Section A-Research paper



# ASSESSING THE EFFICACY OF VARIOUS POLYMERS IN THE FORMULATION OF EFFERVESCENT FLOATING TABLETS FOR ENHANCING THE RELEASE OF DICLOFENAC SODIUM IN THE GASTROINTESTINAL TRACT

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# Abstract

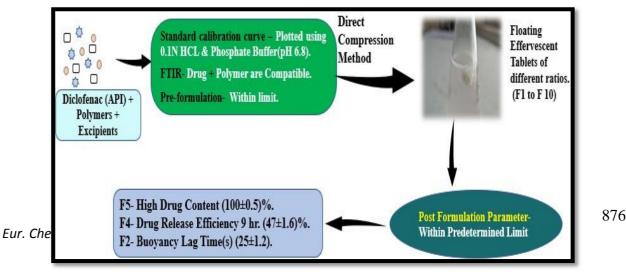
**Objective-** This research intends to construct and evaluate novel Diclofenac sodium gastroretentive effervescent floating tablets.

**Method-** The basis for the floating tablets was the effervescent method, which utilized Citric acid and bicarbonate sodium as a source for the gas. A direct compression system is used to develop the tablets with effervescence. The polymers and drugs applied to the formulation underwent FTIR research. Drug release profile and floatation behaviour have been investigated for several polymers including HPMC K100 LV, Chitosan, Guar gum, Xanthan gum, and Carbopol 934P. A standard calibration curve was plotted using Diclofenac sodium with HCL (0.1N) and phosphate buffer (pH 6.8). After formulation, the tablets were subjected to postformulation investigations, which evaluated their organoleptic properties, drug content, hardness, thickness, weight variation, and friability. Pre-formulation analyses were performed, including solubility, tapped density, Hausner ratio, bulk density, compressibility index, and repose angle.

**Result** Based on the FTIR observations, it was feasible to conclude that the polymers and drug utilized in the formulation are compatible. All the formulations met predetermined limits for thickness, friability, drug content, diameter, hardness, drug buoyancy, weight variation, and drug release. Formulation F5 had the highest percentage of drug content ( $100 \pm 0.3$ ) compared to other formulations. The optimized formulation, F4, exhibited the maximum dissolving efficiency of up to 9 hours ( $47 \pm 1.6$ ) in contrast with the remaining formulations. The buoyancy lag time for Formulation F2 was  $25 \pm 1.2$  seconds.

**Conclusion-** An effervescent floating drug delivery method was formulated with Diclofenac sodium to improve bioavailability and extend therapeutic effectiveness. Various polymer-based formulations demonstrated that increasing the polymer ratio significantly delayed drug release.

**Keywords:** Floating drug delivery system, HPMC K100LV, Chitosan, Diclofenac sodium, Carbopol 34 P.



# Graphical Abstract-

## **1. INTRODUCTION**

Despite their significant limitations, oral dosage forms are still the recommended method of medication administration. Effervescent tablets can serve as an alternative dosage form to provide a lengthened and anticipated drug delivery profile in the gastrointestinal tract (GIT). A new therapeutic option can be created by using gastro-retentive dosage forms to control the duration of stomach residence. When a floating effervescent tablet comes into contact with stomach juice, it produces effervescent CO<sub>2</sub> gas. To regulate drug release and prolong drug retention duration compared to traditional pharmaceuticals, floating drug delivery systems, also known as gastro-retentive drug delivery systems, use various polymeric materials. [1-4]

Diclofenac Sod., a kind of non-steroidal anti-inflammatory drug (NSAID) is utilized to alleviate inflammation. Although it is swiftly consumed after oral ingestion, the gastrointestinal tract inadequately absorbs it. This drug quickly dissolves in a basic pH (5 to 8), but is insoluble in water or acidic pH (1 to 3). Because its duration is just 1-2 hours, multiple dosages are often required to attain therapeutic drug plasma levels. Long-term use of diclofenac can result in gastrointestinal problems, peptic ulcers, and gastrointestinal bleeding. Therefore, extensive research is underway to explore novel drug delivery methods that can achieve an ideal dosing schedule while maintaining the therapeutic effectiveness of the treatment. According to a study, gastro-retentive floating systems provide more consistent drug absorption over an extended period and reduce the chance of local irritation, compared to single-unit dose forms. [1]

The target of this research is to improve the bioavailability of Diclofenac sodium, which has low absorption in the gastrointestinal tract. This will be achieved by developing a floating tablet form that will increase gastro-retention time for absorption and enhance drug bioavailability. The impact of polymers such as HPMC K 100 LV, Carbopol 934 P, Guar gum, Xanthan gum, and chitosan on the floating and effervescent properties will be evaluated.

