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FORMULATION AND EVALUATION OF EMTRICITABINE FLOATING TABLETS

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ABSTRACT

This study aimed to formulate and evaluate floating tablets of Emtricitabine, an antiretroviral drug with a narrow absorption window. Floating drug delivery systems (FDDS) enhance gastric retention and improve bioavailability. Nine formulations (F1–F9) were prepared using HPMC, Guar gum, and Agar by direct compression.Pre- and post-compression parameters were within acceptable limits. Among the formulations, F1 (with HPMC) showed the best performance with 98.4% drug release at 24 hours and an 8-hour floating time. These findings support the potential of floating tablets to enhance Emtricitabine's bioavailability. Further in vivo studies are needed for clinical validation.

INTRODUCTION

The development of novel oral drug delivery systems has become a crucial area of pharmaceutical research aimed at enhancing therapeutic efficacy and patient compliance. Among these, gastroretentive drug delivery systems (GRDDS) have garnered significant interest for their ability to prolong the residence time of dosage forms in the stomach, thereby enhancing the bioavailability of drugs that have a narrow absorption window or are primarily absorbed in the upper gastrointestinal tract.Emtricitabine, a nucleoside reverse transcriptase inhibitor (NRTI), is widely used in the treatment of HIV-1 infection and chronic hepatitis B. It exhibits a short half-life and is mainly absorbed in the upper part of the gastrointestinal tract, which limits its overall bioavailability. Hence, a controlled-release formulation that remains buoyant in the stomach and allows for extended drug release can offer significant therapeutic benefits by maintaining consistent plasma drug levels, reducing dosing frequency, and minimizing side effects.Floating drug delivery systems (FDDS) or hydrodynamically balanced systems are designed to prolong gastric retention by having a lower density than gastric fluids. These systems float on the gastric contents and release the drug in a controlled manner over an extended period. The key to an effective floating tablet formulation lies in the selection of suitable polymers, gas-generating agents, and matrix-forming excipients that ensure buoyancy and sustained release.This study focuses on the formulation and evaluation of floating tablets of Emtricitabine, aiming to optimize the release profile, enhance gastric retention, and improve overall bioavailability. The evaluation involves preformulation studies, formulation development, in vitro buoyancy, drug release testing, and stability studies, ensuring the final product meets desired pharmaceutical quality standards.

METHODS:

Preformulation studies were conducted.

Preformulation is defined as the application of biopharmaceutical principles to the physicochemical properties of the drug.Itis a phase of the R&D process.

FTIR Spectroscopy:

IR spectra of emtricitabine were obtained using a Perkin-ElmerFourier transform infrared spectrophotometer with KBr pellets.

The melting point of emtricitabine was measured.

The melting point of emtricitabine was measured by the capillary tube method.

Loss on drying was measured.

10gms Emtricitabine was heated at a temperature of105ºC in a hot air oven until it reached a constant weight.The formula was

$$\text{Percentage LOD} = \frac{\text{initial weight – final weight}}{\text{Initial weight}} \times 100$$

The formula used to calculate the percentage loss on drying was:

The results of the loss on drying test were recorded and are discussed in the results and discussion

Angle of Repose:

It was measured by the fixed funnel technique .In this technique, a funnelcontaining emtricitabine was kept at a fixed height, and it was allowed to flow to the surface which contains graph paper . This is due to gravitational force. The height and radius of the heap formed was measured. The formula for angle of repose[θ]was$\theta = \tan^{-1}(h/r)$.The results were recorded and given in results and discussion

Bulk Density and Tapped Density:

Bulk densities of granules were determined by pouring gently 20gm of sample through a glass funnel into a 100ml graduated cylinder .The volume occupied by the sample was recorded.Bulk density and tapped density were calculated by the formula

$$\text{Bulk density} = \frac{\text{Mass of powder}}{\text{Volume of powder (untapped)}}$$

$$\text{Tapped density} = \frac{\text{Mass of powder}}{\text{Volume of powder (tapped)}}$$

$\theta = \tan^{-1}(h/r)$. The results were recorded and givenin the results and discussion

Compressibility Index:

CI of the powder was determined from the bulk and tap density as follows

$$\text{Percentage CI} = \frac{\text{(Tapped Density – Bulk Density)}}{\text{Tapped Density}} \times 100$$

The results were recorded and given in the results and discussion.

It was calculated as

Hausner's Ratio:

$$\text{Hausners ratio} = \frac{\text{Tapped Density}}{\text{Bulk Density}}$$

The results were recorded and given in the results and discussions.

