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Formulation and Evaluation of Ciprofloxacin Floating Tablet

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ABSTRACT

Recent advancements in scientific and technological fields have led to the development of rate-controlled oral medication delivery devices that address physiological challenges such as short gastric residence times (GRT) and erratic gastric emptying durations. To prolong GRT, various methods are now employed, including devices that promote delayed gastric emptying, such as swelling and expanding systems, polymeric bioadhesive systems, modified-shape systems, high-density systems, and floating drug delivery systems (FDDS), which are also referred to as hydrodynamically balanced systems (HBS).The development of FDDS involves two techniques, creating both effervescent and non-effervescent floating tablets that rely on a buoyancy mechanism. FDDS can deliver drugs that have low solubility and higher pH levels as they have a limited absorption window in the upper gastrointestinal tract, are unstable in the environment of the lower intestine, and possess local activity. The latest advancements in floating drug delivery systems encompass the physiological and formulation factors that influence gastric retention time. Moreover, this paper thoroughly discusses the formulation methods for both single-unit and multiple-unit floating systems, along with their classification and formulation characteristics. A summary of the applications of floating drug delivery devices and the associated evaluation criteria is also presented in this paper.

Keywords: Floating Tablets, Controlled Drug Release, Patient Compliance, Enhanced Bioavailability.

INTRODUCTION

Mechanism of Floating System

The medication is gradually released from the system at the desired rate while remaining buoyant on the gastric contents. Once the medication has been released, the stomach residual system is emptied. However, to effectively achieve the principle of buoyancy retention, a minimum level of floating force (F) is required to keep the dosage form consistently afloat on the surface of the meal. A novel approach for calculating the resultant weight has been documented in the literature as a method to assess the kinetics of the floating force. The device functions by continuously measuring the force F (expressed over time) necessary to maintain the submerged object in position. If F is greater on the positive side, the object floats more effectively.

GASTROINTESTINAL INTENSION

Advantages of Floating Drug Delivery

- The bioavailability of certain drugs, such as riboflavin and levodopa, is significantly improved with CR-GRDF compared to administering CR polymeric formulations that are not GRDF
- Drugs with a short biological half-life may experience flip-flop pharmacokinetics, leading to decreased dosing frequency. This can also occur with medications when FDDS input is slow and continuous, enhancing patient compliance and improving therapy.
- For localized treatment within the stomach, the extended and sustained release of the medication from FDDS can be beneficial.
- A gradual absorption of the drug into the body diminishes counteractive responses, thereby enhancing the drug's effectiveness.
- The pre-systemic metabolism of the evaluated drug can be significantly improved when the drug is delivered to the metabolic enzymes (specifically cytochrome P-450, CYP-3A4) in a sustained manner.

Disadvantages of Floating Drug Delivery

- For these systems to effectively float and function while delivering medications, they require a significant amont of fluid in the stomach
- They are not suitable for medications that have issues with solubility or stability in the gastrointestinal tract.
- It is not recommended to use drugs like nifedipine, which are well absorbed throughout the gastrointestinal tract and undergo first pass
- .Medications that irritate the gastric mucosa are also considered unsuitable or inappropriate

MATERIAL AND METHOD

Table 3 List of material

Sr.no.	Material	Company Name
1	Ciprofloxacin	Balaji chemical pvt. Ltd, Gandhinagar Gujrat
2	HPMC K4M	Swapnavat Chemical Agency, Aurangabad
3	Sodium Bicarbonate	Swapnavat Chemical Agency, Aurangabad
4	PVP K30	Adora Product Pvt. Ltd. Aurangabad
5	Magnesium stearate	Adora Product Pvt. Ltd. Aurangabad
6	Talc	Swapnavat Chemical Agency Aurangabad
7	Avicel Ph 101	Adora Product Pvt. Ltd. Aurangabad

Table 4 List of equipment used

Sr.no	Equipment	Manufacture	Model no.
1	UV-VIS Spectrophotometer	Jasco	V-630
2	Electronic Balance	Shimadzu, Japan.	BL-220H
3	Rotary Tableting Machine	Karnavati	Rimek Minipress-1
4	FTIR Spectrophotometer	Jasco	FT/IR-4600
5	Friability Test Apparatus	Electrolab, India	ELECTROLAB
6	Vernier Calipers	Indolabs, Chennai	-
7	Dissolution Test Apparatus	Shimadzu, Japan.	60-PLUS
8	Hardness Test Apparatus	Sohamm calibration service	-
9	DSC	Shimadzu, Japan.	TA60WS

