚ **Appearance:** white to pale yellow crystalline compound.
- ✚ **Solubility:** Freely soluble in glacialacetic acid, slightly soluble in methanol, very slightly soluble in water, and practically insoluble in ethanol.
- ✚ **Routes:** Oral (tablet), oral suspension, sub cutaneous, IV.
- ✚ **Dose:** A single oral dose of 40mg given orally at night time for 8 weeks, it produce healing of duodenal ulcer In Zollinger -Ellison syndrome 20 mg dose every 6 hrs is prescribed.
- ✚ **Medicinal uses:** Zollinger-Ellison syndrome for the prevention of aspiration pneumonia, Refluxesophagitis, Nonmalignant gastric ulcer, duodenal ulcer.
- ✚ **Adverse effect:** Diarrhoea, Head ache, Drowsiness, Fatigue, Muscular Pain, Constipation.

### 3. METHODOLOGY

#### 3.1 Drug-Excipients Compatibility Studies

The pure drug famotidine and the solid admixture of drug and various excipients used in the preparation of floating tablet formulations were characterized by FTIR spectroscopy to know the compatibility.

#### 3.2 Formulation Of Famotidine Floating Tablets

Five different batches of the famotidine floating tablets were prepared by direct compression method. Before direct compression all the ingredients were passed through sieve no. 88. The drug famotidine was mixed manually with the polymers (at fixed ratio) and sodium bi carbonate in a glass mortar in increasing order of their weights The powder mixture were blended for 30 minutes. Then at the last magnesium stearate (1%) the lubricant and talc (5%) the glidant were mixed with the drug polymer mixture and blended for 5minutes. Finally the powder blends were compressed separately by using shallow biconcave punches of 7mm in diameter in Cadmach-16 multistage rotary tablet punching machine into the famotidine floating tablets weighing 150mg. Composition of the formulated famotidine floating tablets.

The drug (famotidine) and the polymers HPMC E50, Carbopol930, were utilized at different drug polymer ratio as follows.

- F1- Drug: Polymers 1:2 (Famotidine: HPMC E50) and other excipients.
- F2 Drug: Polymers 1:2 (Famotidine: Carbopol 930) and other excipients
- F3 Drug Polymers 1:1:1 (Famotidine HPMC E50: Carbopol 930) and other excipients
- F4 Drug Polymers 2:3:1 (Famotidine: HPMC E50: Carbopol 930) and other excipients.
- F5 Drug Polymer 5:9:1 (Famotidine: HPMC E50: Carbopol 930) and other excipients.

(In all the formulation, Drug: Total polymer = 1:2)

**Table 1: Composition Of Ingredients For Each Tablets.**

| Ingredient For Each On Tablet              | F1(mg)     | F2(mg)     | F3(mg)     | F4(mg)     | F5(mg)     |
|--|------------|------------|------------|------------|------------|
| <b>Famotidine</b>                          | 40         | 40         | 40         | 40         | 40         |
| <b>Hydroxy Propyl Methyl Cellulose E50</b> | 80         | -          | 40         | 60         | 72         |
| <b>Carbopol</b>                            | -          | 80         | 40         | 20         | 8          |
| <b>Sodium Bicarbonate</b>                  | 21         | 21         | 21         | 21         | 21         |
| <b>Magnesium Stearate</b>                  | 1.5        | 1.5        | 1.5        | 1.5        | 1.5        |
| <b>Talc</b>                                | 7.5        | 7.5        | 7.5        | 7.5        | 7.5        |
| <b>Total Weight Of Each One Tablet</b>     | <b>150</b> | <b>150</b> | <b>150</b> | <b>150</b> | <b>150</b> |

### 3.3 Evaluation Of The Formulated Famotidine Floating tablets

Drug content, Shape, Dimension and density of tablet, Hardness, Friability, Weight variation Analysis, In-vitro buoyancy studies, Swelling index, In vitro drug release,

#### Drug Content

##### A) Standard Graph for The Drug Famotidine

The drug famotidine (100mg) was weighed and transferred into 100ml volumetric flask. Initially 50ml of 0.1N HCl was added and shaken for 30 minutes and volume was made to 100 ml with 0.1N HCl to get the first stock solution. From the stock solution 20ml was pipette out and transferred into 1000ml volumetric flask and volume was made with 0.1NHCl to get second stock solution (20 $\mu$ g). From the second 2.5ml, stock solution a series 5ml, 7.5ml, 10ml, 12.5ml, 15ml, 17.5ml, 20ml, 22.5ml, 25ml, 27.5ml, 30ml, 32.5ml, 35ml, 37.5ml, 40ml, 42.5ml, 45ml, 47.5ml, were pipetted in to a 50ml separate volumetric flask and volume was made with 0.1NHcl to get concentration of 1-19 $\mu$ g/ml respectively. Absorbance of different concentration 1-20 $\mu$ g/ml was measured at max 265 nm. Using microprocessor UV/Visible spectrophotometer (El Model 1371).

## B) Determination Of Drug Content

Twenty tablets were selected randomly and powdered in a mortar. Amount equivalent to 40mg of the drug (average weight of the tablets) were weighed and transferred into 100ml volumetric flask. Initially 50ml of 0.1NHCl was added and shaken for 30 minutes. Then the volume was made up to 100ml with 0.1NHCl. The solution was filtered and 2.5ml of the filtrate was diluted to 100ml with 0.1NHCl and the absorbance was measured at Amax 265 nm using Microprocessor UV/Visible spectrophotometer (El Model 1371).