Compatibility Studies:

IR spectroscopy

IR spectra of pure emtricitabine, polymer and combination of emtricitabine with polymers were obtained by using Perkin-Elmer Fourier transform infrared spectrophotometer. The scanning range used was 4000 to 400cm-1.82 The results were recorded and given in the results and discussion.

Standard Graph of Emtricitabine:

Standard graphs of the drug were prepaed using standard emtricitabine solution in acid buffer PH1.2 ,phosphate buffer PH6.8 and PH7.4 containing 5 to 50g. The absorbance was measured at 275nm .Linear relationship was observed with absorption to concerntrationof drug the values of absorbance related to concentration were given in table6 and graphs were given in fig18.

FORMULATION:

Table 1: Formulation trails of emtricitabine floating tablets (AF1 – AF9)

S.NO	INGREDIENTS	AF_1 (mg)	AF_2 (mg)	AF_3 (mg)	AF_4 (mg)	AF_5 (mg)	AF_6 (mg)	AF_7 (mg)	AF_8 (mg)	AF_9 (mg)
1	Emtricitabine	50	50	50	50	50	50	50	50	50
2	HPMC	100	125	150	-	-	-	-	-	-
3	Guar gum	-	-	-	100	125	150	-	-	-
4	Agar	-	-	-	-	-	-	100	125	150
5	Sodium bicarbonate	150	150	150	150	150	150	150	150	150
6	Citric acid	15	15	15	15	15	15	15	15	15
7	PVPK30	40	40	40	40	40	40	40	40	40
8	Microcrystalline cellulose	125	100	75	125	100	75	125	100	75
9	Talc	10	10	10	10	10	10	10	10	10
10	Magnesium stearate	10	10	10	10	10	10	10	10	10
	Total weight	500	500	500	500	500	500	500	500	500

Emtricitabine floating tablets were prepared by the direct compression method using excipients and polymers to release the drug sustainably after administration. Accurately weighed quantities of excipients were placed in a mortar and gradually mixed with constant kneading to ensure a homogeneous mass .Then, the homogeneous powder was passed through sieve number 40 and the powder was retained on sieve number 100 .Then, the powder was lubricated with magnesium stearate and talc. Finally, the powder was directly compressed into tablets on a tablet punching machine.

EVALUATION OF FLOATING TABLETS:

Standard graph of emtricitabine:

The λmax of Emtricitabine in 0.1NHCl was scanned to be 275nm usingUV spectrometer. The standard graph of emtricitabine was dissolved in the required quantity of 0.1NHCl and madeupthe volume 100ml using 0.1NHCl .To obtain the stock solution of concentration 1mg/ml ,from this 1ml was taken and diluted to 100ml using 0.1NHC lt obtain a working stock solution of concentration .From the above solutions,5,10,15,20,25ml was taken and diluted to 10ml using 0.1NHC lt obtain the concentrationsof 5,10,15,20,25µg/ml.

EVALUATION OF PHYSICAL PROPERTIES:

1. Weight Variation:

Weigh 20 tablets selected at random and calculate the average weight. Not more than two of the individual weights deviate from the average by more than the percentage shown in the tablebelow,and none deviates by more than twice that percentage.

2. Friability:

Weigh 20 tablets selected at random and calculate the average weight. Not more than two of the individual weights deviate from the average by more than the percentage shown in the tablebelow,and none deviates by more than twice that percentage.

3.Hardness:

Weigh 20 tablets selected at random and calculate the average weight. Not more than two of the individual weights deviate from the average by more than the percentage shown in the tablebelow,and none deviates by more than twice that percentage.

4. Content Uniformity:

It isthe amount present in each formulation for formulation (or tablets)Tablets from the formulation was taken and dropped in 100ml 0.1NHCl in a beaker. After 24hrs or when the drug is released completely the same sample was with drawn (about1ml) and diluted to 10ml with 0.1NHCL and absorbance was taken at 275nm using a UVspectrometer .From the standard graph, % drug release was calculated.

5. Thickness:

The thickness of the tablet is measured by using a screwgauge. It gives the changes in weight variation of the tablet

6. Floating Lag Time:

The floating lag time is determined in order to assess the time taken by the dosage to float on the top of the dissolution medium after placing the dosage form in the medium.