#### 2. MATERIALS & METHODS

#### **Drugs and Polymers**

Diclofenac Sod., as gift sample was obtained by IOLCP, Barnala, PB. All the chemical includes Guar Gum, Xanthan Gum, HPMC K100 LV, Carbapol 934 P, Chitosan, NaHC0<sub>3</sub>, PVP, Magnesium Stearate, Citric acid, Talc were obtained from Hi media.

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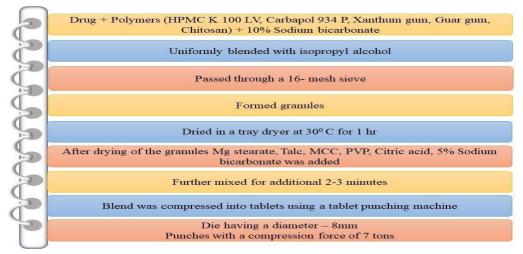
### **Formulation of Diclofenac Sod. Effervescent Floating Tablets**

Utilizing various polymers in varied ratios, all of the formulations were accomplished by utilizing the direct compression method (designated as F-1 to F-10).

Inguadianta	Composition (mg)									
Ingredients	F1	F2	F3	F4	F5	F6	<b>F</b> 7	F8	F9	F10
Diclofenac Sodium	150	150	150	150	150	150	150	150	150	150
HPMC K 100 LV	70	85	_	_	_	_	_	_	20	20
Carbapol 934 P	_	_	65	90	_	_	_	_	_	_
Xanthan Gum	_	_	_	_	40	44	_	_	_	_
Guar Gum	_	_	_	_	_	_	50	54	_	_
Chitosan	_	_	_	_	_	_	_	_	50	60
PVP	10.5	10.5	10.5	10.5	10.5	10.5	10.5	10.5	10.5	10.5
Sodium Bicarbonate	50	50	50	50	50	50	50	50	50	50
Magnesium Stearate	3	3	3	3	3	3	3	3	3	3
Talc	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Citric Acid	9	9	9	9	9	9	9	9	9	9
MCC	55	40	60	35	85	81	75	71	55	45
Total Wt.	350	350	350	350	350	350	350	350	350	350

# Table 1: Diclofenac Sod. Effervescent Buoyant Tablet Formulations

#### Formation of effervescent floating tablet



# Fig. 1: Direct compression method

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# **Evaluation Parameter**

## **Pre-Formulation Evaluation**

## Development of calibration curve (standard plot) for Diclofenac Sod.:

#### a) Formation of HCL (0.1 N)

8.5 millilitre of potent chlorohydric acid was thinned with purified aqua also amount was augmented to 1 L with purified aqua.

### Formation of Calibration curve of Diclofenac with HCl (0.1N)

A precise quantity of 0.1 gram of Diclofenac sod. was weighed and blended in a small amount of HCl (0.1N) in a 0.1 L container. The volume was then made up to 0.1 L using a measuring cylinder, resulting in a mother liquor with a conc. of 1mg/ml. From this mother liquor, 0.01 L was pipetted out and pass on to a 0.1 L graduated vessel as well as vol. was accommodated to 0.1 L with 0.1 N chlorohydric acid to acquire a soln with a conc. of 100  $\mu$ g/ml. A precise quantity of 0.1 gram of Diclofenac sod. was weighed along with blended in a slight amount of HCl (0.1N) in a 0.1 Litre container. The volume was then made up to 0.1 litres using a measuring cylinder, resulting in a stock solution with a conc. of 1 mg/ml. From this mother liquor, 0.01 litre was pipetted out further conveyed to a 0.1 litre graduated vessel also the vol. was adjusted to 0.1 litre with HCl (0.1 N) to acquire a soln with a conc. of 0.1 mg/ml. [2]

#### b) Preparation of PBS (pH 6.8)

In order to make PBS (pH-6.8),  $KH_2PO_4$  (11.45 g) as well as  $Na_2HPO_4$  (28.8 g) were blended in aqua as well as the amount was adjusted to 1 litre. [3]

#### Preparation of standard calibration curve for Diclofenac sod. in PBS (pH-6.8)

To prepare a conc. soln of diclofenac sod., 100mg of the medicine was mixed into 100 ml of PBS with a pH of 6.8, resulting in a concentration of 1 mg/ml. From this solution, dilutions were made to obtain conc. of 0, 5, 10, 15, and 20  $\mu$ g/ml. To determine the peak wavelength of the drug, one of the dilutions was examined at 276 nm wavelength by utilizing a UV/Vis spectrometer. [4]

