WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.453
Volume 15, Issue 1, 729-753. Research Article ISSN 2277–7105

A RESEARCH OF DEVELOPMENT AND CHARACTERIZATION OF CEPHALEXIN LOW DENSITY TABLET USING RATE CONTROLING POLYMER

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Article Received on 29 Nov. 2025,
Article Revised on 20 Dec. 2025,
Article Published on 01 Jan. 2026,

https://doi.org/10.5281/zenodo.18094493

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How to cite this Article: Mr. Shashank Chaurasiya, Rahul Saini, Dr. Vijay Nigam, Ms. Anita Devi Shivhare. (2026). A Research of Development and Characterization of Cephalexin Low Density Tablet Using Rate Controling Polymer. World Journal of Pharmacy and Pharmaceutical Sciences, 15(1), 729–753.

ABSTRACT

Formulation and evaluation of Gas Powered Systems of Cephalexin Tablets was carried out by performing the preformulation studies, formulation of tablets, evaluation parameters, in vitro drug release studies and stability studies. The preformulation studies of API and drug excipients compatibility studies were carried out. IR spectroscopic analysis of drug with excipients was showed that the drug was compatible with excipients which were used in the formulation. The prepared powder blend was evaluated for parameters like angle of repose, bulk density, tapped density, compressibility index and Hausner ratio. The obtained results indicated that it has good flow property for direct compression method. The prepared tablets were evaluated for hardness, weight variation, friability, assay, Swelling Index and Buoyancy Study. All these parameters were found to be within the pharmacopoeial limits. Formulation F5 was selected for drug release and stability study on the basis of appropriate results of post compression stdy. In vitro dissolution study was carried out for F-5 formulation. The drug release was found to be 97.4 % at 10 hrs and showed controlled release pattern. in vitro Buoyancy Study of formulation showed good results. The accelerated stability studies of F-5 formulation at 40oC/75% RH for a period of 3 months indicated that there was no significant change in description, drug content and in vitro dissolution profiles. Formulation showed good release results thus, results of the current study clearly indicate, Cephalexin floating tablet was a stable dosage form and a promising

potential of the Cephalexin gastroretentive system as an alternative to the conventional dosage form for controlled release. However, further clinical studies are needed to assess the utility of gastroretentive Cephalexin floating formulation.

KEYWORDS: GERD, Rabeprazole Sodium, Buffered Tablet, Fast Release Tablet.

INTRODUCTION

Oral administration is the most convenient and chosen means of any drug delivery to the systemic circulation. Oral controlled release drug delivery has been of increasing interest in pharmaceutical field to achieve improved therapeutic advantages, such as ease of dosing administration, patient compliance and flexibility in formulation.

Drug delivery refers to approaches; formulations technologies and system for transporting a pharmaceutical compound in the body as need to safety achieve its desired therapeutic effect.

TYPES OF DRUG DELIVERY SYSTEM

1. CONVENTATIONAL DRUG DELIVERY SYSTEM

- Oral Delivery
- Buccal / Sublingual delivery
- Rectal Delivery
- Intravenous Delivery
- Subcutaneous Delivery
- Intra muscular Delivery etc.,

2. **NOVEL DRUG DELIVERY SYSTEM**

a) Targeted drug delivery

b) Controlled /Sustained Release drug delivery system

c) Gastro retentive drug delivery system:

- Floating Drug delivery system
- Bio / muco adhesive system

GASTRORETENTIVE DRUR DELIVERY SYSTEMS[1]

A controlled drug delivery system with prolonged residence time in the stomach is of particular interest for drug that

i. Are local active in the stomach.

ii. Have an absorption window in the stomach or in the upper small intestine
iii. Are unstable in the intestinal or colonic environment or
iv. Exhibit low solubility at higher value.

PHYSIOLOGICALCONSIDERATIONS[1,2]

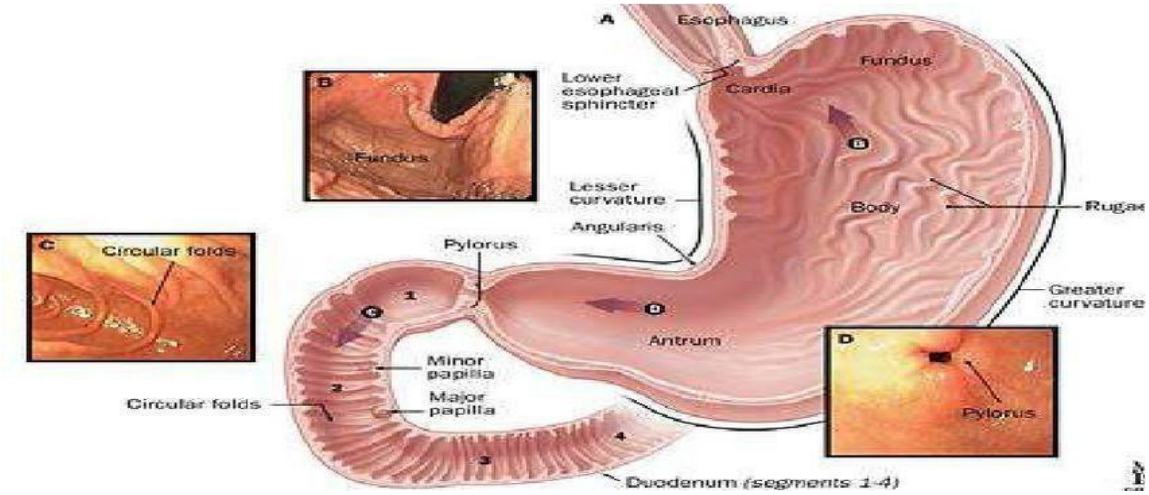

Figure 1.1: Anatomy of stomach.