FORMULATION OF CIPROFLOXACIN FLOATING TABLETS

Ciprofloxacin tablets were formulated using the direct compression technique. All components were accurately measured and passed through sieve number 44. The drug was combined with the other powders in a polythene bag for 10 minutes, and then magnesium stearate was added, followed by an additional 5 minutes of mixing. A 200 mg portion of the mixture was measured and manually placed into the die of a tablet punching machine for direct compression. By this method, nine formulations were created, each with different ratios of three polymers, and the tablets were assessed for various parameters to identify the optimal formulation. The composition of floating tablets of Ciprofloxacin was shown in the table below Table 6.

Table 5 Composition of Ciprofloxacin floating tablets

Ingredients	F1	F2	F3	F4	F5
Ciprofloxacin (mg)	40	40	40	40	40
HPMC K4M (mg)	55	70	70	70	70
Sodium Bicarbonate (mg)	50	25	50	50	25

PVP K30 (mg)	**4**	**4**	**4**	**10**	**10**
Magnesium Stearate (mg)	**4**	**4**	**4**	**4**	**4**
Talc (mg)	**6**	**6**	**6**	**6**	**6**
Avicel PH 101 (mg)	**Q.S**	**Q.S**	**Q.S**	**Q.S**	**Q.S**
Total mg)	**200**	**200**	**200**	**200**	**200**

PRE-FORMULATION STUDY

Physical characteristics of Ciprofloxacin:

The physical characteristics of Ciprofloxacin were found to be colour was white and the odour was odourless.

Melting Point of Ciprofloxacin:

The melting point of Ciprofloxacin was found to be 205°c

IDENTIFICATION AND CHARACTERIZATION OF DRUGS AND EXCIPIENTS BY FT-IR.

FT-IR spectra of pure drug Ciprofloxacin and Ciprofloxacin with HPMC:

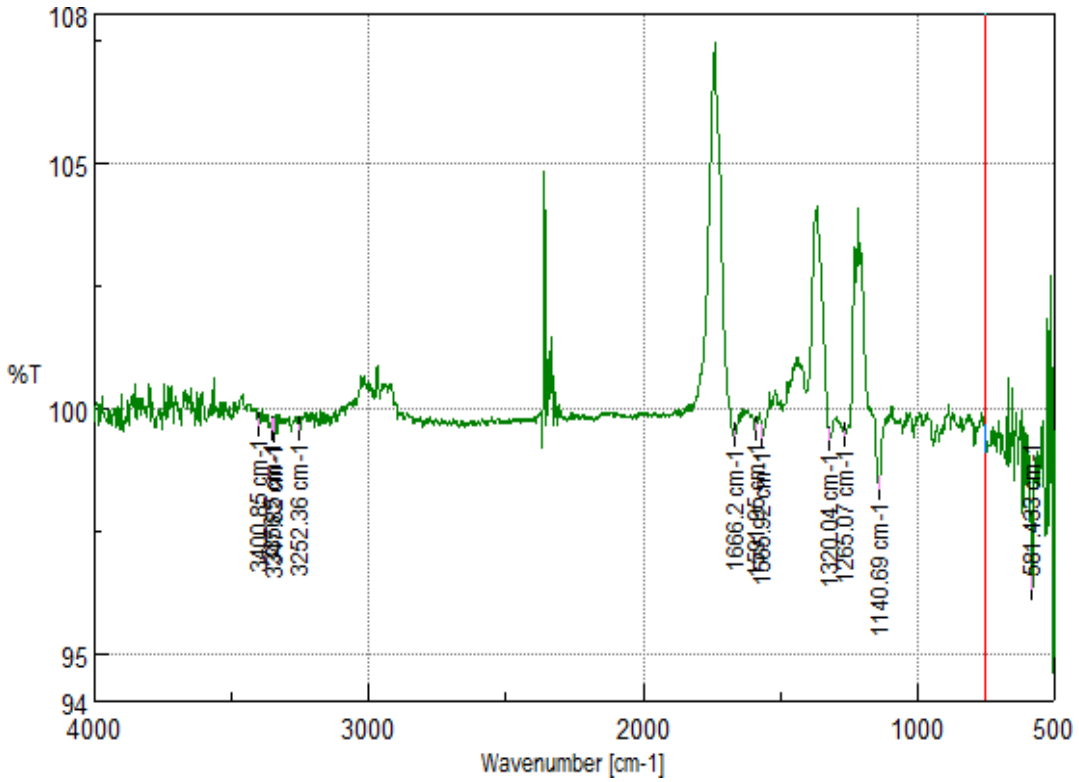


Figure FT-IR spectrum of pure drug Ciprofloxacin

U.V SPECTROPHOTOMETRIC ANALYSIS:

Determination of λmax and Calibration curve of Ciprofloxacin in 0.1 N HCL:

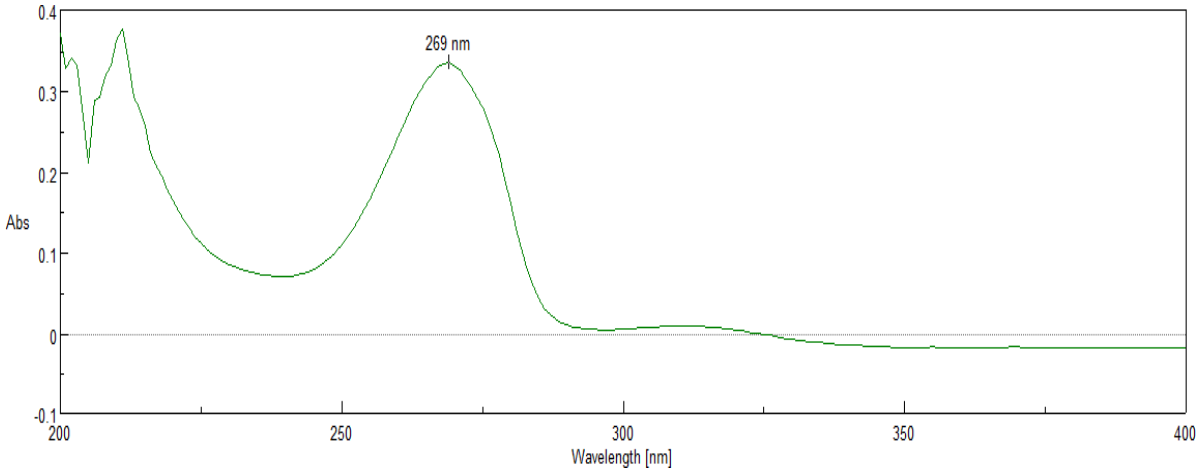


Fig. λmax of Ciprofloxacin in 0.1N HCL

The absorption spectra in the range (200-400nm) were obtained for Ciprofloxacin in 0.1N HCL. The drug exhibited an absorption maximum of 269 nm.

Construction of calibration curve of Ciprofloxacin in 0.1N HCL:

Table 11 Conc. and absorbance of Ciprofloxacin in 0.1N HCL

Sr. No.	Conc. µg/ mL	Absorbance at 269 (nm)
1.	2	0.418
2.	4	0.4613
3.	6	0.552
4.	8	0.6813
5.	10	0.7901