## 4. RESULTS AND DISCUSSION

### 4.1 PRE-FORMULATION PARAMETERS

Table 2: Pre-compression Study.

| Formulation | Bulk Density (gm/cm <sup>3</sup> ) | Carr's Index(%) | Angle Of Repose | Hausner Ratio |
|-------------|------------------------------------|-----------------|-----------------|---------------|
| F1          | 0.4120                             | 12              | 20°.79'         | 1.14          |
| F2          | 0.7170                             | 15              | 24°.02'         | 1.18          |
| F3          | 0.5545                             | 10              | 25°.00'         | 1.11          |
| F4          | 0.4575                             | 12              | 27°.38'         | 1.14          |
| F5          | 0.5842                             | 15              | 23°.15'         | 1.18          |

### 4.2 CONCENTRATION AND THE ABSORBANCE OF THE DRUG FAMOTIDINE (STANDARD GRAPH).

Table 3: Standard Graph.

| S.NO | CONCENTRATION (g/ml) | ABSORBANCE |
|------|----------------------|------------|
| 1.   | 1                    | 0.013      |
| 2.   | 2                    | 0.019      |
| 3.   | 3                    | 0.029      |
| 4.   | 4                    | 0.037      |
| 5.   | 5                    | 0.048      |
| 6.   | 6                    | 0.056      |
| 7.   | 7                    | 0.067      |
| 8.   | 8                    | 0.075      |
| 9.   | 9                    | 0.086      |
| 10.  | 10                   | 0.097      |
| 11.  | 11                   | 0.107      |
| 12.  | 12                   | 0.115      |
| 13.  | 13                   | 0.125      |
| 14.  | 14                   | 0.132      |
| 15.  | 15                   | 0.141      |
| 16.  | 16                   | 0.153      |
| 17.  | 17                   | 0.162      |
| 18.  | 18                   | 0.169      |
| 19.  | 19                   | 0.178      |
| 20.  | 20                   | 0.189      |

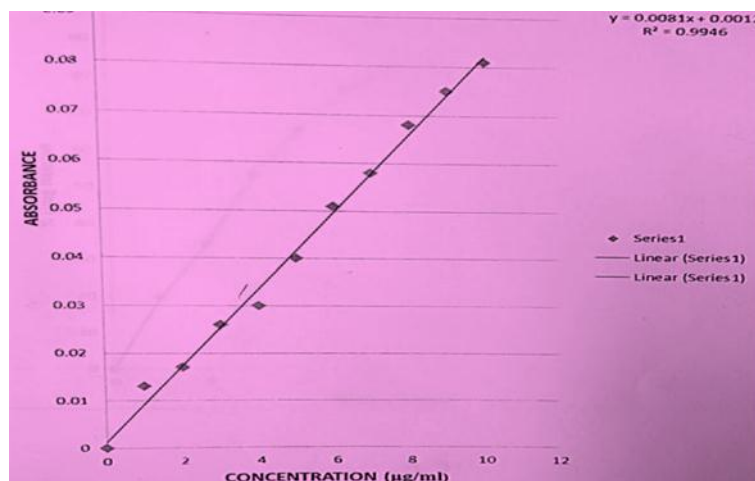


Fig 2: Standard Graph.

#### 4.3 POST-FORMULATION PARAMETERS.

Table 4: Tablet Dimensions.

| Formulation | Shape              | Thickness (mm) | Diameter (mm) | Density Of The Tablet (g/cm <sup>3</sup> ) |
|-------------|--------------------|----------------|---------------|--|
| F1          | Biconcave Circular | 2.5            | 6.5           | 0.00180                                    |
| F2          | Biconcave Circular | 2.5            | 6.5           | 0.00183                                    |
| F3          | Biconcave Circular | 3              | 6.5           | 0.00154                                    |
| F4          | Biconcave Circular | 3              | 6.5           | 0.00150                                    |
| F5          | Biconcave Circular | 3              | 6.5           | 0.00153                                    |

Table 5: Drug Content, %Drug Content, Hardness &amp; Friability.

| Formulation | Drug Content (mg) | Percentage Drug Content | Hardness Kg/cm <sup>2</sup> | Friability Test |
|-------------|-------------------|-------------------------|-----------------------------|-----------------|
| F1          | 39.01±0.005       | 97.5±0.057              | 4.5±0.235                   | 0.1±0.008       |
| F2          | 40.9±0.010        | 102±0.031               | 5±0.230                     | 0.3±0.014       |
| F3          | 39.5±0.012        | 98.76±0.129             | 4±0.280                     | 0.1±0.010       |
| F4          | 41.48±0.016       | 103±0.516               | 4.5±0.470                   | 0.2±0.008       |
| F5          | 40.4±0.090        | 101.2±0.100             | 5±0.400                     | 0.1±0.020       |

#### 4.4 WEIGHT VARIATION ANALYSIS OF FORMULATED FAMOTIDINE FLOATING TABLETS

Table 6: Weight Variation.

| S.NO | WEIGHT OF INDIVIDUAL TABLETS |        |        |        |        |
|------|------------------------------|--------|--------|--------|--------|
|      | F1(g)                        | F2(g)  | F3(g)  | F4(g)  | F5(g)  |
| 1.   | 0.1492                       | 0.1528 | 0.1542 | 0.1492 | 0.1520 |
| 2.   | 0.1498                       | 0.1522 | 0.1536 | 0.1494 | 0.1522 |
| 3.   | 0.1496                       | 0.1528 | 0.1528 | 0.1492 | 0.1508 |
| 4.   | 0.1494                       | 0.1492 | 0.1540 | 0.1486 | 0.1520 |
| 5.   | 0.1488                       | 0.1486 | 0.1500 | 0.1468 | 0.1522 |
| 6.   | 0.1492                       | 0.1526 | 0.1582 | 0.1492 | 0.1546 |

|     |        |        |        |        |        |
|-----|--------|--------|--------|--------|--------|
| 7.  | 0.1540 | 0.1532 | 0.1540 | 0.1480 | 0.1524 |
| 8.  | 0.1498 | 0.1540 | 0.1542 | 0.1490 | 0.1526 |
| 9.  | 0.1492 | 0.1520 | 0.1538 | 0.1494 | 0.1562 |
| 10. | 0.1492 | 0.1540 | 0.1528 | 0.1492 | 0.1520 |
| 11. | 0.1486 | 0.1522 | 0.1546 | 0.1488 | 0.1488 |
| 12. | 0.1492 | 0.1518 | 0.1540 | 0.1488 | 0.1498 |
| 13. | 0.1496 | 0.1520 | 0.1542 | 0.1492 | 0.1488 |
| 14. | 0.1488 | 0.1526 | 0.1540 | 0.1498 | 0.1520 |
| 15. | 0.1496 | 0.1528 | 0.1548 | 0.1488 | 0.1590 |
| 16. | 0.1498 | 0.1532 | 0.1540 | 0.1422 | 0.1522 |
| 17. | 0.1494 | 0.1528 | 0.1544 | 0.1492 | 0.1592 |
| 18. | 0.1498 | 0.1520 | 0.1548 | 0.1494 | 0.1542 |
| 19. | 0.149  | 0.1520 | 0.1546 | 0.1520 | 0.1588 |
| 20. | 0.1488 | 0.1522 | 0.1538 | 0.1498 | 0.1522 |

