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Design and Evaluation of Ondansetron Hydrochloric Floating Tablets

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ABSTRACT: Ondansetron HCl functions as a competitive antagonist of serotonin type 3 receptors. It is utilized effectively in managing nausea and vomiting induced by cytotoxic chemotherapy agents, such as cisplatin, and has been noted for its anxiolytic and neuroleptic effects. Gastroretentive dosage forms are specifically engineered to remain in the gastric region for extended periods, thereby significantly enhancing the gastric residence time of medications. This prolonged retention in the stomach improves bioavailability, minimizes drug wastage, and enhances the solubility of compounds that exhibit lower solubility in high pH conditions. Gastroretention facilitates improved availability of innovative products, offering new therapeutic options and considerable advantages for patients. Floating tablets of Ondansetron HCl were developed and assessed using various evaluation criteria. The results from in vitro release studies were plotted as cumulative percentage release against time. These findings suggested that the release rate was constrained by the dissolution rate of the drug particles and the erosion of the polymer matrix. The in vitro drug release profiles for each tablet batch (F1 to F6) were conducted, revealing that batches F1, F2, and F3 released approximately 90% of the drug after 24 hours.

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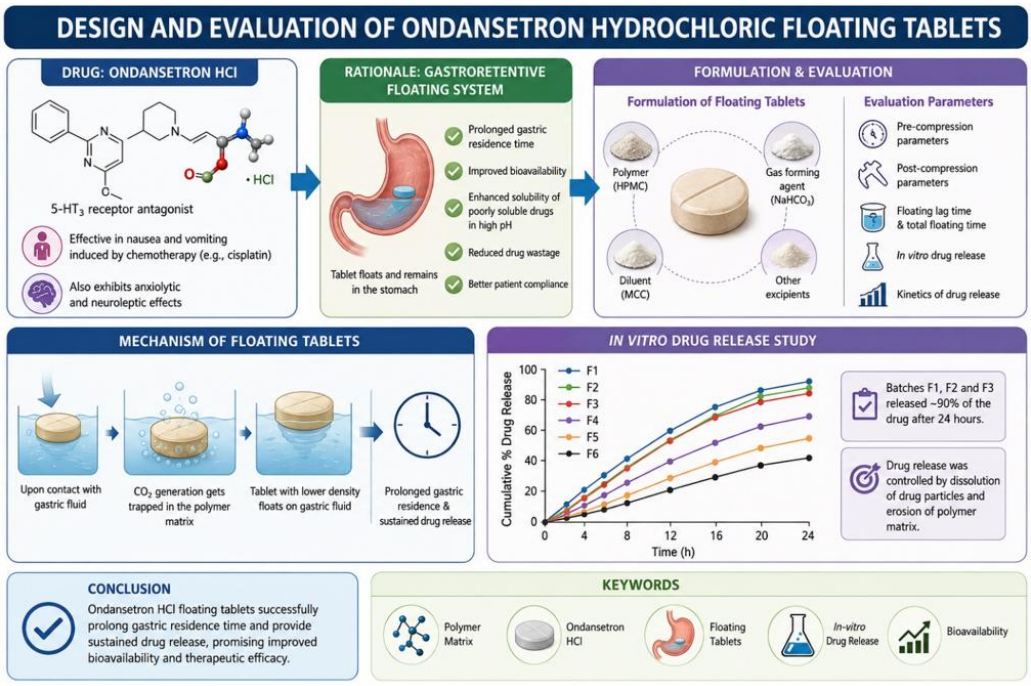
GRAPHICAL ABSTRACT



1. INTRODUCTION

Gastric emptying of dosage forms is an extremely complex process and ability to prolong and control the gastric emptying time is a valuable asset for dosage forms, which reside in the stomach for a longer period of time than conventional dosage forms. Several difficulties are faced in designing controlled release systems for better absorption and enhanced bioavailability. One of such difficulties is the inability to confine the dosage form in the desired area of the gastrointestinal tract. Prolonging gastric retention of the dosage form extends the time for drug absorption therefore improves bioavailability, reduces drug waste, and improves solubility for drugs that are less soluble in a high pH environment. Gastro retentive systems can remain in the gastric region for several hours and hence significantly prolong the gastric residence time of drugs. The controlled gastric retention of solid dosage forms may be achieved by the mechanisms of muco adhesion, flotation, sedimentation, expansion, modified shape systems, or by the simultaneous administration of pharmacological agents that delay gastric emptying.