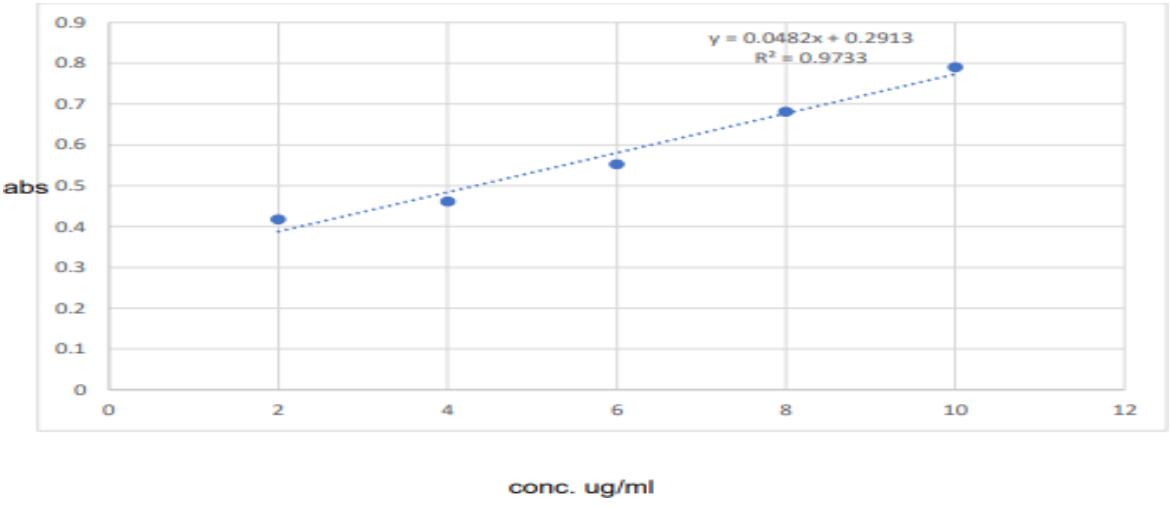


Fig. Calibration curve of Ciprofloxacin in 0.1N HCL

Table 15 Solubility Determination

Sr.no.	Ingredient	Solubility mg/ml
1	Distilled Water	0.1
2	Methanol	50
3	Ether	8
4	Chloroform	0.98

EVALUATION OF FLOATING TABLETS OF CIPROFLOXACIN

Pre-Compression Parameters:

The powder value's bulk density is used to determine the compressibility index and Hausner ratio. The compressibility index of all formulations indicates a good flow property in Table 18.

Table 18 Pre-Compression parameters

Formulation	Parameter				
	LBD (gm/ml)	TBD (gm/ml)	Compressibility Index (%)	Angle of Repose	Hausner Ratio (%)
F1	0.55	0.66	16.06%	26.57	1.2
F2	0.54	0.62	12.9%	27.30	1.14
F3	0.53	0.63	15.8%	25.40	1.16
F4	0.55	0.64	14.06%	28.2	1.16
F5	0.51	0.60	15.%	26.3	1.17

Post-Compression Parameters:

Formulation	Parameter				
	Weight Variation (%)	Thickness (mm)	Hardness (kg/cm^2)	Friability (%)	Drug Content (%)
F1	1.01	6.01	5.20	0.58	97.30
F2	1.41	6.24	5.69	0.79	97.20
F3	1.21	6.69	5.79	0.45	96.10
F4	1.65	6.54	5.21	0.55	95.30
F5	1.21	6.22	5.21	0.65	98.40

FLOATING TEST

When the tablet containing the effervescent ingredient comes into touch with the acidic medium (0.1 N HCl), carbon dioxide is produced inside the tablet. The tablets floated and stayed buoyant after being submerged in 0.1 N HCl at 37°C. The floating lag time results for all nine formulas in one minute. The F2 and F9 formulas have more than 13 hours of combined floating time.

Table 20 Floating parameter

Formulation	Parameter	
	Floating lag time (sec)	Total floating time (Hrs.)
F1	70	10 Hrs.
F2	65	13 Hrs. 15 min.
F3	80	9 Hrs. 55 min
F4	60	11 Hrs. 30 min.
F5	58	12 Hrs.

SWELLING STUDY

The swelling ratio, influenced by the network structure, hydrophilicity, and ionization of functional groups, determines the water volume within the hydrogel at equilibrium. A swelling assessment was performed on each batch for a duration of eight hours. The findings indicated that the swelling of the tablets increased for all formulations for about 4-5 hours before it began to decline. The swelling index results are presented in Table 21, while the plot of the swelling index over time reveals an upward trend as a consequence of the polymer's hydrophilicity that gradually takes up water. As the polymer hydrates, expands, and swells, a gel barrier forms on the exterior surface of its upper layer. The process of hydration swelling release continues toward new tissues as the gelatinous layer gradually breaks down and/or disperses.