#### 4.4.1 Average Weight For F1-F5 (g).

Table 7: Average Weight.

|                       |                   |                   |                   |                   |                   |
|-----------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| <b>AVERAGE WEIGHT</b> | 0.1495±<br>0.0039 | 0.1522±<br>0.0004 | 0.1540±<br>0.0003 | 0.1493±<br>0.0001 | 0.1531±<br>0.0021 |
|-----------------------|-------------------|-------------------|-------------------|-------------------|-------------------|

#### 4.4.2 Weight Variation Tolerance For The Formulated Famotidine Floating Tablet.

Table 8: Weight Variation Tolerance For The Formulated Famotidine Floating Tablet.

| S.NO | F1    | F2   | F3   | F4    | F5    |
|------|-------|------|------|-------|-------|
| 1.   | +0.2  | -0.3 | -0.1 | 0.06  | 0.7   |
| 2.   | -0.2  | 0    | 0.2  | -0.06 | 0.5   |
| 3.   | -0.06 | -0.3 | 0.7  | 0.06  | 1.5   |
| 4.   | 0.06  | 1.9  | 0    | 0.4   | 0.7   |
| 5.   | 0.4   | 2.3  | 2.5  | 1.6   | 0.5   |
| 6.   | 0.2   | -0.2 | -2.7 | 0.06  | -0.9  |
| 7.   | -3.0  | -0.6 | 0    | 0.8   | 0.4   |
| 8.   | -0.2  | -1.1 | -0.1 | 0.2   | 0.3   |
| 9.   | 0.2   | 0.1  | 0.1  | -0.06 | -2.02 |
| 10.  | 0.2   | -1.1 | 0.7  | 0.06  | 0.7   |
| 11.  | 0.6   | 0    | -0.3 | 0.3   | 2.8   |
| 12.  | 0.2   | 0.2  | 0    | 0.3   | 2.1   |
| 13.  | -0.06 | 0.1  | -0.1 | 0.06  | 2.8   |
| 14.  | 0.4   | -0.2 | 0    | -0.3  | 0.7   |
| 15.  | -0.06 | -0.3 | -0.5 | 0.3   | -3.8  |
| 16.  | -0.2  | -0.6 | 0    | -1.9  | 0.5   |
| 17.  | 0.06  | -0.3 | -0.2 | 0.06  | -3.9  |
| 18.  | -0.2  | 0.1  | -0.5 | -0.06 | -0.7  |
| 19.  | 0.3   | 0.1  | -0.3 | -0.01 | 2.8   |
| 20.  | 0.4   | 0    | 0.1  | -0.3  | 0.5   |



#### 4.5 FLOATING PROPERTIES OF FORMULATED FAMOTIDINE TABLETS

Table 9: Floating Properties.

| S.No | Formulation | Floating Lag Time (Sec) | Total Floating Time (Hour) |
|------|-------------|-------------------------|----------------------------|
| 1.   | F1          | 17                      | >24hrs                     |
| 2.   | F2          | 6                       | >30min                     |
| 3.   | F3          | <1                      | >24hrs                     |
| 4.   | F4          | 2                       | >24hrs                     |
| 5.   | F5          | 10                      | >24hrs                     |

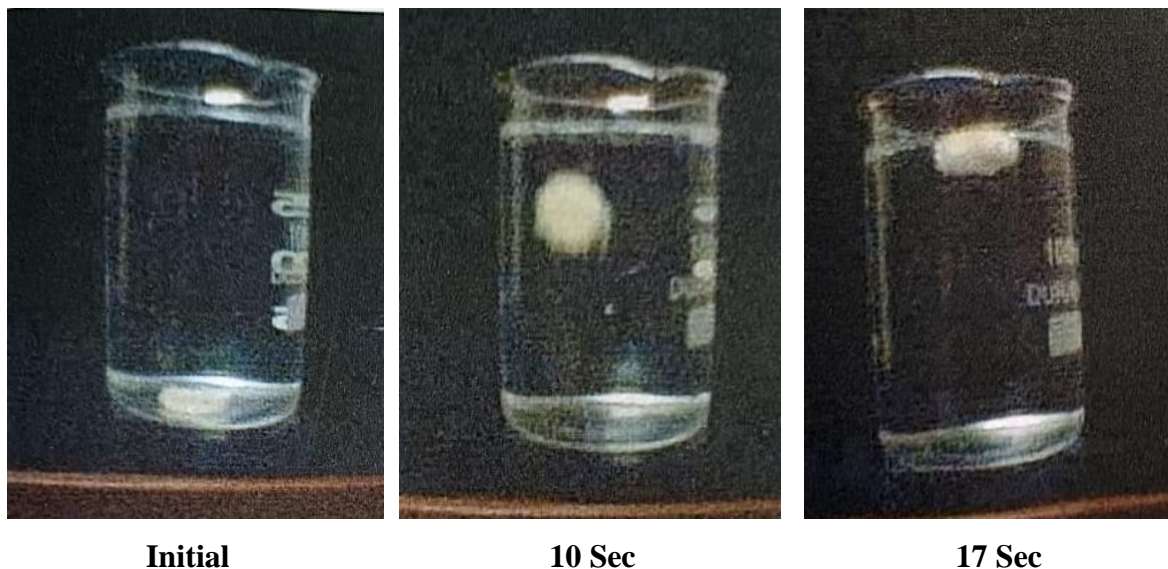


Fig: 3 Floating Tablet.