Floating Drug Delivery Systems (FDDS) represent a promising strategy for enhancing gastric retention. Despite the challenges that must be addressed to ensure extended gastric retention, numerous companies are actively pursuing the commercialization of this technology. Various methodologies have been employed in the design of floating dosage forms, encompassing both single and multiple-unit systems. Floating drug delivery systems can be categorized based on formulation variables into effervescent and non-effervescent systems. Plasma concentration-time profiles indicate that sustained-release floating capsules provide a longer duration of action (16 hours) compared to conventional MICARD capsules, which last for 8 hours. These systems are particularly beneficial for medications that are predominantly absorbed in the stomach or the proximal small intestine, such as Riboflavin and Furosemide. Notably, Furosemide is mainly absorbed in the stomach, followed by absorption in the duodenum.[1-3]

2. FACTORS AFFECTING GASTRIC RETENTION: -

2.1. Density

The gastric retention time (GRT) is influenced by the buoyancy of the dosage form, which is in turn determined by its density.

2.2. Size

Dosage forms with a diameter exceeding 7.5 mm exhibit a greater GRT in comparison to those measuring 9.9 mm in diameter.

2.3. Shape of Dosage Form

Devices shaped like tetrahedrons and rings, possessing flexural moduli of 48 and 22.5 kilopounds per square inch (KSI) respectively, demonstrate superior GRT, achieving approximately 90% to 100% retention over a 24-hour period when compared to other configurations.

2.4. Single or Multiple Unit Formulation

Multiple unit formulations provide a more consistent release profile and are less affected by the failure of individual units. They facilitate the co-administration of units with varying release characteristics or incompatible components, thereby offering a greater safety margin against dosage form failure than single unit formulations.

2.5. Fed or Unfed State

In a fasting state, gastrointestinal motility is marked by intervals of vigorous motor activity known as the migrating myoelectric complex (MMC), occurring every 1.5 to 2 hours. This complex clears undigested contents from the stomach, and if the formulation is administered during an MMC, the GRT is likely to be significantly reduced. Conversely, in a fed state, the MMC is postponed, resulting in a notably extended GRT.

2.6. Nature of Meal

The introduction of indigestible polymers or fatty acid salts can alter the stomach's motility pattern to that of a fed state, thereby reducing the gastric emptying rate and extending the duration of drug release.

2.7. Caloric Content

A meal rich in proteins and fats can prolong GRT by four to ten hours.

2.8. Frequency of Feed

The GRT may increase by over 400 minutes when multiple meals are consumed in succession, as opposed to a single meal, due to the reduced frequency of the MMC.

2.9. Gender

The average ambulatory GRT for males (3.4±0.6 hours) is shorter than that of their female counterparts of the same age and race (4.6±1.2 hours), irrespective of weight, height, and body surface area.

2.10. Age

Individuals in the elderly demographic, particularly those aged 70 and above, exhibit a notably prolonged gastric residence time (GRT).

2.11. Posture

The GRT may differ when comparing the supine position to that of an upright ambulatory state in patients.

2.12. Concomitant Drug Administration

The use of anticholinergics such as atropine and propantheline, opioids like codeine, and prokinetic agents including metoclopramide and cisapride can influence GRT.

2.13. Biological Factors

Conditions such as diabetes and Crohn's disease, among others, play a role. Recently, numerous medications have been developed as floating drug delivery systems aimed at achieving sustained and controlled release by confining the drug's release to the stomach. Intensive research in recent years has led to advancements in floating drug delivery systems. The current study aimed to formulate and assess floating tablets of Ondansetron hydrochloride to enhance the drug's sustained action efficacy. There remains a persistent demand for the creation of controlled release formulations that facilitate the concurrent delivery of drugs like Ondansetron hydrochloride, utilizing technology that is cost-effective, reproducible, and straightforward to manufacture and scale up within an industrial setting with minimal infrastructure requirements. [4-5]

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3. MATERIAL AND METHODS

Table 1: List of Chemicals.