7. Floating Time:

It is the time the tablet constantly floats on the dissolution medium (i.e duration of floating) in the dissolution medium

8 Dissolution Studies:

Emtricitabine floating tablets were kept in dissolution medium 0.1NHCl (900ml) for the initial 2hours and operated at a temperature 37±0.50C and rotated at 75rpm. Then pH6.8 phosphate buffer (900ml) was used as the dissolution medium .Freshly prepared dissolution medium is used always. Type paddle apparatus is used. About 5ml of the dissolution medium was pipetted out for every 15,30,60,120,240,480,960 minutes,and the volume was adjusted using by replacing it with 5mlof 0.1NHCl or with pH6.8 phosphate buffer. The samples collected were analysedusing UV spectrometer at 275nm.

RESULTS AND DISCUSSION

Preformulation studies were conducted.

In preformulation studies drug characteristics was performed, and the results were complies with pharmacopoieal values;

A. Standard graph of Emtricitabine: The dissolution studies for the floating tablet have to be conducted in 0.1NHCl .Hence,UVspectrum of emtricitabine in 0.1NHCl was recorded on Elico spectrophotometer. The spectrum has shown λmaxof 275nm which is selected for the construction of standard graph of emtricitabine in 0.1NHCl .Aplot of absorbance Vs concentration of emtricitabine in 0.1NHC l is found to be linear in the concentration range of 5-25µg/ml indicating a perfect relation between drug concentration and absorbance.