Stomach Physiology[2,3]

The stomach is categorized into 3 anatomic regions: fundus, body, and antrum (pylorus). The part of fundus and body turns as a reservoir for undigested material, whereas the antrum is the main site for mixing motions and act as a pump for gastric emptying by propelling actions. The separation between stomach and duodenum is the pylorus. The pylorus, plays a major role in gastric residence time of GRDF due to its size.

The stomach provides for short term food reservation and quick consumption of relatively large meal. The primary substantial metabolism of enzymes is promoted in stomach of proteins. The peristalsis of stomach mix up and grind consumed food with secretions of the stomach, turning food in simplified liquid form. The liquefied bulk is transported to the small intestine for further digestion.

Different Features of Stomach	
Gastric pH	Fasted healthy subject 1.1 ± 0.15 Fed healthy subject 3.6 ± 0.4
Volume	Resting volume is about 25-50 ml
Intestinal pH	In the duodenum, the section closest to the pyloric sphincter of the stomach may be acidic (due to the HCl).
Gastric secretion	Acid, pepsin, gastrin, mucus and some enzymes

	about 60ml with approximately 4ml of hydrogen ions per hour.
Intestinal secretion	Pancreatic secretion: trypsin, chymotrypsin and carboxy Polypeptidase, pancreatic amylase, pancreatic lipase
Intestinal Enzymes	Peptidase, disaccharides, intestinal lipase, intestinal amylase.
Effect of food on Gastric secretion :	About 3 liter of secretions are added to the food.

Table 1.1: Transit times of different dosage forms across the segments of GIT.

		Transit time (hours)	
Dosage form	**Gastric**	**Small intestine**	**Total**
Tablets	2.7±1.5	3.1±0.4	5.8
Pellets	1.2±1.3	3.4±1.0	4.6
Capsules	0.8±1.2	3.2±0.8	4.0
Solution	0.3±0.07	4.1±0.5	4.4

pH (Hydrogen Ion Concentration)

The pH of the stomach in fasting state is ~1.5 to 2.0 and in fed state is 2.0 to 6.0. A large volume of water administered with an oral dosage form raises the pH of stomach contents to 6.0 to 9.0. Stomach doesn't get time to produce sufficient acid when the liquid empties the stomach. The various pH of the gastro intestinal tract is shown below,

Table 1.2: The mean pH (+ S.D.) along the G.I. Tract in normal subjects.

Region	Mean pH
Stomach	1.8 + 0.6
Proximal Small Intestine	6.6 + 0.5
Mid Small Intestine	7.4 + 0.4
Distal Small Intestine	7.5 + 0.5
Right Colon	6.3 + 0.6
Mid Colon	6.6 + 0.8
Left Colon	7.1 + 0.7

FACTORS CONTROLLING GRDDS.[4] Factors controlling GRDDS are shown in Figure 1.2 and some of the factors are enumerated below:

1. **Density:**
2. **Size:**
3. **Shape:**
4. **Single or multiple unit formulation:**
5. **Fed or Unfed State:**
6. **Nature of Meal:**
7. **Frequency of Feed**:

8. **Caloric Content:**
9. **Gender:**
10. **Age:**
11. **Disease State:**
12. **Concomitant Intake of Drug:**
13. **Posture:**

APPROACHES TO GASTRICRETENTION[5]

To enhance the gastro retention of the orally administered drugs by different approaches which including floating and non-floating systems.[11]

I. FLOATING DRUG DELIVERY SYSTEMS

The concept of FDDS was described in the literature as early as. FDDS have a bulk density less than gastric fluids and so remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. While the system is floating on the gastric contents the drug is released slowly at the desired rate from the system. This results in an increased GRT and a better control of fluctuations in plasma drug concentration.

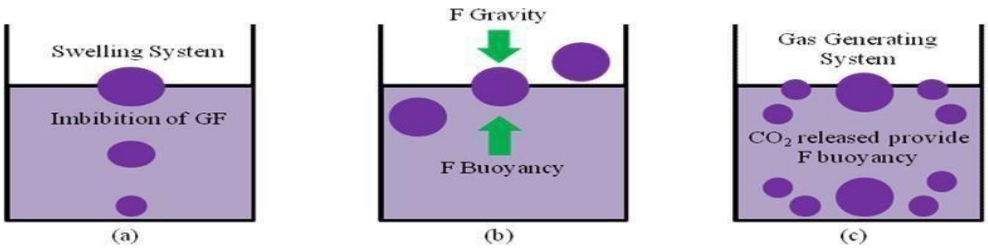

Figure 1.4: Mechanism of floating system [a=swelling system, b=force of gravity and c=gas generating system

Mechanism of action involves in floating drug delivery systems[6]

Floating system on the gastric, the drug are released slowly at the desired rate from the system. After release of drug, the residual system are emptied from the stomach besides a minimal gastric content needed to allow the proper achievement of the buoyancy retention principle, a minimal level of floating force (F) is also required to keep the dosage form dependably buoyant on the surface of the meal18.