Sr. No.	Materials	Company Name
01	Ondansetron HCl	Ranbaxy Lab Ltd (Dewas)
02	Methanol	Merck (Mumbai)
03	Acetone	SDFCL (Mumbai)
04	HCl	SDFCL (Mumbai)
05	Chloroform	SDFCL (Mumbai)
06	Ethanol	Jigansu Huaxi Int. Ltd
07	Potassium di hydrogen phosphate	Sunchem (Satna)
08	Di sodium hydrogen phosphate	Merck (Mumbai)
09	Citric Acid	Merck (Mumbai)
10	Ammonia Solution	Merck (Mumbai)
11	Ammonium Chloride	Merck (Mumbai)
12	HPMC K4 M	SDFCL (Mumbai)
13	HPMC K100M	SDFCL (Mumbai)
14	Carbopol	CDH
15	Magnesium Stearate	SDFCL(Mumbai)
16	Talc	CDH
17	Starch	SDFCL(Mumbai)
18	Sodium bi carbonate	CDH
19	Micro crystalline cellulose	SDFCL(Mumbai)
20	NaOH	SDFCL (Mumbai)

4. FORMULATION OF FLOATING TABLETS OF ONDANSETRON HYDROCHLORIDE

4.1. Granules Preparation

4.1.1. Dry granulation

Dry granulation involves the precise crushing of precompacted powders that have been densified through the slugging process. All components are accurately measured. The active pharmaceutical ingredient (API), polymers, and lactose are sifted using a 40-mesh sieve. Sodium bicarbonate, magnesium stearate, and talc are individually passed through an 18-mesh sieve. The two mixtures are then combined in a polybag and blended for approximately six minutes. Slugs are formed using flat punches in a compression machine, ensuring they are compressed to a minimum hardness.

4.1.2. Fabrication of tablet for *In-vitro* studies

For research purposes, six formulations incorporating various excipients were developed, as detailed in Table 4.3. The mixture was subjected to sieving to ensure particle uniformity, after which any remaining particles were triturated and blended once more. Floating tablets were produced utilizing the wet compression method. The tablets were compressed using a 10 mm die

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and punch set in a manually operated tablet compression machine (Lab Tech. instruments). [6-9]

Table 2: Formulation of Ondansetron HCl floating tablets.

Ingredients (mg)	F1	F2	F3	F4	F5	F6
Ondansetron HCl	24	24	24	24	24	24
HPMC E15M	100	-	-	50	-	50
HPMC K100M	-	100	-	50	50	-
Carbopol	-	-	100	-	50	50
Sodium Bicarbonate	60	60	60	60	60	60
Micro Crystalline Cellulose	14	14	14	14	14	14
Magnesium Stearate	2	2	2	2	2	2
Talc	4	4	4	4	4	4
Starch	2	2	2	2	2	2
Citric acid	2	2	2	2	2	2

5. RESULTS AND DISCUSSION

The floating tablets that were prepared were assessed according to pharmacopeial standards, and additional parameters that necessitate special attention or modification are also addressed in this discussion.

5.1. General Appearances

White, biconvex tablet with beveled edges having around 11mm diameter. [10]

5.2. Weight variation Test

In order to examine weight variation, a random selection of 20 tablets from each formulation was gathered during the compression process. These tablets were then weighed using an electronic balance to determine the average weight of each tablet. Additionally, the weight of each individual tablet was recorded.

Limit: Weight of all individual tablets should be in the limit of average wt ±5%. [11, 12]

5.3. Crushing Strength

A notable challenge in achieving substantial strength in floating tablets lies in its impact on the floating lag time. Typically, the strength of floating tablets is maintained within a lower range to minimize lag time and enhance the release of the effervescent system. The hardness of the tablet was assessed using standard hardness testing equipment.[13]

5.4. Friability

The Tablet Friability test was conducted utilizing the apparatus from Scientific. A total of ten tablets were weighed and subsequently rotated at a speed of 25 revolutions per minute for a duration of four minutes. Following this process, the tablets were reweighed after the fines were removed using a no. 60 mesh screen, and the percentage of weight loss was determined using the specified formula.[14, 15]

$$\% \textbf{ Friability} = \frac{\textbf{Wt. of 20 tablet before rotation} - \textbf{Wt. of 20 tablets after rotation}}{\textbf{Wt. of 20 tablets before rotation}} \times \mathbf{100}$$