Table 2: Standard plot of emtricitabine

CONCENTRATION(µg/ml)	ABSORBANCE
5	0.065
10	0.131
15	0.192
20	0.252
25	0.321

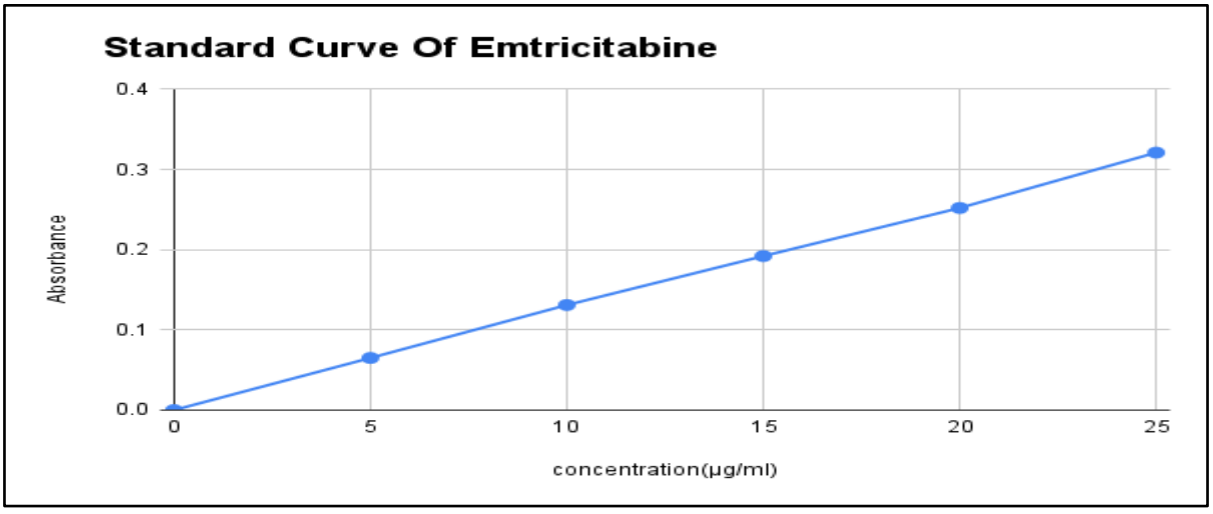


Fig 1: Standard Curve Of Emtricitabine

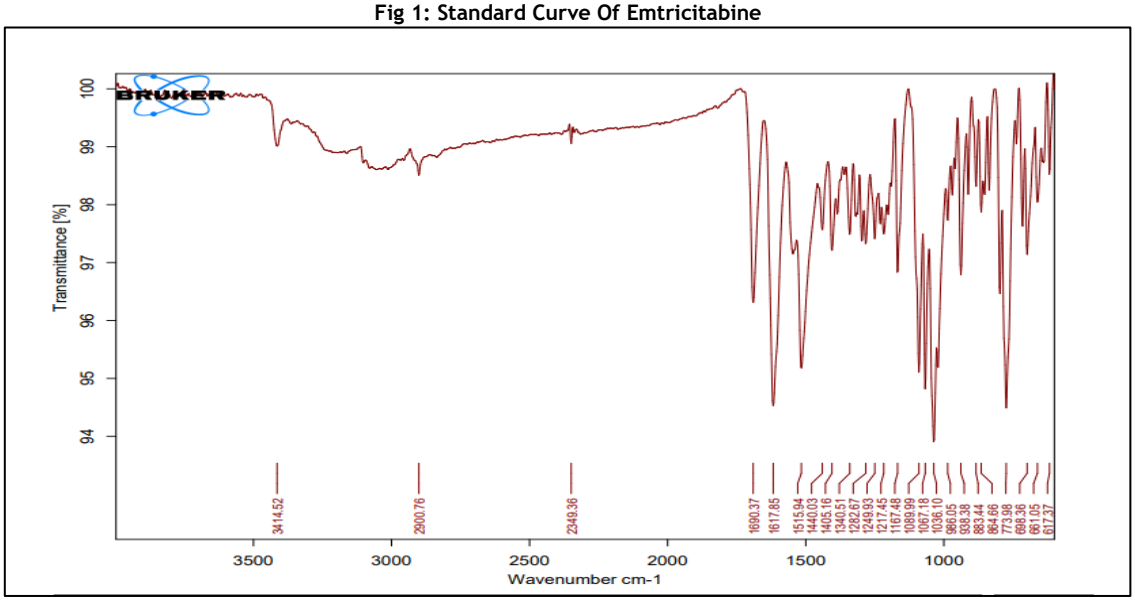


Fig 2: FTIR Of Emtricitabine

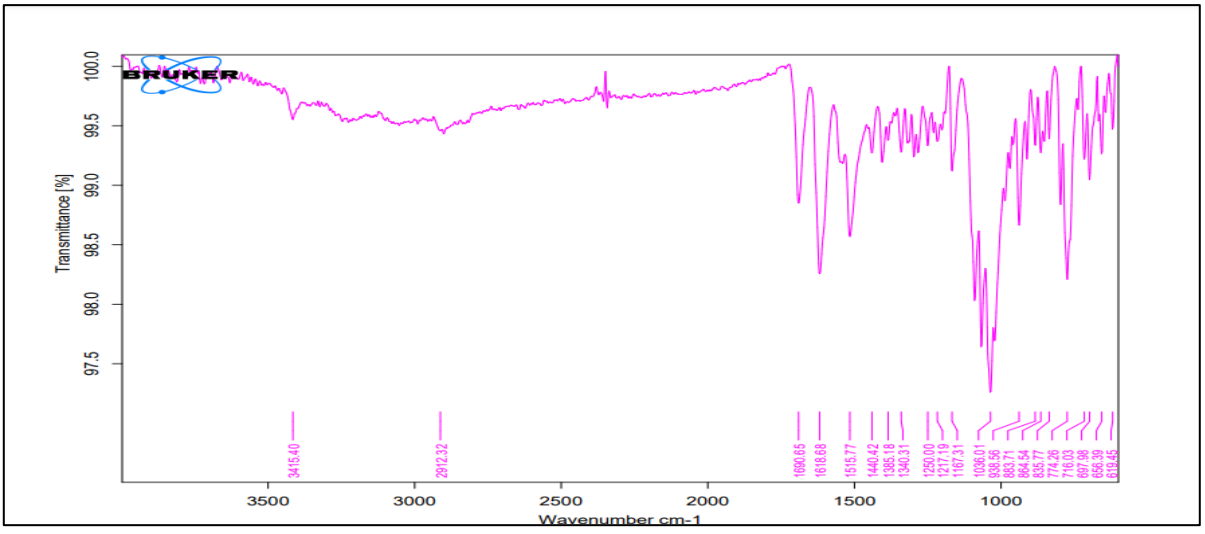


Fig 3: FTIR of Emtricitabine + HPMC

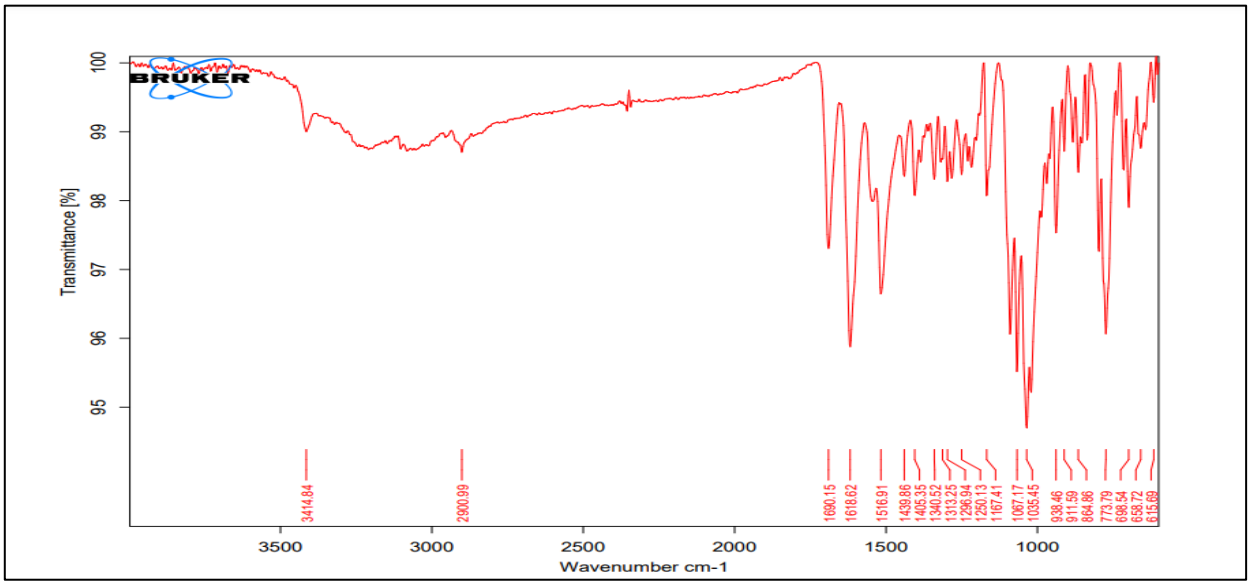