**FTIR analysis:** Drug and polymer samples were prepared on KBr disks and subjected to screening over a frequency range of 4000 to 400 cm<sup>-1</sup>. The spectra were analysed to identify potential interactions between the drug and polymer and characterize functional groups. [2]

### **Solubility Analysis**

To formulate highly concentrated. soln of Diclofenac sod. in water, HCl (0.1N), PBS with pH 6.4, PBS with (pH-6.8), and PBS with (pH-7.2), each mixture should be set aside for 24 hours and then filtered. The filtered liquid should be collected, and its absorbance at 221 nm should be measured. The solubility of the compound could be determined utilizing the following equation. [5]

Solubility = 
$$\frac{A_t}{A_s} \times C_s \times (\frac{D_t}{W_d} \times 1000) \times 100$$

Where,  $A_t$  = Test absorbance.  $A_s$  = Std absorbance.  $C_s$  = Std conc. of drug.  $D_t$  = Dilution factor.  $W_d$  = Wt. of medicine

# Angle of repose

The top point of view that a fixed hill can achieve due to factors such as friction, cohesion, and the shape of molecules. It states that the inherent angle formed in the middle of the surface of a pile along with the ground plane, and it is similar to the material's wt., coefficient of friction, surface area.

# Method

To calculate the angle of slope, the funnel method was utilised. The funnel's stature was adjusted so the channel's spout exactly grazes the mound of blended components. The precisely weighed mix. was permitted to stream unreservedly via the funnel above the plane. The height as well as length of the powdery cone were calculated plus angle of slope was calculated

utilizing the equation below. [2],[6]

$$\Theta = \tan - 1 \frac{h}{r}$$

Where,

h (ht. of heap), r (radius of heap),  $\Theta$  (angle of repose).

# **Volumetric Density**

Volumetric density refers to the proportion of the wt. of a powder to its bulk volume. The volumetric density is typically influenced through the particle's shape, with more spherical particles resulting in higher bulk density. Furthermore, the bulk density decreases as the granules increase in size.

# Method

The effective powder constituent (API) was weighed out along with put into a 0.1 litre graduated flask without any tapping. The API was ascertained in volume. The equation for determining bulk density was employed. [2],[6]

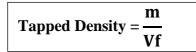
Volumetric Density or Bulk Density = Bulk Mass Bulk Volume

# **Tapped density**

Tapped density of a powder sample can be determined by tapping a graduated cylinder holding the sample. The early volume is measured as well as the cylinder is gently tapped while observing the volume until tiniest further volume changes occur. Mechanical tapping can also be accomplished by lifting the cylinder as well as permit it to let fall a specific space based on its weight. Using a gadget that revolve the cylinder during tapping may be favoured to keep down any potential particle breakage.

### Method

To determine the tapped bulk density of a powder, the graduate cylinder containing the powder sample is struck 500 times initially, unless otherwise specified as well as tapped volume Va is computed using the closest standard value. Then, further 750 taps are applied, totalling 1250 taps, and the  $2^{nd}$  tapped vol., Vb, is computed using the closest standard value. When every contrast btw the 2 measurements is below 2%, Vb is considered the final tapped vol., Vf. If necessary, continue in sets of 1,250 taps until the contrast btw successive readings is <2%. Every tapped bulk density in grams per millilitre can be calculated using the formula. [2],[6]



Where,

M (initial wt. of material in gram), Vf (vol. of material after tapping).

#### **Compressibility Carr's index**

The compressibility Carr's index is an indicator of a powder's compressibility, serving as a measure of the strength of inter-particle associations. A freely-flowing powder typically has fewer inter-particle connections, resulting in similar tapped measurements. In contrast, less fluid powders usually have higher inter-particle contacts, resulting in a considerable contrast between bulk and tapped densities. The compressibility Carr's index is determined utilizing this formula, which represents these differences. [2],[6]

Compressibility Carr's index =  $\frac{\text{Tapped Density} - \text{Bulk Density}}{\text{Tapped Density}} \times 100$ 

#### Hausner's ratio

It states that the approaching signal of powder flow clarity. Formula employ to enumerate are

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### as follows. [2]

Hausner's ratio = 
$$\frac{t}{d}$$

Where,

't' is the tapped density

'd' is bulk density.

Lower H (1.25) indicates better flow properties than higher ones (>1.25).