5.5. Content uniformity test

Each of the five tablets was weighed separately and subsequently ground into a powder. The amount of powder corresponding

to the average weight of the tablets was measured, and the drug was extracted using 0.1 N hydrochloric acid. Any undissolved residue was removed through filtration. The resulting filtrate was then analyzed using a UV spectrometer at a wavelength of 310 nm following appropriate dilution. The absorbance value obtained was applied to the previously established standard curve equation for ondansetron hydrochloride.[16]

5.6. Thickness Diameter

The thickness of the tablets was measured utilizing Vernier calipers. A random selection of five tablets was made, and the thickness of each tablet was assessed by placing it between the lower jaws of the calipers. The average thickness was then calculated, and the data was documented.[16]

5.7. *In-vitro* buoyancy studies

The in-vitro buoyancy was assessed using the floating lag time method. Tablets were immersed in a 250 ml beaker filled with 0.1 N HCl. The duration required for the tablets to ascend to the surface and achieve buoyancy was recorded as the floating lag time. Measurements were taken for both the interval from the introduction of the dosage form to its buoyancy in 0.1 N HCl and the period during which the dosage form maintained its buoyancy. The time taken for the dosage form to reach the surface of the medium is referred to as Floating Lag Time (FLT) or Buoyancy Lag Time (BLT), while the total time the dosage form remains buoyant is termed Total Floating Time (TFT).[17, 18]

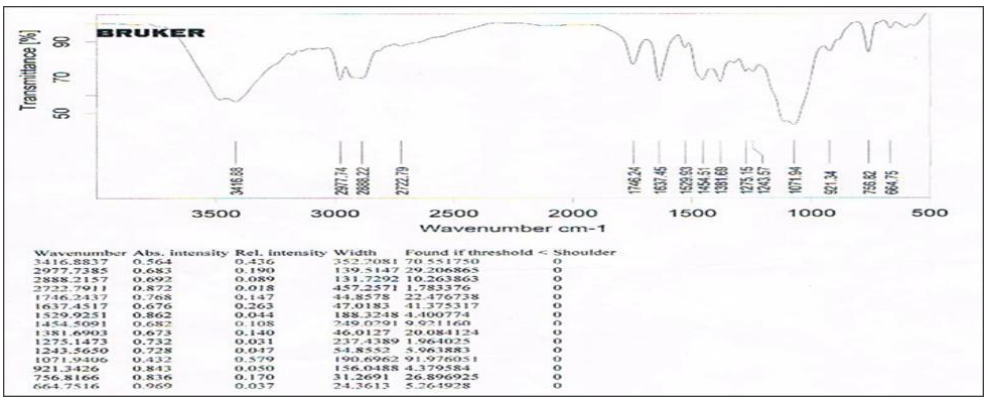
5.8. *In-Vitro* dissolution studies

The release rate of Ondansetron HCl from floating tablets was assessed utilizing the dissolution testing apparatus II (paddle method) as outlined in The United States Pharmacopoeia (USP) XXIV. The dissolution test was conducted with 900 ml of 0.1 N HCl, maintained at a temperature of 37 ± 0.5°C and a rotation speed of 50 rpm. A 1 ml sample of the solution was extracted from the dissolution apparatus, and an equivalent volume of fresh dissolution medium was added to replace the withdrawn sample. The samples were analyzed using UV spectroscopy at a wavelength of 310 nm following appropriate dilutions. The absorbance data obtained were applied to the standard curve equation to calculate the total cumulative amount of drug released.[19, 20]

5.9. Drug release testing

In vitro release studies were conducted utilizing the USP Type II dissolution test apparatus. The experiments were performed in 900 ml of 0.1N HCl over a duration of 13 hours, with a stirring speed of 50 rpm at a temperature of 37±0.5°C. At specified intervals of one hour, 5 ml aliquots were withdrawn and subsequently filtered. From the filtrate, 1 ml was diluted to 5 ml with the mobile phase, and a sample concentration of 20 µg/ml was injected into the HPLC system for analysis at a wavelength of 254 nm using photodiode array detectors. To maintain sink conditions, 5 ml of 0.1N HCl was replenished in the dissolution vessel after each aliquot withdrawal. The peak area obtained from the HPLC analysis was utilized to determine the percentage of drug release, with the mean calculated from three batches for each individual batch.[19, 20]