Fig 4: FTIR of Emtricitabine + Guar Gum

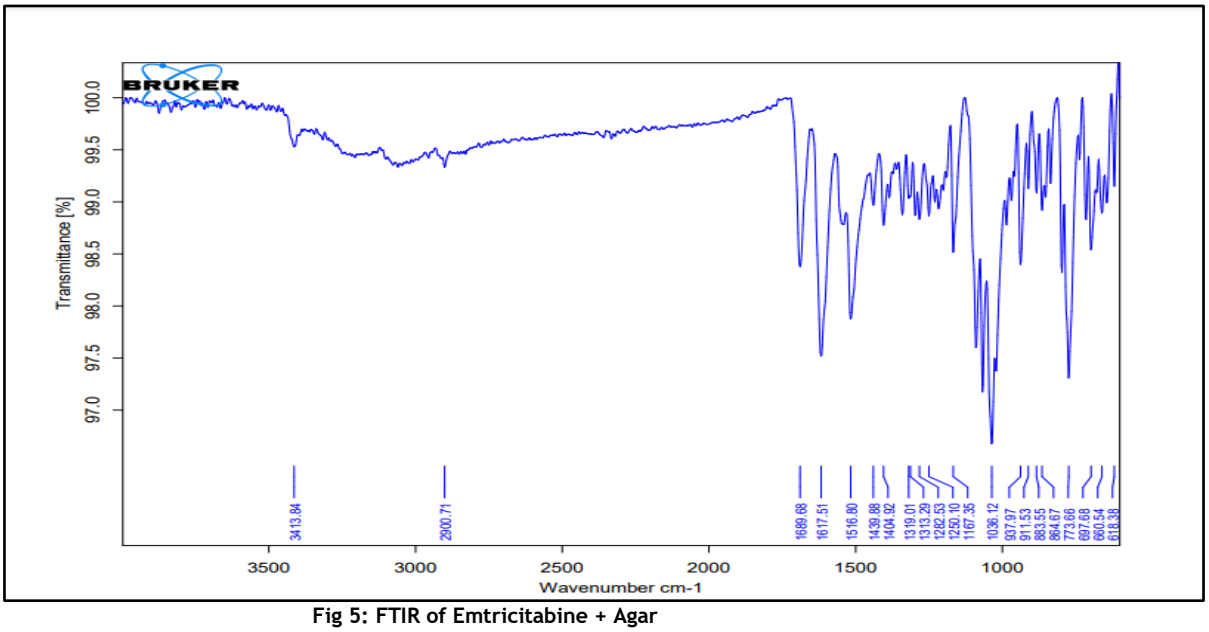


Fig 5: FTIR of Emtricitabine + Agar

B. Evaluation of Floating

It is always necessary that the dosage forms prepared have to be evaluated for their characteristic properties .Hence quality control tests of tablets are performed to assess various properties of tablets.