F=F buoyancy – F gravity F= (DF-Ds) g

Where,

F=total vertical force, DF= fluid density,

Ds = object density, v = volume and g = acceleration due to gravity

DIFFUSION

On contact with aqueous fluids in the gastrointestinal tract (GIT), water diffuses into the interior of the particles. Drug dissolution occurs and the drug solutions diffuse across the release coat to the exterior.

Erosion

Some coatings can be designed to erode gradually with time, thereby releasing the drug contained within the particles.

Osmosis

In allowing water to enter under the right circumstances, an osmotic pressure can be built up within the interior of the particle. The drug is forced out of the particle into the exterior through the coating.[18]

TYPES OF FLOATING DRUG DELIVERY SYSTEMS

Based on the mechanism of buoyancy and two distinctly different technologies have been utilized in the development of FDDS.

I. Effervescent Floating Drug Delivery System
II. Non- Effervescent Floating Drug Delivery System

I.1. EFFERVESCENT FLOATINGDRUG DELIVERY SYSTEM1[7]

Floating systems come under low density approach. In this approach, the density of pellets should be less than 1 g/ml, so as to float the pellets or tablets in the gastric fluid and, release the drug slowly for a longer period of time.

II. NON-FLOATING SYSTEM

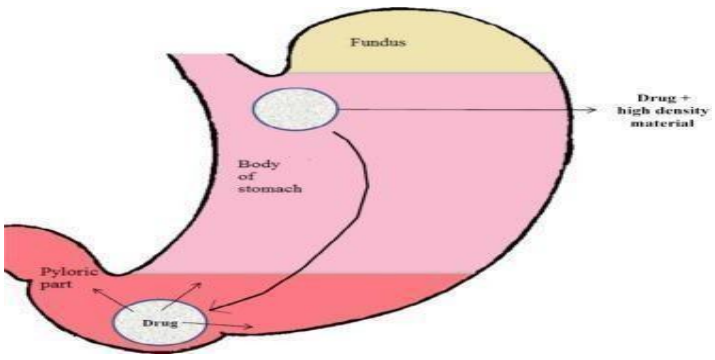

Figure 1.10: GRDDS based on high density.

II.1. BIO/MUCO-ADHESIVE SYSTEMS[9]

Bio/muco-adhesive systems, bind to the gastric epithelial cell surface or mucin, which extends the GRT of drug delivery system in the stomach. The ability to provide adhesion of a drug delivery system to the gastrointestinal wall provides longer residence time in a particular organ site, it improved effect in terms of local action or systemic effect. Binding of polymers to the mucin/epithelial surface can be divided into three categories:

POLYMERS AND OTHER INGREDIENTS USED IN GRDDS TABLETS[15]

Following types of ingredients can be incorporated into HBS dosage form in addition to the drugs

1. Hydrocolloids (20%-75%)

They can be synthetics, anionic or non-ionic like hydrophilic gums, modified cellulose derivatives. E.g. Acacia, pectin, Chitosan, agar, casein, bentonite, Veegum, HPMC (K4M, K100M and K15M), Gellan Gum (Gel rite®), Sodium CMC, MC, HPC.

2. Inert fatty materials (5%-75%)

Edible, inert fatty materials having a specific gravity of less than one can be used to decrease the hydrophilic property of formulation and hence increase buoyancy. E.g. Beeswax, fatty acids, long chain fatty alcohols, Gelucires® 39/01 and 43/01.

3. Effervescent agents

E.g. Sodium bicarbonate, citric acid, tartaric acid, Di- SGC, CG.

4. Release rate accelerants (5%-60%)

E.g. lactose, mannitol.

5. Release rate retardants (5%-60%)

E.g. Dicalcium phosphate, talc, magnesium stearate.

6. Buoyancy increasing agents (upto80%)

E.g. Ethyl cellulose, Polysaccharides.

7. Low density material

E.g. Polypropylene foam powder.

EVALUATION PARAMETERS FLOATING DRUG DELIVERY SYSTEM1.[16]

i) Floating time

The test for floating time is usually prepared in simulated gastric fluid or 0.1 mole. lit-1 HCl maintained at 37^0 C, by using USP dissolution apparatus containing 900ml of 0.1 molar HCl as the dissolution medium. The time taken by the dosage form to float is termed as floating lag time and the time for which the dosage form floats is termed as the floating or floatation time.

ii) Drug release

Dissolution tests are performed using the dissolution apparatus. Samples are withdrawn periodically from the dissolution medium with replacement and then analyzed for their drug content after an appropriate dilution.

iii) Measurement of buoyancy capabilities of the FDDS

The floating behavior was evaluated with resultant weight measurement. The experiment was carried out in two different media like deionized water and simulated meal, in order to monitor possible difference. The results showed that higher molecular weight polymers with slow rate of hydration had enhanced floating behavior and which was more in simulated meal medium compared to deionized water.

iv) Content uniformity, Hardness, Friability (Tablets)

These test are performed as per described in specified monographs.