5.10. FTIR Spectra of drug and excipients compatibility study



Wavenumber	Abs. intensity	Rel. intensity	Width	Found if threshold <	Shoulder
3416.8837	0.564	0.436	352.2081	70.551750	0
2977.7385	0.683	0.190	139.5147	29.206865	0
2888.2157	0.692	0.089	131.7292	10.263863	0
2722.7918	0.872	0.018	457.2571	1.783376	0
1746.2437	0.768	0.147	44.8578	22.476738	0
1637.4517	0.676	0.263	47.0183	41.375317	0
1529.9251	0.862	0.044	188.3248	4.400774	0
1454.5091	0.682	0.108	249.0791	9.971160	0
1381.6903	0.673	0.140	46.0127	20.084124	0
1275.1473	0.732	0.031	237.4389	1.964025	0
1243.5650	0.728	0.047	54.8553	3.963883	0
1071.9406	0.432	0.579	190.6962	91.976051	0
921.3426	0.843	0.050	156.0488	4.379584	0
756.8166	0.836	0.170	31.2691	26.896925	0
664.7516	0.969	0.037	24.3613	5.261928	0

Fig. 1: FTIR Spectra of Ondansetron + HPMC K100M + Carbapol

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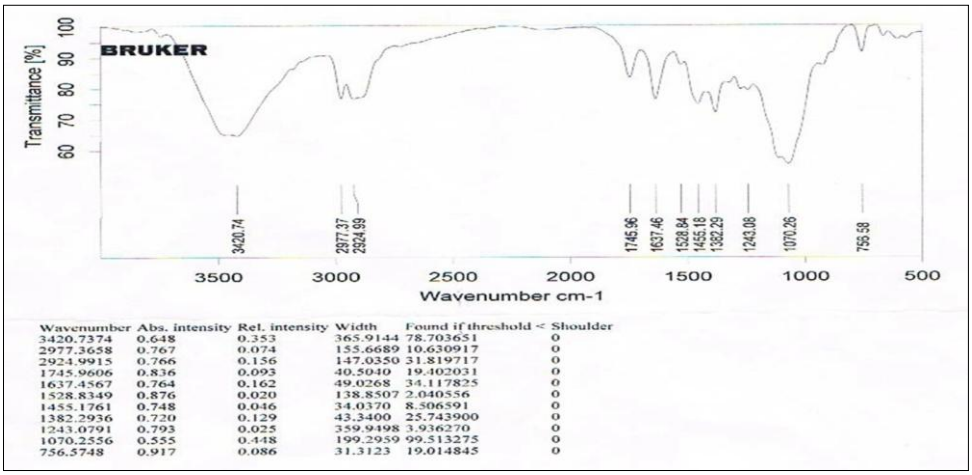
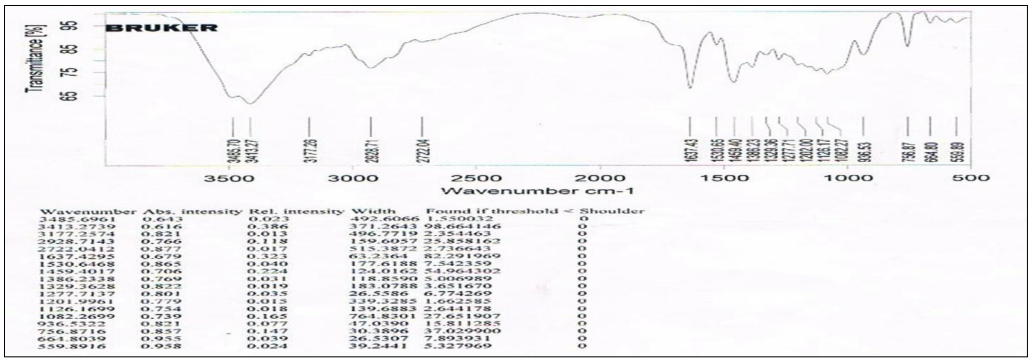