Table 3: Preformulation-Flow properties

Formulation	Angle of repose(θ)	Bulk density(gm/cm^3)	Tapped density(gm/cm^3)	Hausner ratio(HR)
F1	28.2±0.01	0.56±0.01	0.70±0.04	1.23±0.01
F2	26.4±0.02	0.55±0.02	0.65±0.03	1.22±0.02
F3	27.5±0.03	0.55±0.01	0.70±0.01	1.26±0.03
F4	26.8±0.04	0.54±0.03	0.72±0.03	1.36±0.01
F5	26.9±0.05	0.53±0.03	0.66±0.03	1.27±0.02
F6	27.9±0.01	0.53±0.02	0.65±0.04	1.29±0.04
F7	26.4±0.05	0.52±0.03	0.69±0.01	1.23±0.02
F8	26.9±0.03	0.51±0.04	0.70±0.05	1.27±0.05
F9	27.9±0.05	0.51±0.02	0.66±0.01	1.24±0.02

Weight variation: tablets exhibit variation due to improper filling of die cavity, uneven distribution of ingredients in the compression and variation in compressional pressure.

The total weight of each formulation is not maintained constant but the weight variation is in the range of +/-5%w/w indicating good control of compression process.

Table 4: Weight Variation for (F1-F9)

SN.O	FORMULATIONS	WEGHIT VARIATION (mg)
1	F1	480±0.25

2	F2	490±0.02
3	F3	469±0.33
4	F4	467±0.42
5	F5	500±0.12
6	F6	500±0.10
7	F7	460±0.34
8	F8	500±0.33
9	F9	480±0.34

Friability: It isa measure of tablet strength .It is related to tablets ability to with stand both shock and abrasion without crumbing during the handling of manufacture ,jacking ,shipmentand consumer use.

The friability was determined as the percentage loss in the weight of the tablets. A loss of less than 0.5to1% in weight is generally considered acceptable.

Table 5: Percentage Friability for (F1-F9)

S.NO	FORMULATION	FRIABILITY(%)
1	F1	0.45±0.01
2	F2	0.36±0.06
3	F3	0.45±0.04
4	F4	0.50±0.02
5	F5	0.49±0.03
6	F6	0.39±0.05
7	F7	0.42±0.03
8	F8	0.49±0.01
9	F9	0.45±0.04

Hardness: Hardness was measured using the Pfizer hardness tester,which measures the pressure required to break the diametrical placed tablets by the pressure with coiled spring.

Table 6: Hardness for (F1-F9)

S.NO	FORMULATION	HARDENESS
1	F1	4.5±0.02
2	F2	5.0±0.02
3	F3	4.5±0.012
4	F4	5.0±0.016
5	F5	5.5±0.09
6	F6	4.5±0.04
7	F7	4.7±0.02
8	F8	5.0±0.06
9	F9	5.5±0.2

Thickness: The thickness of the tablet is measured by using screw gauge.Itgives the changes in weight variation of the tablet.

Table 7: Thickness for (F1-F9)

S.NO	FORMULATION	THICKNESS
1	F1	3.0±0.2
2	F2	2.9±0.05
3	F3	3.1±0.02
4	F4	3.2±0.02
5	F5	3.0±0.02
6	F6	3.2±0.04
7	F7	2.8±0.03
8	F8	3.0±0.01
9	F9	3.2±0.2

Floating lag time: The floating lag time is determined in order to assess the time taken by the dosage to float on the top of the dissolution medium, after placing the dosage form in the medium.

Table 8: Floating lag time (sec) & Floating time (hrs) for (F1-F9)

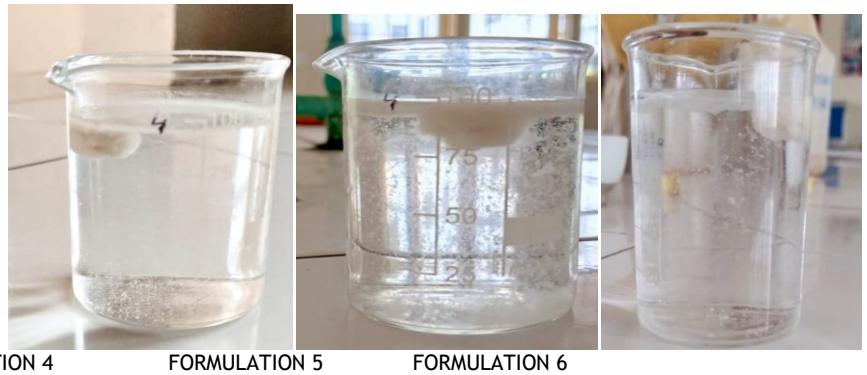
S.NO	FORMULATION	FLOATING TIME (sec)	FLOATING TIME (hrs)
1	F1	75	8
2	F2	25	9
3	F3	30	6
4	F4	120	6
5	F5	240	9
6	F6	20	7
7	F7	30	9
8	F8	35	6