#### 4.6 INVITRO DRUG RELEASE

##### 4.6.1 INVITRO DRUG RELEASE STUDY FOR THE FORMULATION F1.

Table 10: In-vitro Drug Release Study For The Formulation F1.

| FORMULATION 1 |                |                     |                         |
|---------------|----------------|---------------------|-------------------------|
| S.NO          | TIMES IN HOURS | AMOUNT OF DRUG (mg) | PERCENTAGE DRUG RELEASE |
| 1.            | 1              | 7.8                 | 19.9                    |
| 2.            | 2              | 13.6                | 34.8                    |
| 3.            | 3              | 21                  | 53.8                    |
| 4.            | 4              | 26                  | 66.6                    |
| 5.            | 5              | 30.4                | 77.9                    |
| 6.            | 6              | 32.7                | 83.8                    |
| 7.            | 7              | 32.9                | 84.3                    |
| 8.1           | 8              | 33.5                | 85.8                    |
| 9.            | 9              | 34.1                | 87.4                    |
| 10.           | 10             | 34.6                | 88.6                    |



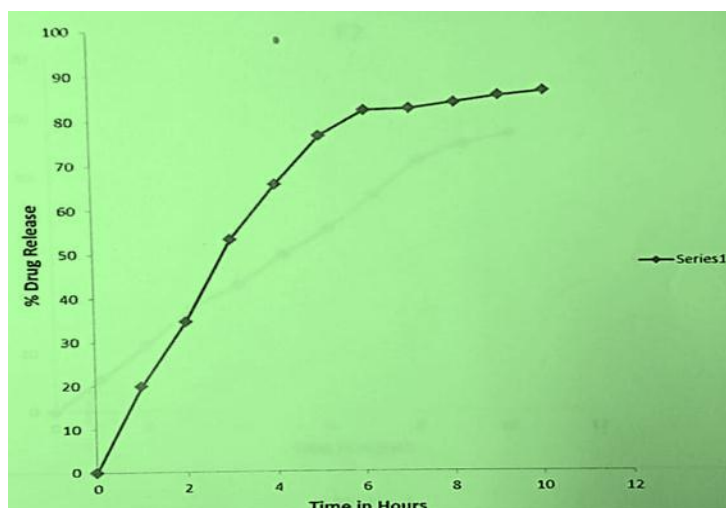


Fig. 4: In-vitro Drug Release Study For The Formulation F1.

#### 4.6.2 INVITRO DRUG RELEASE STUDY FOR THE FORMULATION F2.

Table 11: In-vitro Drug Release Study For The Formulation F2.

| FORMULATION 2 |                |                     |                         |
|---------------|----------------|---------------------|-------------------------|
| S.NO          | TIMES IN HOURS | AMOUNT OF DRUG (mg) | PERCENTAGE DRUG RELEASE |
| 1.            | 1              | 4.5                 | 11                      |
| 2.            | 2              | 9.4                 | 22.9                    |
| 3.            | 3              | 14.7                | 35.9                    |
| 4.            | 4              | 17.9                | 43.7                    |
| 5.            | 5              | 22.1                | 54                      |
| 6.            | 6              | 26                  | 63.5                    |
| 7.            | 7              | 30.7                | 75                      |
| 8.            | 8              | 35.6                | 87                      |
| 9.            | 9              | 36.4                | 93                      |
| 10.           | 10             | 39.4                | 96.3                    |

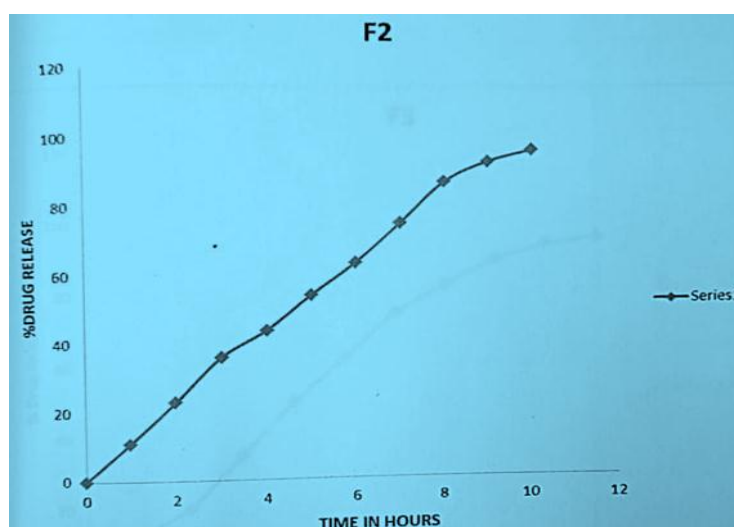
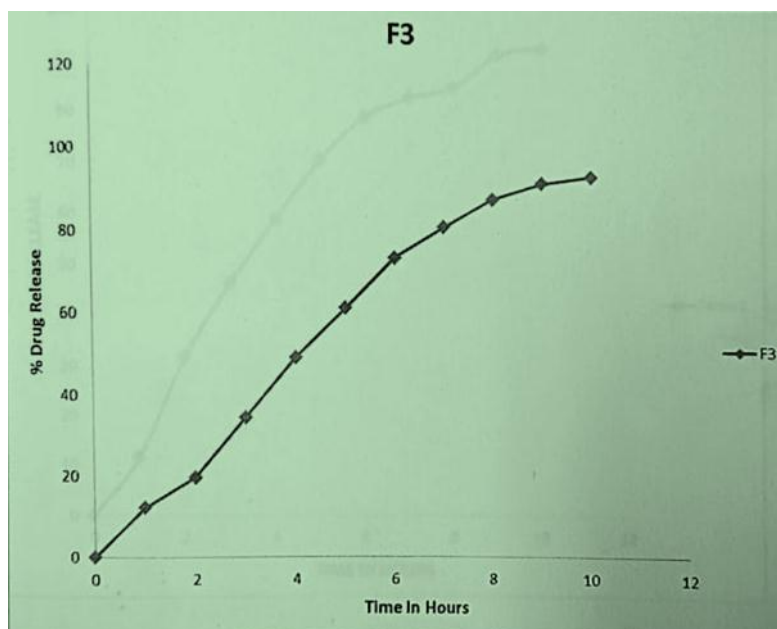


Fig. 5 In-vitro Drug Release Study For The Formulation F2.