Wavenumber	Abs. intensity	Rel. intensity	Width	Found if threshold <	Shoulder
3420.7374	0.648	0.353	365.9144	78.703651	0
2977.3658	0.767	0.074	155.6689	10.630917	0
2924.9915	0.766	0.156	147.0350	31.819717	0
1745.9606	0.836	0.093	40.5040	19.402031	0
1637.4567	0.764	0.162	49.0268	34.117825	0
1528.8349	0.876	0.020	138.8507	2.040556	0
1455.1761	0.748	0.046	34.0370	8.506591	0
1382.2936	0.720	0.129	43.3400	25.743900	0
1243.0791	0.793	0.025	359.9498	3.936270	0
1070.2556	0.555	0.448	199.2959	99.513275	0
756.5748	0.917	0.086	31.3123	19.014845	0

Fig. 2: FTIR Spectra of Ondansetron + HPMC E15M + HPMC K100M



Wavenumber	Abs. intensity	Rel. intensity	Width	Found if threshold <	Shoulder
3485.6961	0.643	0.023	492.6066	1.550032	0
3413.2739	0.616	0.386	371.2643	98.6641146	0
3177.2574	0.821	0.013	496.7719	2.354463	0
2928.7143	0.766	0.118	159.6057	25.858162	0
2722.0412	0.877	0.017	515.3872	2.736643	0
1637.4295	0.679	0.333	63.2364	82.291969	0
1530.0698	0.865	0.040	177.6188	7.542359	0
1459.4017	0.7068	0.224	124.0162	54.964302	0
1388.2338	0.769	0.031	118.8590	5.006989	0
1328.3628	0.852	0.019	183.0788	3.651670	0
1277.7137	0.8401	0.035	26.5586	6.774269	0
1201.9961	0.779	0.015	339.3285	1.662585	0
1126.1699	0.7534	0.018	139.6883	2.644178	0
1062.2699	0.739	0.165	764.8301	27.651907	0
936.5322	0.8821	0.077	47.0390	15.811285	0
756.8716	0.857	0.147	30.3896	37.029900	0
664.8039	0.955	0.039	26.5307	7.893931	0
559.8916	0.938	0.024	39.2441	5.327969	0

Fig. 3: FTIR Spectra of Ondansetron + HPMC E15M + Carbapol.

Table 3: Physical Properties of Tablets of Batch F1 to F6.

Batches	Thickness (mm)	Hardness (Kg/cm²)	Friability (%)	Weight Variation (mg)	Drug content uniformity Percentage
F1	3	3.6	0.97	200.15	97.01
F2	3.05	3.8	0.74	201.5	96.01
F3	3.03	2.3	0.92	201.1	96
F4	3.09	3.3	0.78	199.85	96.3
F5	3.07	4.0	0.87	200.26	97
F6	3.22	3.7	0.77	201.5	93.5

5.11. *In- vitro* Buoyancy Study

Table 4: Tablet Density, Buoyancy Lag Time, Total Floating Time.

Batch	Tablet Density (g/cc)	Buoyancy Lag Time (Sec)	Total Floating Time (hrs)
F1	0.92	61	>24 hrs
F2	0.83	52	>24 hrs
F3	0.87	103	>24 hrs
F4	0.96	71	>24 hrs
F5	0.98	58	>24 hrs
F6	0.83	135	>24 hrs

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5.12. *In-Vitro* Dissolution Study

The six formulations of Ondansetron floating tablets that were prepared underwent in-vitro release studies, which were conducted utilizing a dissolution apparatus and 0.1N HCl (pH 1.2).

Table 5: Cumulative % Drug Released from Tablet Formulations F1 to F6.