# **Post- Formulation study**

### **General Character**

The prepared tablets were evaluated for their overall guise and scrutinizes were build regarding their design, hue, feel as well as scent. [7]

### Thickness

The thickness in milli meters was separately evaluated for pre-weighed tablets with the use of Vernier callipers. The regular thickness and standard deviation (should be maintained within  $\pm$  5% of a standard figure) were computed.[2],[4]

# Hardness

The firmness of every tablet was examined by employing ten randomly chosen tablets from every batch through a Monsanto tablet solidity evaluator. The result signals the solidity of the tablet in kg/cm<sup>2</sup>.[4],[8]

# Friability

The Roche friabilator was employed to conduct the frangible test. A total of twenty tabs were measured and positioned into the plastic chamber of the friabilator, which revolved at a rate of twenty-five revolutions /minute for 4 mins., falling the tablets from a height of six inches. Once 100 rotations were completed, every tab. were dusted, reweighed along with the % age of friability was computed. The percentage of friability was calculated by comparing the initial

and final weight and expressed as a percentage. The friability of the tablets should not exceed 1%. [4],[8]

The friability was calculated using the formula below:

$$\%$$
F =  $\frac{a-h}{a} \times 100$ 

Where,

a (initial wt. of tabs)

b (wt. after friability test).

# Weight variation

20 tablets were arbitrarily chosen from every assemblage of formulations then singly measured. The mean wt. was determined as well as compared to the personal weight. The proportion deviation was then computed and the outcome was checked versus IP standards. [4]

# **Drug content**

A precise amount of powder parallel to hundred milligram of diclofenac sod. was weighed along with added to 0.1 litre graduate flasks holding approximately 50 millilitre of buffer solution (pH 6.8). The tablets were then crushed, and the resulting mixture was analyzed for the quantity of diclofenac sodium using a UV/Vis spectrophotometer at 276 nm. [4]

#### **In-vitro dissolution**

Dissolution test (In- vitro) was conducted using a USP type I (Basket) apparatus rotating at a speed of 100 revolutions per minute. The dissolution receptacle was filled with 0.9 litters of HCl (0.1 N) as the dissolution medium and the tablet was added and kept at a temperature of  $37 \pm 0.5$ °C. Every fixed time period, 5 ml of the solution was withdrawn and replenished with fresh dissolution medium over a period of 9 hours. The samples were then analyzed using a UV spectrophotometer to measure their absorbance at 276 nm. [9]

# **Buoyancy studies (In-vitro)**

Diclofenac tablets were specifically prepared and introduced into a container with a volume of 0.1 litter, which was filled with HCl (0.1 N) as the dissolution medium. The Floating Lag Time (FLT), i.e., the time taken by the tablet to ascend to one-third of the surface of the dissolving solution, and the Total Floating Time (TFT), i.e., the duration for which the tablet floated on the surface of the dissolution medium, were both precisely determined. [9],[1]

# 3. RESULT

### **Evaluation Parameter**

### **Pre-Formulation Evaluation**

### **Development of calibration curve (standard plot) for Diclofenac Sod.**

a) Standard curve of Diclofenac sod with (0.1N) Chlorohydric acid (Table 2)

S. No.	Conc. (µg/ml)	Abs. $\pm$ S.D.
I.	2	0.07
II.	4	0.13
III.	6	0.22
IV.	8	0.3
v.	10	0.37
VI.	12	0.45

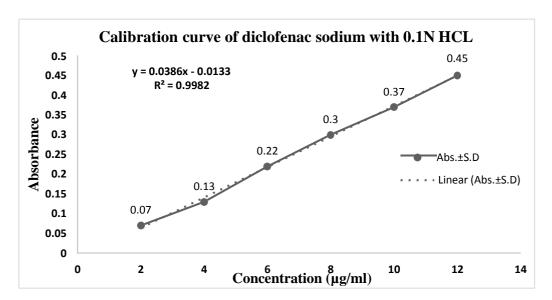


Fig. 2: Calibration curve of diclofenac sod with (0.1N) Chlorohydric acid

S. No.	Conc. (µg/ml)	Abs. ± S.D.
I.	0	0
II.	2	0.071
III.	4	0.122
IV.	6	0.177
V.	8	0.235
VI.	10	0.295

b) Calibration curve for Diclofenac sod. in PBS (pH-6.8) (Table. 3)

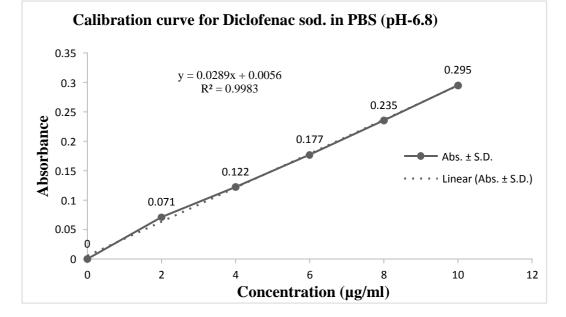


Fig. 3: Calibration curve for diclofenac sod in PBS (pH-6.8)

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## **FTIR** analysis

IR SPECTRUM OF PURE DICLOFENAC SOD.