Resultant weight: The *in vitro* measuring apparatus has been conceived to determine the real floating capabilities of buoyant dosage form as a function of time. It operates by force equivalent to the force F required to keep the object totally submerged in the fluid. This force determine the resultants weight of the object when immersed and may be used to quantify its floating or non-floating capabilities. The magnitude and direction of the force and the resultant weight corresponds to the Victoria sum of buoyancy (F buoy) and gravity (F grav) forces acting on the objects as shown in the equal. In which the F is total vertical force (resultant weight of the object). G is the acceleration due to gravity, df if the fluid density, ds is the object mass and V is the volume of the object.

v) X-Ray /Gamma scintigraphy

X-Ray /Gamma scintigraphy is a popularly used evaluation parameter for floating dosage form these days. It helps to locate dosage form in the GIT and by which one can predict and correlate the emptying time and the passage of dosage form in the GIT. Here the inclusion of a

ratio –opaque material into a solid dosage form enables it to be visualized by X-rays. Similarly, the inclusion of a γ-emitting ratio nuclide in a formulation allows indirect external observation using γ-camera or scinti scanner.

2. Research Envisaged

Development and Evaluation of low density tablet of Cephalexin using rate Controlling polymer.

OBJECTIVE

The present work is aimed to formulate Cephalexin floating tablets using different hydrophilic and hydrophobic polymers like HPMC, Ethyl cellulose, Xanthum gum, guar gum and gas generating agent Sodium bicarbonate.

The objective of the present work is to develop Gastro retentive dosage form that could retain the agent namely Cephalexin in the stomach for longer periods of time delivering the drug to the site of action, i.e., stomach.

Cephalexin is an antimicrobial agent. It is soluble in water with 75% bioavailability. HPMC is used as a swelling agent, Guar gum and Xanthum gum is used as binding agent. Ethyl cellulose is used as matrix form agent. PVP is used as a suspending agent. Sodium bicarbonate is used as a gas forming agent. MCC is used as a disinter grant and diluents. Magnesium stearate is used as a lubricant.

The prepared Cephalexin tablets will be evaluated for drug content, entrapment efficiency, post compression studies, In-vitro buoyancy studies, swelling index studies, in-vitro dissolution studies, release kinetics, stability studies.

3. Plan of Work

PHASE - 1: Preformulation studies

- Literature survey
- Procurement of Drug
- Analytical investigation of drug and systematic excipient selection

- Color, Taste, Odour, Melting Point, Solubility & Partition coefficient determination studies
- Identification of drug by UV absorption maxima & FTIR studies

- DSC Thermo grams study
- Drug excipient compatibility studies

➢ Preparation of Calibration curves

➢ Pre compression studies

PHASE-2: Formulation of Floating Tablet of Cephalexin PHASE-3: Evaluation of Prepared Formulation

➢ Post compression studies

➢ Drug content

➢ *In-vitro* Buoyancy Studies

➢ Swelling Index Study

➢ *In-vitro* Dissolution release studies

➢ Release Kinetics

DRUG PROFILE

Cephalexin

Trade Name: Cefalexin, Keflex

Structure

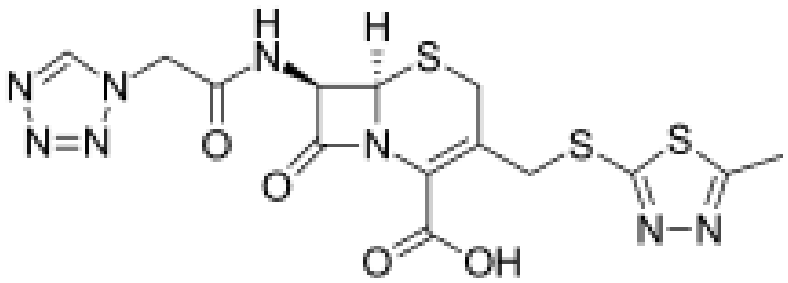

Figure 3.1: Structure of Cepfalexin.

➢ **IUPAC Name:** (7*R*)-3-methyl-7-(α-D-phenylglycylamino)-3-cephem-4-carboxylic acid monohydrate

➢ **Empirical formula:** $C_{16}H_{17}N_3O_4S$

➢ **Molecular weight:** 347.39 $g \cdot mol^{-1}$

➢ **Melting point:** 326.8 ^0C

➢ **Description:** White to off-white crystalline solid with a bitter taste

➢ **Category:** Antibacterial

➢ **Solubility:** low to moderate **water** solubility, with values often cited around 1-2

mg/mL at room temperature and up to 10 mg/mL or higher in some conditions. It is considered insoluble in common organic solvents like alcohol, chloroform, and ether.

- **Storage:** Stored in tightly closed, light resistant container in a cool, dry place.
- **Drug class:** First generation cephalosporin
- **Mechanism:** Cephalexin is a first generation cephalosporin antibiotic. Cephalosporins contain a beta lactam and dihydrothiazide. Unlike penicillins, cephalosprins are more resistant to the action of beta lactamase. Cephalexin inhibits bacterial cell wall synthesis, leading breakdown and eventualy cell death.

PHARMACOKINETIC DATA

- BIOAVAILABILITY: Well absorbed (100% by oral)
- ROUTE OF ADMINISTRATION: Oral routes
- EXCRETION: Urine (Kidney)
- MELTING POINT: 326.8 DEGREE CELCIUS

Prescribed for

Cephalexin is effective against susceptible bacteria causing infections of the middle ear (otitis media), tonsils (tonsillitis), throat, larynx (laryngitis), bronchi (bronchitis, lungs (pneumonia), and skin and soft tissue.