Time (Hours)	F1	F2	F3	F4	F5	F6
3	18.54	20.81	20.90	21.92	21.09	18.95
6	30.55	32.68	34.65	24.35	37.87	33.29
9	53.16	55.33	57.63	56.49	58.78	48.26
12	59.78	67.44	65.06	64.72	70.65	63.44
15	70.45	71.83	72.29	71.79	76.58	68.06
18	76.79	78.78	77.57	76.64	81.60	75.48
21	80.18	84.75	85.43	85.69	88.39	81.14
24	88.29	89.70	90.45	94.96	97.87	95.34

The outcomes from the in-vitro release studies were represented by plotting the cumulative percentage of drug release against time. The findings suggested that the rate of release was constrained by both the dissolution rate of the drug particles and the erosion of the polymer matrix. The in-vitro drug release profiles for tablets from each batch (F1 to F6) were conducted, with the results presented in Table 6.0. The cumulative percentage of drug release versus time (in hours) was illustrated in Fig. 4.

The in-vitro dissolution data indicated that formulations F1, F2, and F3 released approximately 90% of the drug after 24 hours. Among all the formulations, F5 demonstrated the highest efficacy, releasing 97% of the drug within the same time frame. This suggests that F5 exhibited superior controlled release compared to the other formulations.

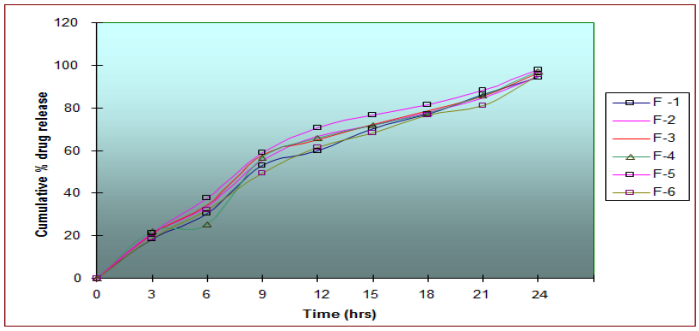

Fig. 4: shows the cumulative % release of drug vs. time.

5.13. Stability study

The most effective formulation was chosen from the prepared options for the stability study. The aim of stability testing is to evaluate how the quality of the drug substance or product changes over time when exposed to environmental factors such as humidity, temperature, and light. To determine the stability of the drug and formulation, stability studies were conducted in accordance with ICH and WHO guidelines. The optimized BFT (RK3), packaged in aluminum with a polyethylene inner coating, along with various replicates, was stored in a humidity chamber at conditions of 45 °C and 75% relative humidity, 25 °C and 60% relative humidity, and 60 °C and 75% relative humidity for a duration of three months. Upon completion of the studies, the samples were analyzed for drug content, in-vitro dissolution, floating behavior, and other physicochemical characteristics.

6. CONCLUSION

Some drugs are absorbed in a particular portion of the GIT only and are absorbed to a different extent in various segments of the GIT. Such drugs are said to have an absorption window, which identifies the drug's primary region of absorption in the GIT. Sustained release SR gastro retentive dosage forms (GRDF) enable prolonged and continuous input of drug to the upper part of gastro intestinal tract improve bioavailability of medications that are characterized by a narrow absorption window. GRDF retained in stomach and release the in a sustained manner over there. Ondansetron HCl which is better to absorbed stomach and upper intestine was formulated as floating tablet using hydrophilic polymer and gas generating agents. Formulation was optimized on basis of floating time and *in-vitro* release. From the experimental work it is concluded gastroretentive tablets of Ondansetron HCL were successfully prepared by effervescent technique using different gel forming polymers- HPMC (E15M, K100M, 15cps, 3cps), and carbopol 934. A combination of sodium bicarbonate (or calcium carbonate) and citric acid was necessary to achieve optimum buoyancy. The viscosity of the gel-forming polymer HPMC influenced the i*n-vitro* buoyancy from *in-vitro* buoyancy study the polymers can be arranged with respect to total floating time as Carbopol 934 < HPMC K100M < HPMC E15M. The different gel, forming polymers can be arranged in order of release rate as: HPMC KI00M< HPMC E15M< Carbopol 934. The polymers HPMC 15 cps and 3 cps were used in combination with the higher viscosity grades to avoid their rapid salvation and exhibited better sustained release characteristics. Hence a combination of low viscosity grade HPMC with higher viscosity grade may be used to achieve prolonged release of Ondansetron HCL from tablets. The prepared gastroretentive test formulation was found to exhibit satisfactory physico-chemical characteristics at the end of 30 days, during the stability studies. The optimized formulation was found to be stable at 40^0C/ 75% RH.

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