9	F9	30	8

FORMULATION 1 FLOATING TIME:65min

FORMULATION 2 FLOATING TIME: 23:30sec

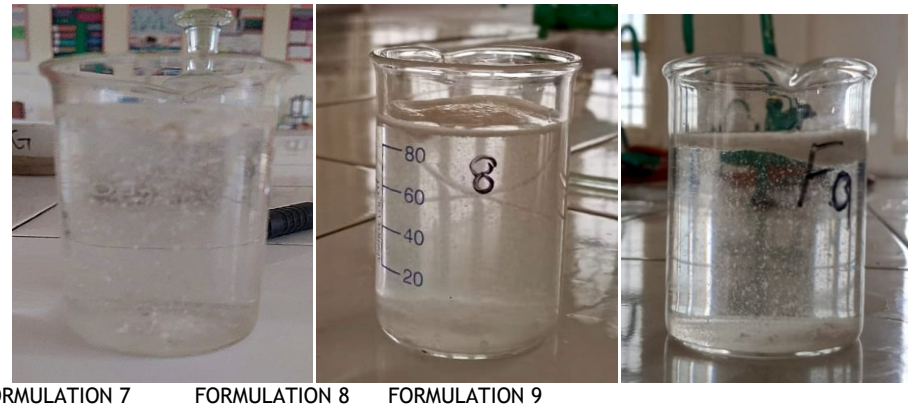
FORMULATION 3 FLOATING TIME: 13:50sec



FORMULATION 4 FLOATING TIME :20min

FORMULATION 5 FLOATING TIME : 1:20sec

FORMULATION 6 FLOATING TIME :1min



FORMULATION 7 FLOATING TIME: 30sec

FORMULATION 8 FLOATING TIME:14sec

FORMULATION 9 FLOATING TIME:6sec

Fig 6: Floating Time of different Formulations

Drug content:

Table 9: % Drug content for (F1-F9)

S.NO	FORMULATION	DRUG CONTENT(%)
1	F1	98.5±0.1
2	F2	97.5±0.2
3	F3	98.5±0.3
4	F4	97.4±0.1
5	F5	98.3±0.5
6	F6	97.5±0.1
7	F7	98.2±0.5
8	F8	98.3±0.6
9	F9	97.5±0.4

Dissolution studies:

Freshly prepared dissolution medium i.e900ml 0.1NHCl in each dissolution vessel of dissolution paddle apparatus maintained at temperature 37+/-0.50C and rotated at 75rpm .The tablets of emtricitabine were placed in dissolution medium .About 5mlof the dissolution medium was pipetted out for every 15,30,60,120,240,480 ,960 min and the volume wasadjusted using by replacing with 5ml of 0.1NHCl. The above samples i.e5ml

(7samples) were collected in a volumetric flask and make up the volume to 10ml with 0.1NHCl. Finally the absorbance of the solution was taken using UV spectrometer at 275n

Table 10: Percentage cumulative drug release

TIME(h)	% CUMULATIVE DRUG RELEASE								
FORMULATION	AF1	AF2	AF3	AF4	AF5	AF6	AF7	AF8	AF9
0	0	0	0	0	0	0	0	0	0
1	20.3	12.7	16.5	17.5	13.7	14.8	12.6	15.7	18.5
2	43.5	13.1	23.4	22.8	21.8	20.5	14.9	21.6	20.6
4	59.1	28.9	32.6	34.6	36.3	32.3	33.6	36.7	31.2
8	72.6	38.2	45.3	45.8	44.4	44.6	44.7	48.3	44.9
12	80.5	45.7	58.6	56.3	43.9	55.7	56.5	62.1	62.5
16	85.6	55.9	71.2	72.4	72.6	71.4	71.7	72.7	71.3
20	95.3	62.1	86.5	83.4	82.1	81.6	81.1	78.5	76.8
24	98.4	95.4	72.2	86.3	88.5	84.1	83.2	80.5	80.3