**4.6.3 INVITRO DRUG RELEASE STUDY FOR THE FORMULATION F3.****Table 12: In-vitro Drug Release Study For The Formulation F3.**

| FORMULATION 3 |                |                     |                         |
|---------------|----------------|---------------------|-------------------------|
| S.NO          | TIMES IN HOURS | AMOUNT OF DRUG (mg) | PERCENTAGE DRUG RELEASE |
| 1.            | 1              | 4.9                 | 12.4                    |
| 2.            | 2              | 7.9                 | 20                      |
| 3.            | 3              | 13.8                | 34.9                    |
| 4.            | 4              | 19.7                | 49.8                    |
| 5.            | 5              | 24.6                | 62.2                    |
| 6.            | 6              | 29.6                | 74.9                    |
| 7.            | 7              | 32.7                | 82.7                    |
| 8.            | 8              | 35.5                | 89.8                    |
| 9.            | 9              | 37.1                | 93.9                    |
| 10.           | 10             | 37.8                | 95.6                    |

**Fig. 6: In-vitro Drug Release Study For The Formulation F3.****4.6.4 INVITRO DRUG RELEASE STUDY FOR THE FORMULATION F4****Table 13: In-vitro Drug Release Study For The Formulation F4.**

| FORMULATION 4 |                |                     |                         |
|---------------|----------------|---------------------|-------------------------|
| S.NO          | TIMES IN HOURS | AMOUNT OF DRUG (mg) | PERCENTAGE DRUG RELEASE |
| 1.            | 1              | 4.9                 | 11.8                    |
| 2.            | 2              | 13.2                | 31.8                    |
| 3.            | 3              | 19.4                | 46.7                    |
| 4.            | 4              | 24.8                | 59.7                    |
| 5.            | 5              | 29.8                | 71.8                    |
| 6.            | 6              | 33.5                | 80.7                    |

|     |    |      |       |
|-----|----|------|-------|
| 7.  | 7  | 35.2 | 84.8  |
| 8.  | 8  | 36.1 | 87.08 |
| 9.  | 9  | 36.5 | 93    |
| 10. | 10 | 39.5 | 95.2  |

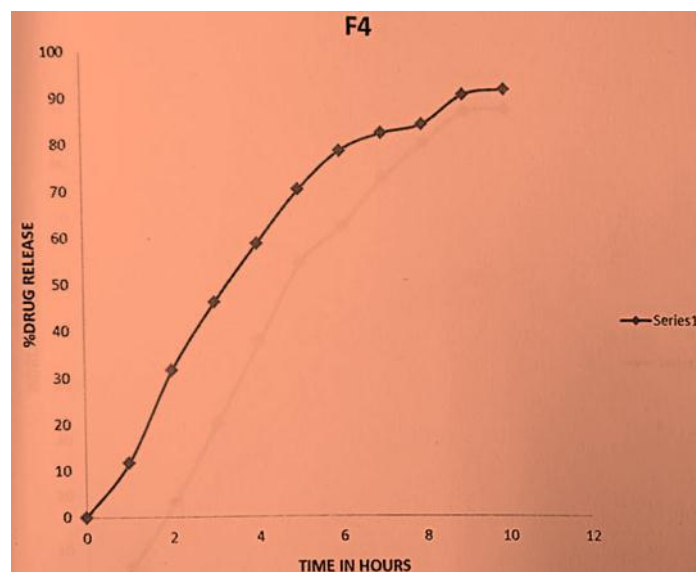


Fig 7: In-vitro Drug Release Study For The Formulation F4.

#### 4.6.5 INVITRO DRUG RELEASE STUDY FOR THE FORMULATION F5

Table 14: In-vitro Drug Release Study For The Formulation F5.

| FORMULATION 5 |                |                     |                         |
|---------------|----------------|---------------------|-------------------------|
| S.NO          | TIMES IN HOURS | AMOUNT OF DRUG (mg) | PERCENTAGE DRUG RELEASE |
| 1.            | 1              | 2.8                 | 6.9                     |
| 2.            | 2              | 7.6                 | 18.8                    |
| 3.            | 3              | 13.3                | 32.9                    |
| 4.            | 4              | 16.9                | 48                      |
| 5.            | 5              | 25.4                | 62.8                    |
| 6.            | 6              | 28.2                | 69.8                    |
| 7.            | 7              | 31.9                | 78.9                    |
| 8.            | 8              | 34.7                | 85.8                    |
| 9.            | 9              | 37.1                | 91.8                    |
| 10.           | 10             | 37.3                | 92.3                    |

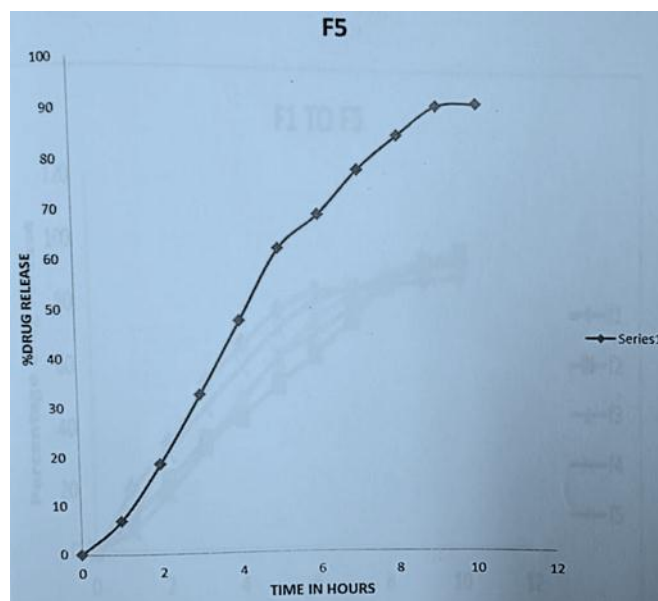


Fig. 8: In-vitro Drug Release Study For The Formulation F5.

#### 4.6.6 INVITRO DRUG RELEASE STUDY FOR FORMULATION F1-F5

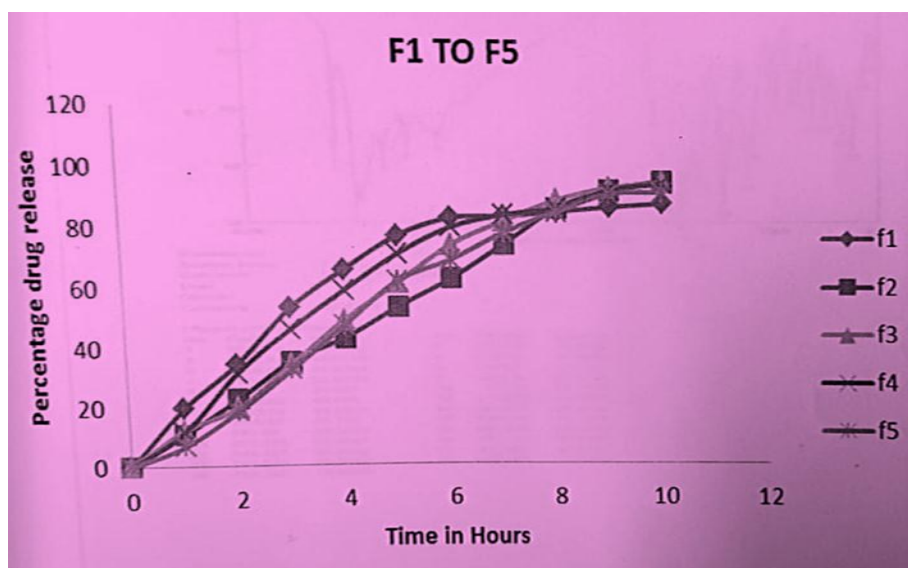


Fig. 9: In-vitro Drug Release Study For The Formulation F1 - F5.