Dosing

Cephalexin is taken once or twice daily, depending on the nature and severity of the infection. The capsules or suspension can be taken with or without food. Patients with advanced renal diseases may need to .take lower doses.

Pregnancy

There are no adequate studies of Cephalexin in pregnant women. However, studies in animals suggest no important effects on the fetus. Cephalexin therefore can be used in pregnancy if the physician feels that it is necessary.

Side effects

Cephalexin generally is well tolerated. The most common side effects are diarrhea or loose stools, nausea, abdominal pain, and vomiting, each of which may occur in fewer than one in thirty persons who receive the drug. Rarer side effects include abnormal liver tests and allergic reactions. Cephalexin may cause false test.

Clinical Pharmacology

Pharmacokinetics and Drug Metabolism

Absorption

Oral Bioauailabittty: Maximal plasma Cephalexin concentrations occur 2 to 4 hours postdose following capsule or suspension administration. Plasma Cephalexin concentrations increase with dose, but the increases are less than dose-proportional from 300 mg (7 mg/kg) to 600 mg (14 mg/kg). Following administration of suspension to healthy adults, Cephalexin bioavailability is 120% relative to capsules. Estimated bioavailability of Cephalexin capsules is 21% following administration of a 300 mg capsule dose, and 16% following administration of a 600 mg capsule dose. Estimated absolute bioavailability of Cephalexin suspension is 25%.

Effect of Food

Although the rate (Cmax) and extent (AUC) of Cephalexin absorption from the capsules are reduced by 16% and 10%, respectively, when given with a high-fat meal, the magnitude of these reductions is not likely to be clinically significant. Therefore, Cephalexin may be taken without regard to food.

Metabolism and Excretion

Cephalexin is not appreciably metabolized. Activity is primarily due to parent drug. Cephalexin is eliminated principally via renal excretion with a mean plasma elimination half-life (ty2) of 1.7 (±0.6) hours. In healthy subjects with normal renal function, renal clearance is 2.0 (±1.0) mL/min/kg, and apparent oral clearance is 11.6 (±6.0) and 15.5 (±5.4) mL/min/kg following doses of 300 and 600 mg, respectively. Mean percent of dose recovered unchanged in the urine following 300- and 600-mg doses is 18.4% (±6.4) and 11.6% (±4.6), respectively. Cephalexin clearance is reduced in patients with renal dysfunction Because renal excretion is the predominant pathway of elimination, dosage should be adjusted in patients with markedly compromised renal function or who are undergoing hemodialysis.

MATERIAL AND METHODS

List of Materials used in the formulation

Table 5.1: List of Materials used in the formulation.

S.No.	Material	Company
1	Cephalexin	M/s Hetero Drugs Ltd., Hyderabad, India
2	HPMC	Sisco research laboratories Pvt.

		Ltd., Mumbai
3	Xanthum Gum	MYL CHEM Mumbai
4	Guar Gum	MYL CHEM Mumbai
5	PVP	Sisco research laboratories Pvt., Ltd Mumbai
6	Ethyl Cellulose	MYL CHEM Mumbai
7	Sodium Bicarbonate	SD Fine Chemicals Ltd., Mumbai
8	Micro Crystalline Cellulose	SD Fine Chemicals Ltd., Mumbai
9	Magnesium Stearate	SD Fine Chemicals Ltd., Mumbai
10	Hydrochloric acid	SD Fine Chemicals Ltd., Mumbai

B. Equipment's Used

Table 5.2: List of Equipment Used For the Formulation.

S. No	Name of the Equipment	Make/Model
1	Dissolution apparatus	Jyoti Scientific, India
2	Tablet punching machine	Cad mach
3	U.V. Spectrophotometer	Shimadzu 1800
4	Analytical Balance	Jyoti Scientific, India
5	Friability Apparatus	Electro Lab
6	Hardness tester	Jyoti Scientific, India
7	FT-IR Spectrometer	Bruker, India

5.1 Preformulaion study

Preformulation studies are designed to determine the compatibility of initial excipients with the active substance for a biopharmaceutical, physicochemical and analytical investigation in support of promising experimental formulations. Successful formulations take into account a drug's interactions with the physicochemical properties of other ingredients and their interactions with each other to produce a safe, stable, beneficial and marketed product. The basic purpose of the preformulation activity are to provide a rational basis for the formulation approaches, to maximize the formulation activity is careful consideration of a complete physicochemical profile of the active ingredients available prior to initiating a formulation development activity.

6. Experimental work & Result Discussion

5 Preformulation Studies

6.1 Description

The colour, odour, nature and taste of the API were evaluated. It was found to be as per the monograph.

Table 6.1: Description of Cephalexin.

S. No.	Tests	Results
1	Colour	White
2	Odor	Unpleasant

5.4 Solubility study

Solubility study of Cephalexin is reported in table 6.2.

Table 6.2: Solubility Study of Cephalexin.

S.No.	Solvent	Solubility
1.	Water	+ - - -
2.	0.1N HCl	++ --
3.	Phosphate Buffer (6.8 pH)	+++ -

5.5 Melting point determination

The melting point of RPS was found to be 169.5^{o} C.