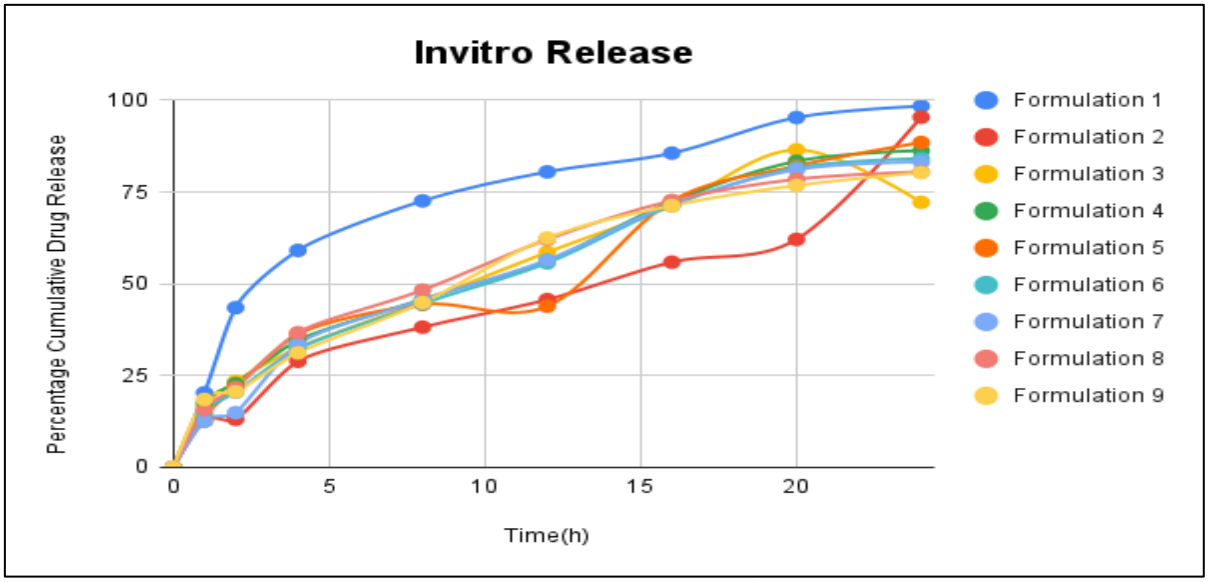


Fig 7: Cumulative Percentage of Drug Release Curve

CONCLUSION

Floating drug delivery systems prolongs the gastric residence time which in turn produces increased drug bio availability due to its less density than the aqeousmedium,Itfloats in the gastric fluid.These drug delivery systems are suitable in the stomach or in upper small lintestine due to its narrow absorption window.

Human immuno deficiency virus(HIV)Is a virus that attacks the body's immune system .Acquiredimmuno deficiency syndrome(AIDS) occursthe most advanced stage of infection. HIV targets the body's white blood cells ,weakening the immune system.This makes it easier to get sick with diseases like tuberculosis ,infections and some cancers.

EMTRICITABINE is an anti retro viral medicine.Itis used with other medicines to treat HIV.Thismedicine is not a cure for HIV.This medicine can lower,but not fully prevent ,the risk of spreading HIV toothers.Floating tablets of emtricitabine were developed to prolong gastric residencetimeand increase its bio availability.

Floating tablets of emtricitabine were prepared using individual and combination of polymers.The polymers HPMC,Guargum and Agar were used in different ratios totally 9 formulations (F1toF9) were designed and formulated.The flow properties bulk density,tap density, angle ofrepose for the granules were determined and the results were found to be within the limit for al ltheformulations.The emtricitabine floating tablets were prepared by direct compression method which is easy ,simple and time consuming. These formulations (F1toF9) were evaluated for various tests like weight variation ,contentuniformity ,friability, hardness and dissolution studies.Thehardness,weight variation and friability of the tablets were within the limits for all the formulations.The floating lag time for the prepared formulation was ideal for floating drug delivery systems. The percentage drug release of the formulations F1,F2,F3,F4,F5,F6,F7,F8,F9 was 98.4 ,94.4 ,72.2 ,86.3 ,88.5, 84.1,
83.2 ,80.5,80.3 upto24 hours. The formulation F1 prepared with HPMC showed good floating time and it was the best formulation with the floating time of 8hours and drug release of about 98.4% at the end of 24th hour. The present research work focuses on the floating tablets of emtricitabine and succeeded in the formulation but still research to be continued to in vivo studies to prove the effectiveness to prepare emtricitabine floating tablets.

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