#### 4.7 SWELLING INDEX

Table 15: Swelling Index.

| AT THE END OF 60 MINUTES |        |        |        |        |
|--------------------------|--------|--------|--------|--------|
| F1 (%)                   | F2 (%) | F3 (%) | F4 (%) | F5 (%) |
| 30.0                     | 39.9   | 38.9   | 37.99  | 34.4   |

## 4.8 FI-IR SPECTRUM

### 4.8.1 FTIR STUDIES FOR SAMPLE- 1

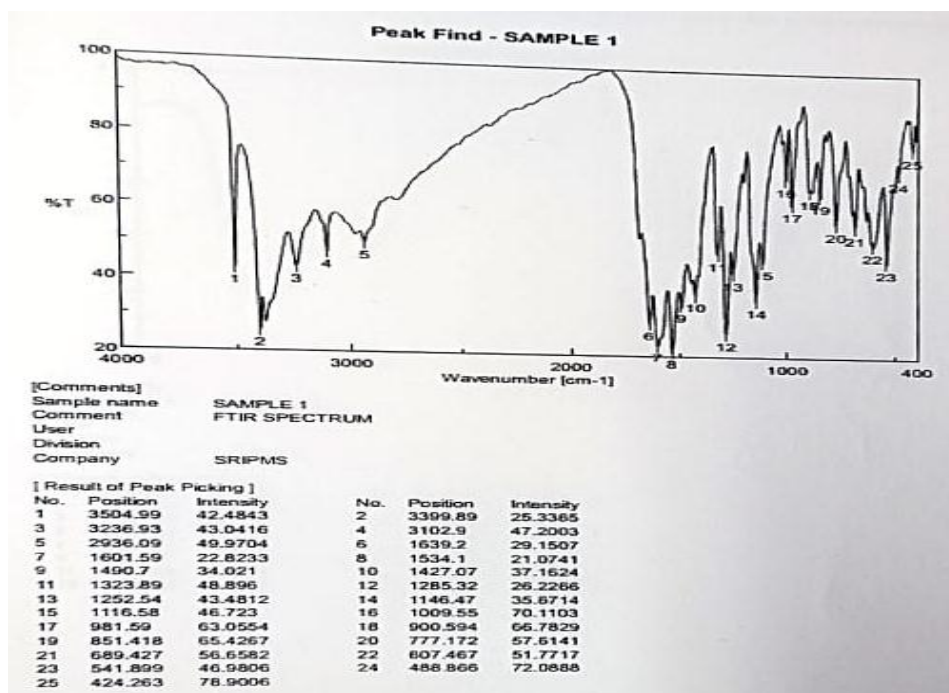


Fig. 10: FTIR Studies For Sample- F1.

### 4.8.2 FTIR STUDIES FOR SAMPLE- 2

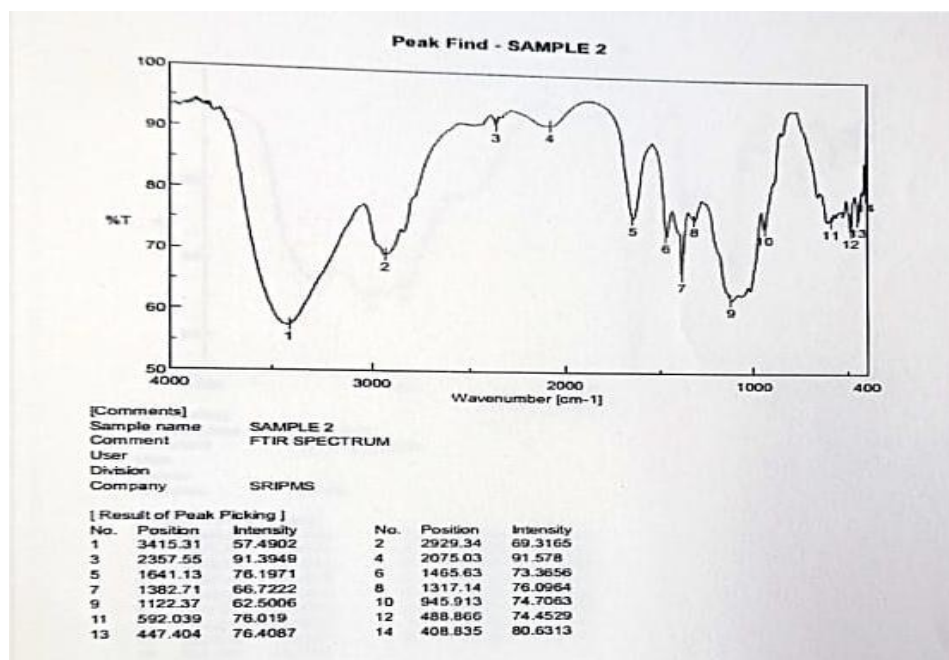


Fig. 11: FTIR Studies For Sample- F2.