5.6 Determination of λ_{max}

Solution was scanned under UV-Vis Spectrophotometer and λmax was determined. It was found to be as per the monograph./////////tyhg.

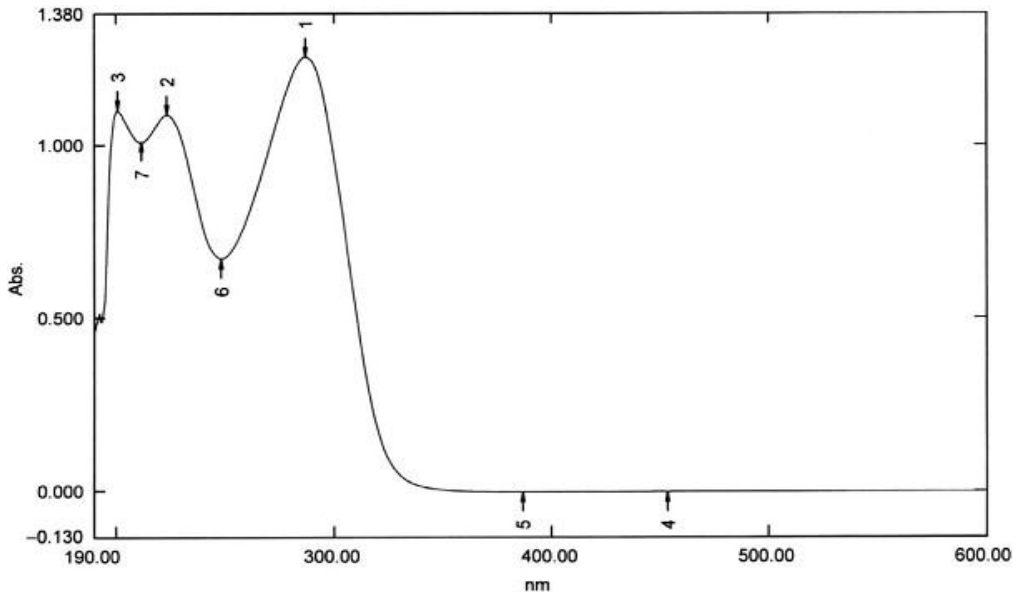

Figure 6.1: UV spectra of Cephalexin.

Table 6.3: Wavelength of maximum absorption of Cephalexin in 0.1N HCL.

Sl. No.	Solvent	Λmax
1	0.1N HCL	258.5, 260.5, and 263 nm

Table 6.4: Partition coefficient of Cephalexin in 0.1N HCL.

Sl. No.	Solvent	Partition coefficient
1	n-octanol	1.2

Table 6.5: Standard calibration Curve data of Cephalexin in 0.1N HCL.

Sl. No	Concentration (µg/ml)	Absorbance at λmax 263 nm
1	0	0
2	2	0.124
3	4	0.321
4	6	0.413
5	8	0.509
6	10	0.648
7	12	0.779
8	14	0.948

From the spectra of Cephalexin physical mixture of drug and selected ingredients it was observed that all characteristic peaks of Cephalexin, were present in the combination spectrum, thus indicating compatibility between drug and selected ingredients. FTIR Spectra shown in Fig and table.

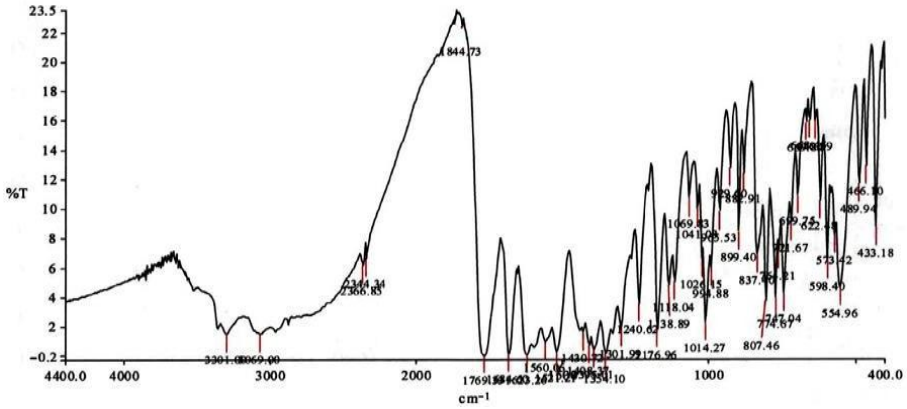

Figure 6.3: Standard FTIR spectra of Cephalexin.

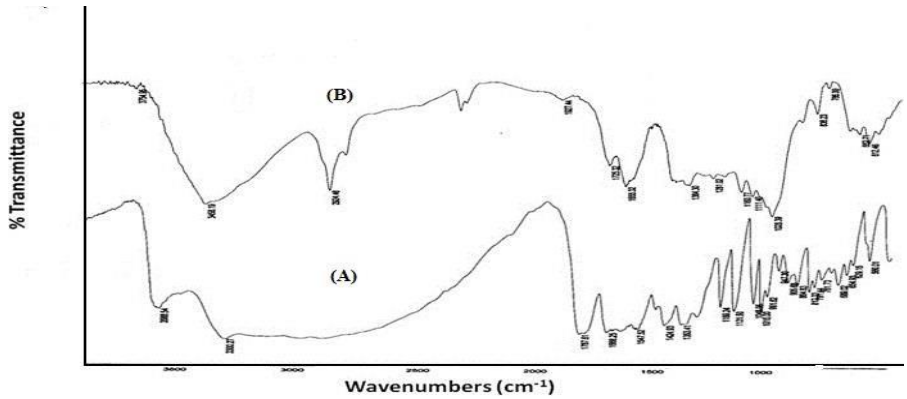

Figure 6.4: FTIR Spectra of Plane Cephalexin (A) and Floating Tablet Formulation (B).