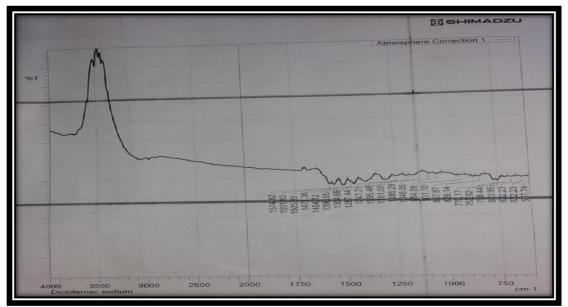


Fig. 4: IR spectrum of pure diclofenac sod.

IR SPECTRUM OF DICLOFENAC SOD. +XANTHAN GUM

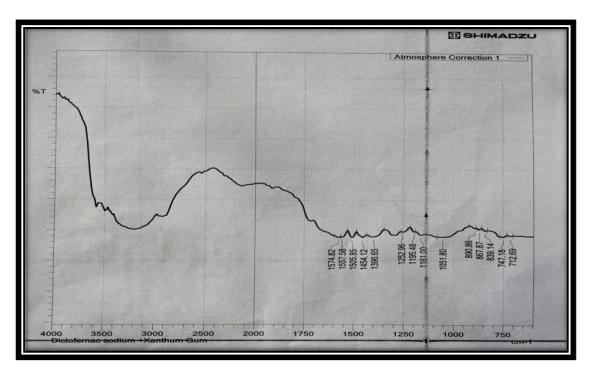
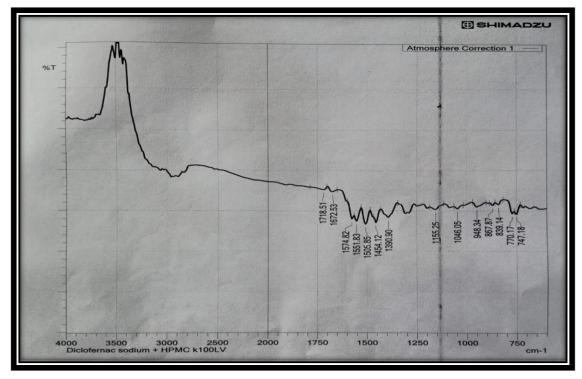


Fig. 5: IR spectrum of diclofenac sod. with xanthan gum

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# IR SPECTRUM OF DICLOFENAC SOD. + HPMC K100LV

Fig. 6: IR spectrum of diclofenac sod. with HPMC K100LV

IR SPECTRUM OF DICLOFENAC SOD. +CARBAPOL 934P

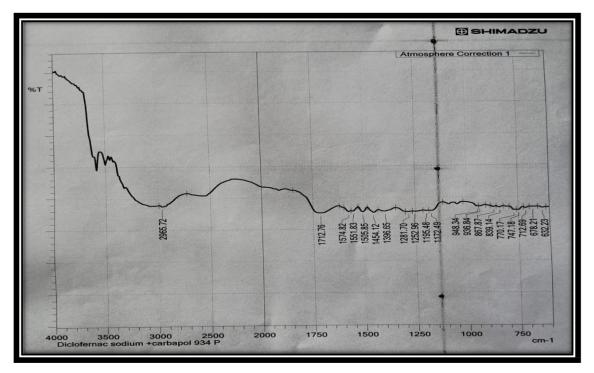
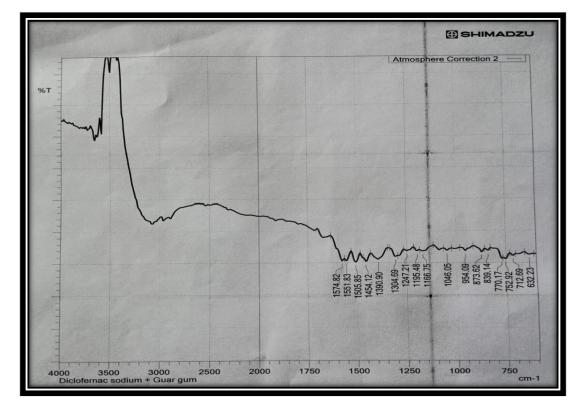


Fig. 7: IR spectrum of diclofenac sod. with carbapol 934 P

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# IR SPECTRUM OF DICLOFENAC SOD.+GUAR GUM