## 4.8.3 FTIR STUDIES FOR SAMPLE – 3

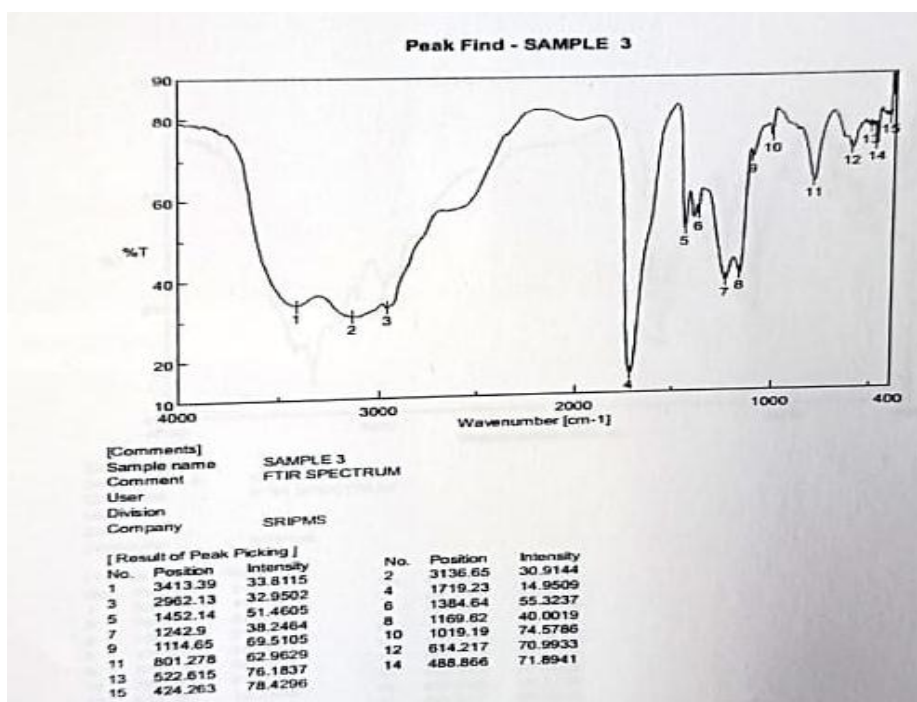


Fig. 12: FTIR Studies For Sample- F3.

## 4.8.4 FTIR STUDIES FOR SAMPLE- 4

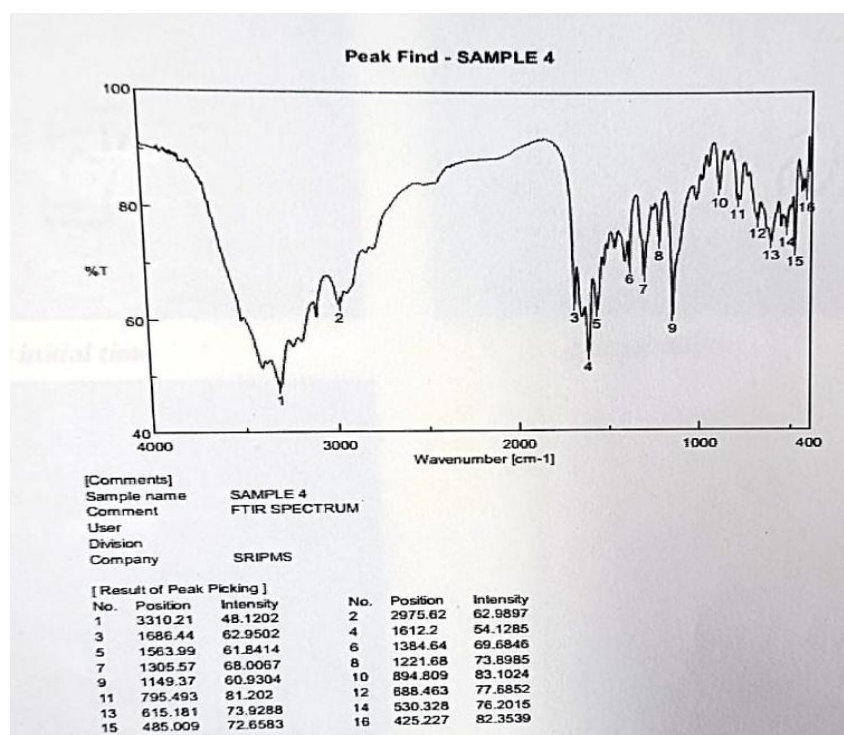


Fig. 13: FTIR Studies For Sample- F4.



#### 4.8.5 FTIR STUDIES FOR SAMPLE- 5

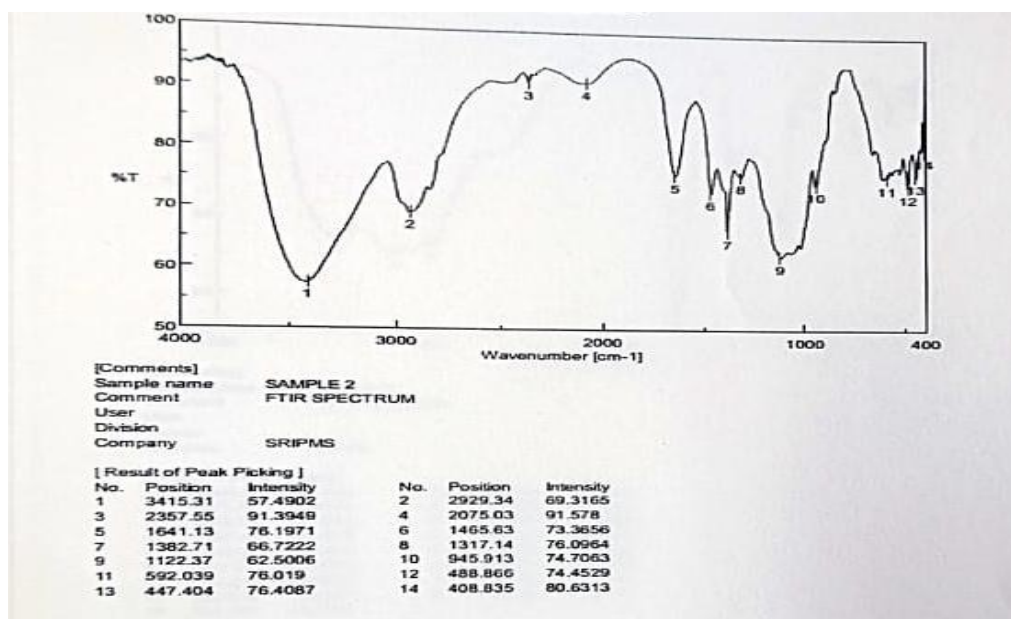


Fig: 14 FTIR Studies For Sample- F5.

## 4.9 DISCUSSION

### Pre-formulation / Pre-compression Parameters

**4.9.1 Bulk density:** Bulk density of the powder blend F1, F2, F3, F4, F5, range from 0.412gm /cm<sup>3</sup>, 0.7170gm /cm<sup>3</sup>, 0.5545gm /cm<sup>3</sup>, 0.4575gm /cm<sup>3</sup>, 0.5842gm /cm<sup>3</sup>, respectively. Each value represents mean value of three determinations.