Table 21 Swelling index

Time (Hrs.)	Swelling index %				
	F1	F2	F3	F4	F5
1	34.68	30.14	45.36	44.25	49.50
2	51.21	47.33	55.69	58.65	62.65
3	61.45	54.83	68.25	69.25	80.65
4	71.56	65.44	76.24	75.45	88.95
5	87.45	78.33	85.69	82.36	86.26
6	75.65	55.42	59.78	55.98	63.11
7	52.25	39.22	36.20	35.45	33.15
8	28.36	27.93	30.45	29.21	17.20

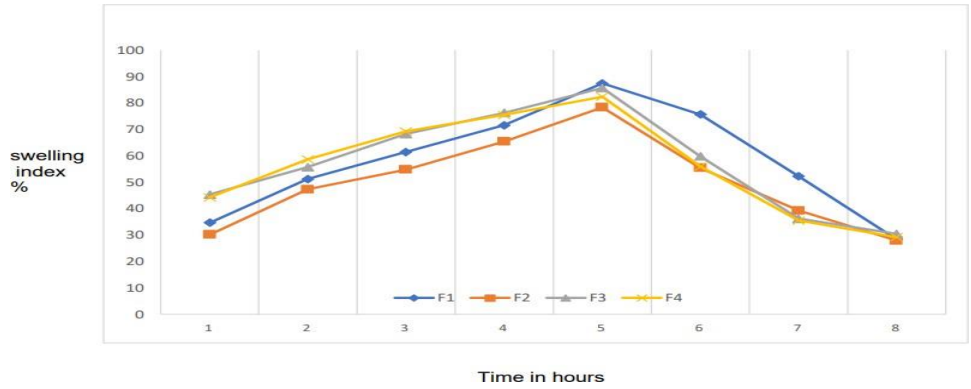
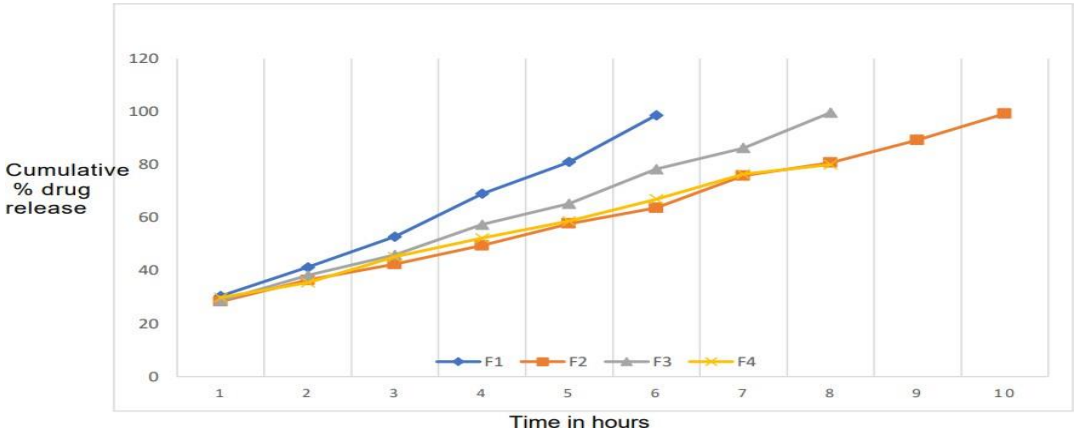


Fig. Swelling index of F1 to F4



IN-VITRO DISSOLUTION STUDIES

Time (hrs.)	Cumulative % drug release				
	F1	F2	F3	F4	F5
1	30.41	28.29	28.65	29.83	29.40
2	41.25	36.45	38.20	35.45	38.71
3	52.79	42.42	45.90	45.21	55.26
4	68.98	49.42	57.36	52.23	69.30
5	80.95	57.69	65.28	58.65	79.35

Fig. Cumulative % drug release of F1 to F4

8. CONCLUSION

- Hydrodynamically balanced tablets of Ciprofloxacin can be formulated with an approach to increase gastric residence and thereby improve drug bioavailability.
- An attempt to develop floating tablets of Ciprofloxacin by using sodium bicarbonate as a gas- generating agent and HPMC as a hydrophilic polymer by direct compression the technique was achieved.
- The formulated tablets showed compliance for various physiochemical parameters viz. tablet dimensions, total floating time, tablet density, and drug content.
- The dissolution studies formulations of F8 and F9 were good release and the F2 formulation was excellent.

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