Fig. 8: IR spectrum of diclofenac sod. with guar gum

IR SPECTRUM OF DICLOFENAC SOD.+CHITOSAN

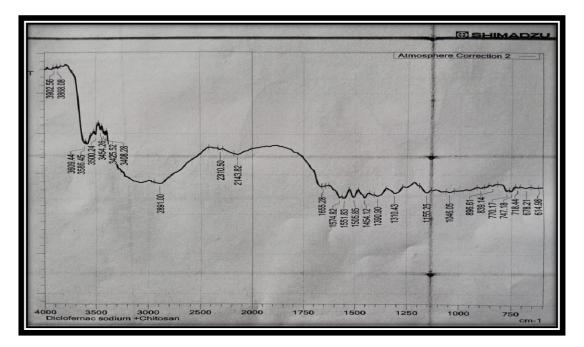
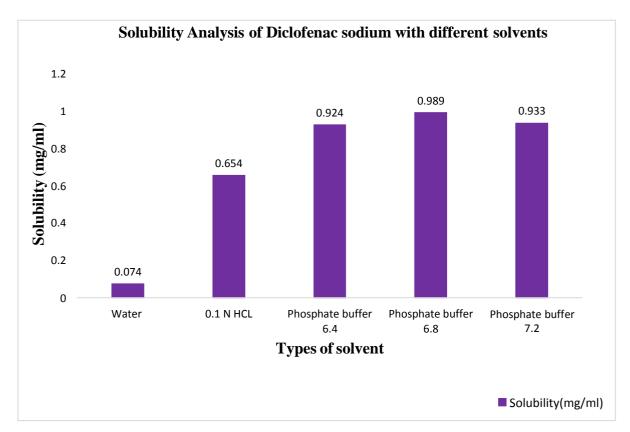


Fig. 9: IR spectrum of diclofenac sod. with chitosan

Types of solvents	Solubility (mg/ml)
Water	0.074
HCL (0.1 N)	0.654
PBS (pH-6.4)	0.924
PBS (pH-6.8)	0.989
PBS (pH-7.2)	0.933





# **Precompression evaluation**

The findings of the precompression assessment parameters, for example, angle of slope, tapped density, bulk density, Compressibility carr's index, and hausner's ratio, are displayed in the Table no. 5. All of the pre-compression assessment parameters were inside the Pharmacopoeia limits.

Formulation	Angle of	Tapped	Bulk	Compressibility	Hausner's
No.	Repose	Density	Density	Carr's Index	Ratio
F1	24.43±0.90	0.62±0.2	0.53±0.1	14.51±0.09	1.16±0.040
F2	24.86±0.60	0.58±0.4	0.49±0.3	15.51±0.63	1.18±0.009
F3	25.60±0.02	0.62±0.1	0.51±0.2	17.74±0.3	1.21±0.063
F4	25.12±0.03	0.53±0.7	0.49±0.1	16.98±0.04	1.20±0.001
F5	21.39±0.47	0.83±0.5	0.74±0.3	10.84±0.06	1.12±0.005
F6	21.04±0.50	0.82±0.1	0.73±0.1	10.97±0.05	1.12±0.003
<b>F</b> 7	22.63±0.41	0.56±0.2	0.49±0.1	12.5±0.2	1.14±0.030
F8	22.95±0.32	0.58±0.1	0.50±0.2	13.79±0.1	1.16±0.060
F9	25.24±0.17	0.39±0.4	0.33±0.4	15.38±0.07	1.18±0.050
F10	24.32±0.15	0.40±0.1	0.32±0.6	20±0.1	1.25±0.010

 Table 5. Precompression evaluation parameters of diclofenac sodium

# Post formulation study

# **General Appearance (Table 6)**

S. No.	Parameter	Appearance
1	Shape	Round-flat
2	Colour	White to off-white
3	Texture	Smooth



Fig. 11: Compressed Diclofenac Floating Tablets

# **Post-compression evaluation**

The results of Hardness, Friability, Thickness, Wt. variation, Drug content are manifested in table given below.

Formulation	Drug Content	Friability	Hardness	Thickness	Wt. Variation
No.	(%)	(%)	(Kg/cm3)		
F1	99.5±0.8	0.42±0.04	6.5±0.8	4.36±0.08	348.94±1.1
F2	99.3±0.6	0.51±0.31	6.7±0.3	4.25±0.07	349.23±0.75
F3	98.3±0.8	0.65±0.01	5.2±0.6	3.01±0.02	349.10±0.3
F4	98.6±0.6	0.87±0.03	5.5±0.4	2.97±0.06	349.28±0.5
F5	101±0.3	0.34±0.02	5.5±1.2	4.21±0.03	349.26±0.2
Fő	100±0.04	0.40±0.08	5.6±1.10	4.29±0.06	349.56±0.7
<b>F</b> 7	98.68±0.08	0.04±0.09	6.27±0.6	4.38±0.07	348.97±0.1
F8	99.32±0.06	0.03±0.07	7.85±0.1	4.32±0.08	349.85±0.2
F9	99.79±0.3	0.65±0.44	8±0.4	4.20±0.02	347.90±0.4
F10	99.54±0.9	0.71±0.02	6.4±0.2	4.33±0.04	349.71±0.1