S. No	Wave Number (cm-1)	Functional Group
1.	3302, 3170	–NH –
2.	2980	CH aliphatic
3.	1784	B-Lactum
4.	1520	–NH –
5.	1350, 1334	NH2
6.	11611, 1429	-COOH
7.	1010	NO

6.6 Evaluation of Powder Blend (Post compression evaluation of Cephalexin tablet)

Precompression studies of powdered blend were performed on parameters like bulk density, tapped density, compressibility index, Hausner's ratio and angle of repose as shown in the table below. Angle of repose was found to be 26.62, 27.46, 28.32, 28.06, 27.58 and 28.44. Bulk density was found to be 0.721, 0.710, 0.415, 0.454, 0.458 and 0.445 g/cm3, tapped density 0.872, 0.879, 0.483, 0.525, 0.505 and 0.502 g/cm3, Hausner's ratio 1.206, 1.251, 1.178, 1.155,1.119 and 1.123, Carrs index 17.126, 19.714, 15.113, 15.602, 12.234 and 12.585 were found for F1, F2, F3,F4, F5 and F6 formulation respectively and reported in table.

All the tablets showed elegance in appearance. The hardness of the tablets was measured by Monsonto hardness tester. The hardness of all the formulations was found to be in the range of 7.2 to 7.6 kg/cm2. It indicates all the tablets have adequate mechanical strength.

Twenty tablets of each formulation were selected for weight variation test. The accepted percentage deviation was ±7.5 for 130-324mg weight tablets. It was within the I.P. limit and all the tablets passed the weight variation test. Friability test was carried out by Roche friabilitor. The maximum weight loss should be not more than 1%. All the tablets passed the friability test.

The concentration of the natural polymers increases the floating lag time also increases and total floating time observed for all the formulations was >10 hours.

In-vitro drug release studies were done for the selected study formulations. The drug release was found to show maximum drug release in case of F5 with 97.4% in 10 hrs. as shown in table and figure.

Table 6.7: Evaluation of Powder Blend (Post compression evaluation of Cephalexin tablet)

Formulation code	Bulk density (gm/mL)	Tapped density (gm/mL)	Compressibility index (%)	Hausner's ratio	Angle of repose (θ)
F1	0.721	0.872	17.126	1.206	26.62
F2	0.710	0.879	19.714	1.251	27.46
F3	0.415	0.483	15.113	1.178	28.32
F4	0.454	0.525	15.602	1.155	28.06
F5	0.458	0.505	12.234	1.119	27.58
F6	0.445	0.502	12.585	1.123	28.44

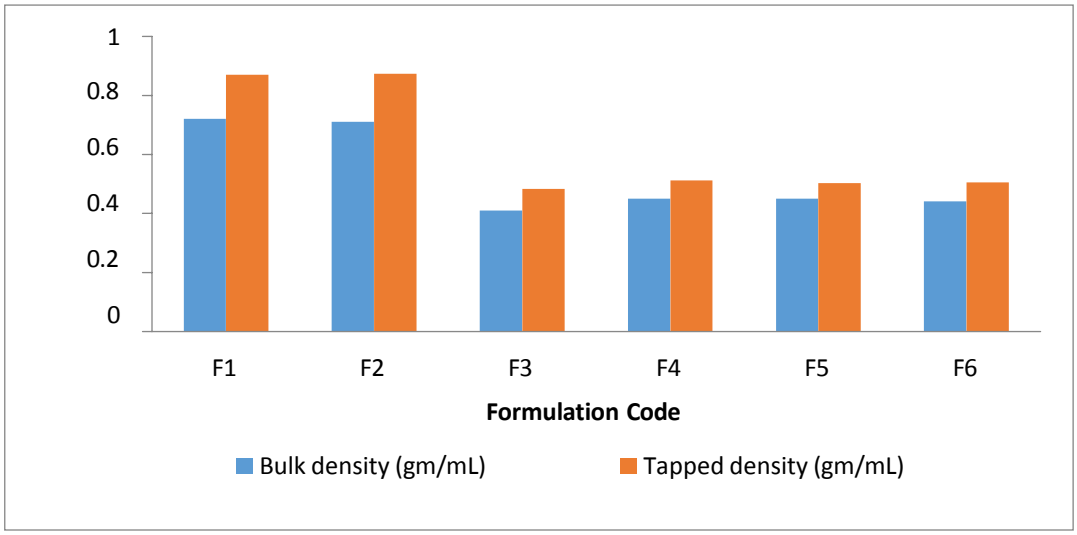

Figure 6.5: FTIR spectra of Cephalexin.