**4.9.2 Compressibility index\ Carr's index:** Carr's index for the powder blend F1, F2, F3, F4, F5, range from 12%, 15%, 10%, 12%, 15%, respectively. Each value represents mean value of three determinations.

**4.9.3 Angle of repose:** The 'Ø' value which represents the angle of repose for the powder blend F1, F2, F3, F4, F5, were found be 20deg 79', 24deg 02', 25, 27 deg 38' 23 deg 15 deg' respectively. Each value represents mean value of three determinations.

**4.9.4 Hausner ratio:** Hausner ratio for the powder blend F1, F2, F3, F4, F5, were found to be 1.14, 1.18, 1.11, 1.14, 1.18, respectively. Each value represents mean value of three determinations.

**4.9.5 Drug-excipients compatibility studies:** The pure drug famotidine and the powder blend of drug and the excipients were characterized by FTIR studies. The peak in 3504.99cm<sup>-1</sup> - 1 3399.89cm<sup>-1</sup> indicates the N-H stretching. The peak 2936.09 cm<sup>-1</sup> and



1639.2  $\text{cm}^{-1}$  it indicates the C-H stretching and C = N stretching. The peak 1601.59 and 1534.1 it indicates both are C-C stretching (Aromatic). The peak 1490.7 indicates the C = C stretching (Aromatic). The FTIR spectrum of the pure drug shows the peak at the following values which are characteristics of the drug 3504.99  $\text{cm}^{-1}$  N-H stretching, 2936.09  $\text{cm}^{-1}$  C-H stretching, C = N stretching, 1601.59  $\text{cm}^{-1}$  C = C stretching 0.1534  $\text{cm}^{-1}$  0.1  $\text{cm}^{-1}$  C = C stretching 0.1285  $\text{cm}^{-1}$  0.32  $\text{cm}^{-1}$  C - N vibrations 1147  $\text{cm}^{-1}$  C = S stretching, 1116.58  $\text{cm}^{-1}$  C = S stretching. 1109.57  $\text{cm}^{-1}$  O-H bending (alcohols). There was no significant difference in the FTIR spectra of pure drug Famotidine and the formulations.

## Evaluation Of formulated Famotidine Floating Tablets

### 4.9.6 Drug Content

**A. Standard graph for the drug famotidine:** Standard graph for the drug famotidine was plotted using 0.1N HCl. The linearity was best observed in the concentration range 0.1 g/ml.  $r^2=0.9946$ .

**B. Determination of Drug content:** Drug content of the formulated famotidine floating tablets F1, F2, F3, F4, F5 were found to be 39.01  $\pm 0.005$  mg, 40.9 plus/minus 0.01 mg, 39.5 plus/minus 0.012 mg, 41.48 plus/minus 0.016 mg, 40.4 plus/minus 0.09 respectively. Each value represents mean value of three determinations.

**4.9.7 Shape of the tablet:** All the tablet are circular and biconcave in shape.

**4.9.8 Tablet dimension:** The thickness of the tablets from each batch F1, F2, F3, F4, F5 were found as 2.5mm, 2.5mm, 3mm, 3mm, 3mm, respectively. The diameter of the tablets from each batch F1, F2, F3, F4, F5 were found to be 6.5mm.

**4.9.9 Tablet density:** Tablet density from each formulation F1, F2, F3, F4, F5 were found to be 0.0018g / $\text{cm}^2$ , 0.00183g / $\text{cm}^2$ , 3.00154g / $\text{cm}^2$ , 0.0015g / $\text{cm}^2$ , 0.00153g / $\text{cm}^2$  respectively.

**4.9.10 Hardness Test:** Hardness of the formulated (F1, F2, F3, F4, F5,) famotidine floating tablet were found to be 4.5 $\pm 0.235$  kg/ $\text{cm}^2$ , 5 $\pm 0.23$  kg/ $\text{cm}^2$ , 4 $\pm 0.28$  kg/ $\text{cm}^2$ , 4.5 $\pm 0.47$  kg/ $\text{cm}^2$ , 5 $\pm 0.400$  kg/ $\text{cm}^2$  respectively. Each value represents mean value of three determinations.

**4.9.11 Friability Test:** Friability of the formulated famotidine floating tablets was found by Roche friabilator. The percentage weight loss ranges from 0.1 %, 0.3%, 0.1%, 0.2%, 0.1% for

the batches F1, F2, F3, F4, F5, respectively. Each value represents mean value of three determinations.

**4.9.12 Weight variation analysis:** The percentage weight variation for the formulated famotidine floating tablets were found to be within the limit (within the range of  $\pm 7.5\%$ ).

#### 4.9.13 In vitro buoyancy studies

**A. The floating lag time:** The floating lag time for the formulated famotidine floating tablets F1, F2, F3, F4, F5 were found to be 17sec, 6sec, <1sec, 2sec, 10sec respectively.

**B. Total floating time:** Total floating time for the formulated famotidine floating time F1, F2, F3, F4, F5 were found to be >24hrs, >30mins, >24hrs, >24hrs, >24hrs, respectively.

**4.9.14 Swelling Index:** Swelling Index of the formulated famotidine floating tablets at the end of the 60 minutes were found to be 30.0%, 39.9%, 38.9%, 37.9%, 34.4% for F1, F2, F3, F4, F5 for respectively.

#### 4.9.15 In vitro drug release study

The percentage drug release at the end of the 10 hours for the formulated famotidine floating tablets F1, F2, F3, F4, F5 found to be 88.6%, 96.3%, 95.6%, 95.2% , 92.3% respectively.

## 5. CONCLUSION

The study successfully developed and evaluated floating gastro-retentive tablets of famotidine using combinations of HPMC E50 and Carbopol 930. Pre-compression and post-compression parameters were within acceptable limits, indicating good flow properties and mechanical strength. FTIR studies established compatibility between famotidine and excipients. Among all formulations, F2, F3, and F4 demonstrated efficient floating behavior, appropriate swelling, and prolonged drug release up to 10 hours. Formulation F2 exhibited the highest drug release (96.3%), making it the most promising among the tested batches. Overall, the formulated floating tablets significantly enhanced gastric residence time and provided sustained release of famotidine, offering potential benefits for improved patient compliance and therapeutic efficacy in treating acid-related disorders.

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