## Table 7. Post-compression Evaluation of Diclofenac Sodium Floating Tablets

# In-vitro dissolution

# Table 8. In-vitro Dissolution of Diclofenac Sod. Floating tablets

Formulation No.	Drug release at 3h (%)	Drug release at 6h (%)	Drug release at 9h (%)
F1	25±1.1	49±2.1	71±1.0
F2	19±12	42±2.4	67±1.3
F3	14±1.3	30±2.0	59±1.5
F4	11±1.6	23±1.2	47±1.6
F5	31.6±0.8	45±0.2	61.9±0.1
F6	35.9±0.2	47.9±0.9	64.5±0.7
<b>F</b> 7	38.6±0.8	48.1±0.2	62.9±0.4
F8	39.5±0.2	51.3±0.8	63.5±0.9
F9	54.9±0.2	66.4±0.1	81.1±0.9
F10	62.5±0.2	69.9±0.5	85.4±0.4

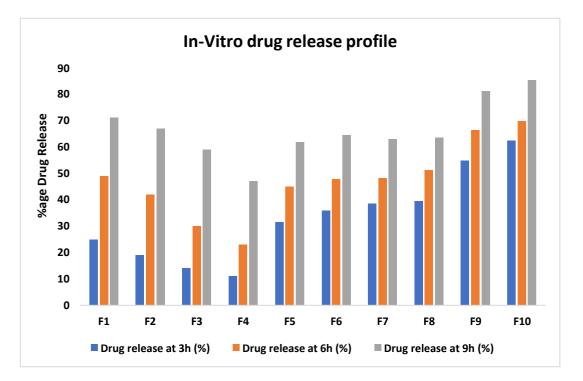


Fig. 12: In-vitro drug release profile of Diclofenac Sod. Floating Tabs

**Buoyancy investigation (In-vitro)** 

Table 9. In-vitro	Buovancy	investigation	of Diclofenac	Sod. Floating Tablets
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Formulation No.	Buoyancy Lag Time (s)	Total buoyancy time (h)
F1	31 ± 0.7	<24
F2	25 ± 1.2	<24
F3	110 ± 0.9	24
F4	136 ± 1.7	>24
F5	$177 \pm 0.3$	>12
F6	$173 \pm 0.1$	>12
<b>F</b> 7	$153 \pm 0.8$	>12
F8	$149 \pm 0.5$	>12
F9	95 ± 1.8	>12
F10	$103 \pm 0.7$	>12



Fig. 13: Buoyancy studies (In-vitro) on Diclofenac Floating Tablets

# 4. DISCUSSION

The duration of gastric retention can be extended by utilizing floating drug delivery devices that are formulated with a lower density than the stomach fluid. By virtue of this feature, the delivery system can remain afloat on the surface of the stomach's contents for an extended duration without altering the rate at which the stomach empties. The tablets were manufactured using effervescent technology and a direct compression method, with sodium bicarbonate utilized as a gas-generating agent. The study investigated the physical compatibility between the drug and the polymer. Additionally, a standard graph of diclofenac sod. in chlorohydric acid (0.1N) and PBS, pH 6.8 was created, with slopes of y = 0.0386x - 0.0133 and y = 0.0289x+ 0.0056, respectively. The regression coefficients were  $R^2 = 0.9982$  for 0.1 N HCL and  $R^2 =$ 0.9983 for Phosphate Buffer (pH 6.8). A buoyant tablet of diclofenac sod. was prepared using direct compression, including artificial polymer. Diclofenac shows greater solubility of 0.989 mg/ml in PBS (pH 6.8). The tablets of various formulations (F1 - F10) were evaluated for the parameters mentioned earlier. FTIR assessment shows the compatibility between diclofenac sodium and various polymer used in this study. Pre-compression data reveals F3 shows 25.60  $\pm$  0.002 angle of repose which is highest among all other formulation. While F5 have high tapped density  $0.83 \pm 0.5$  & bulk density  $0.74 \pm 0.3$ . Carr's index & Hausner ratio with value  $20 \pm 0.1$  &  $1.25 \pm 0.010$  is greater in F10 as compared to other prepared formulations. Postcompression study of different formulation involves F5 formulation have higher drug content  $101 \pm 0.3$  & F3 found to have lower drug content  $98.3 \pm 0.8$  with respect to other formulation.

F4 reveals greater friability of  $0.7 \pm 0.03$ , F9 have higher hardness with  $8 \pm 0.4$  value, F7 gives value for higher thickness  $4.38 \pm 0.07$  & weight variation is more in F8 with  $349.85 \pm 0.2$  when compared to other formulated tablets. Drug release profile at 9h of F10 is higher  $85.4 \pm 0.4$  & is lower for F4 47  $\pm$  1.6 then other prepared formulation. F5 have delay in floating lag time of  $177 \pm 0.3$  with total floating time >12 h, while F2 reveals floating lag time of  $25 \pm 1.2$  with total floating time of <24 h. The ideal floating effervescent preparation criteria were met by the manufactured formulations F4 and F2, whereas all parameters did not satisfy the criteria for the other formulations.

### **5. CONCLUSION**

A direct compression process was used to manufacture Diclofenac sodium effervescent floating tablets with different polymers at varying concentrations. Systematic studies were conducted to evaluate the generated systems for various characteristics. FTIR studies showed no interaction. The developed tablets demonstrated acceptable outcomes for multiple criteria, including solubility, Hausner ratio, Carr's index, bulk density, tapped density, tablet hardness, friability, weight variation, thickness, and angle of repose. The tablets were also acceptable in terms of chipping, capping, and sticking. Tablets containing sodium bicarbonate with a hardness of  $6.5\pm0.8 - 8\pm0.4$  (Kg/cm2) exhibited favourable results for floating lag time (FLT), total floating time (TFT), and sustained drug release profile. Ten formulations with different concentrations of HPMC K100 LV, Chitosan, Guar gum, Xanthan gum, MCC, and Carbopol 934P were prepared. The best formulation, F4, exhibited a sustained drug release profile with a floating lag time of  $136 \pm 1.7$  seconds and a total floating duration of over 24 hours, while releasing  $47 \pm 1.6$  percent of the drug over a 9-hour period. The F2 formulation exhibited fine floatation properties with a floating delay period of  $25 \pm 1.2$  seconds.

#### **CONFLICTS OF INTERESTS**

The authors declares that there are no conflicts of interest.

#### **AUTHORS CONTRIBUTION**

Simran Chuadhary: Collect data, writing manuscript Shad Ahmad: Writing manuscript- equal Swheta : Method and Material Palak and Jyoti: Performed the research Nirpendra Singh: Conceptual and reviewing the manuscript

Shiv Kumar Kushawaha: Superwise and reveiwing the manuscript

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## 6. REFERENCES

- Devi, C.M., et al., 2019. Formulation and evaluation of gastroretentive floating tablets of diclofenac sodium based on effervescent technology. Int J Pharm Biol Sci, 9: p. 249-55.
- Kyavars, E.S., 2020. Formulation and Evaluation of Floating Tablets of Ranitidine Hydrochloride. indo American Journal of Pharmaceutical Sciences, 07 (07): p. 811-822.
- 3. Sultana, T., et al., 2017. In vitro dissolution study and assay of diclofenac sodium from marketed solid dosage form in Bangladesh. J Bioanal Biomed, 9(1): p. 118-122.
- Tapan K. G., et al., 2012. In vitro evaluation of commercially available enteric coated tablet containing diclofenac sodium. International Journal of Research in Pharmaceutical & Biomedical Sciences, Vol. 3 (2): p. 875-881.
- Anjali, M.S., 2021. Formulation and Evaluation of Diclofenac Sodium Fast Disintegrating Tablets Using Natural Polymer Tangerine Peels. International Journal of Pharmaceutical Research and Applications, 6(4 July-Aug 2021): p. pp: 635-643.
- 6. Ganesh, G., et al., 2010. Preparation and evaluation of sustained release matrix tablet of diclofenac sodium using natural polymer. Journal of pharmaceutical sciences and research, 2(6): p. 360.
- Eswer, G. and M. Saritha, 2011. Formulation and evaluation of atenolol floating tablets using different polymers: guargum, sodium alginate, Hpmc100cps and Carbopol940. International Journal of Pharmaceutical & Biological Archives, 2(4): p. 1148.
- Swain, R. and S. Pendela, 2016. Formulation and evaluation of gastro-bilayer floating tablets of simvastatin as immediate release layer and atenolol as sustained release layer. Indian Journal of pharmaceutical sciences, 78(4): p. 458-468.
- Nanjwade, B.K., et al., 2012. Development and evaluation of gastroretentive floating tablets of glipizide based on effervescent technology. J Drug Metab Toxicol, 3(3): p. 1-5.