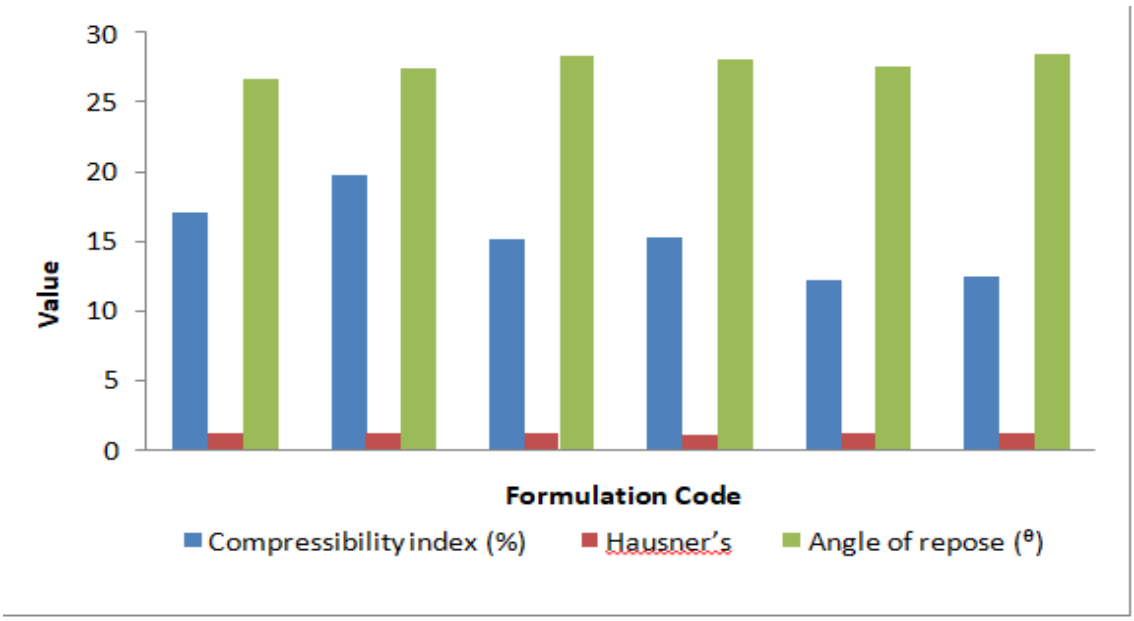

Figure 6.6: FTIR spectra of Cephalexin.

Table 6.8: Post compression evaluation parameters of Cephalexin floating tablets.

Formulation No.	Avg. Weight (Mean± S.D) (n=20)	Hardness (kg/cm2) (n=3)	Friability (Mean±S.D) (n=6)	% Drug content (mg)	Buoyancy Lag time (min)	Total floating Time (hr.)
F1	353.44±0.6	7.2±0.4	0.546	98.25±0.7	26	5
F2	350.23±0.9	7.5±0.4	0.612	99.34±0.5	18	6
F3	347.67±0.3	7.4±0.6	0.527	98.33±0.6	20	10
F4	351.71±0.4	7.6±0.1	0.511	99.12±0.6	30	8
F5	346.38±0.8	7.6±0.6	0.525	99.05±0.6	61	8
F6	354.26±0.8	7.3±0.4	0.555	98.68±0.5	35	10

* All the values are expressed

as mean ± SD; n=3.

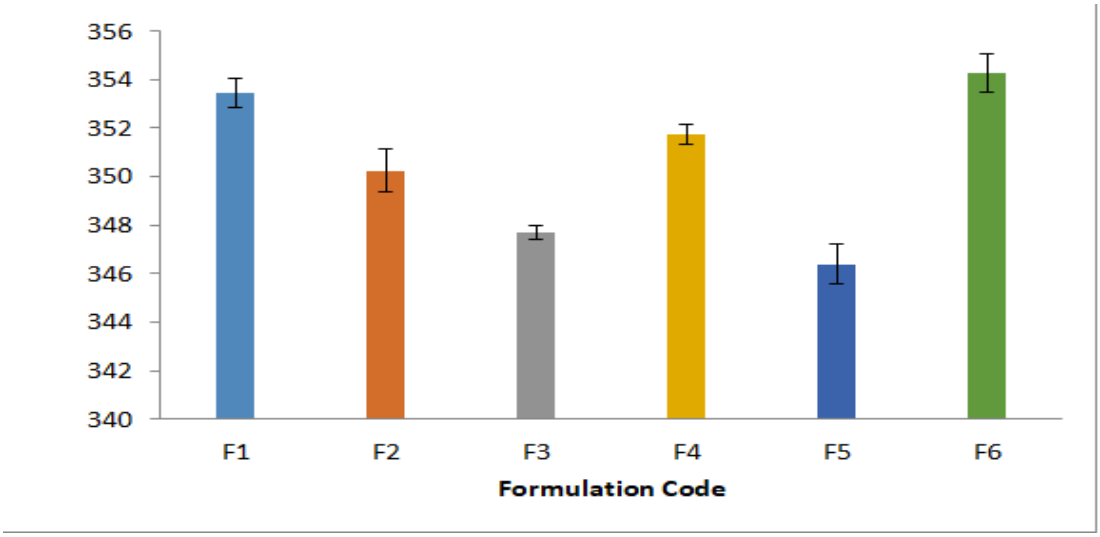

Figure 6.8: Hardness Studies of Cephalexin Floating Tablets Formulations.

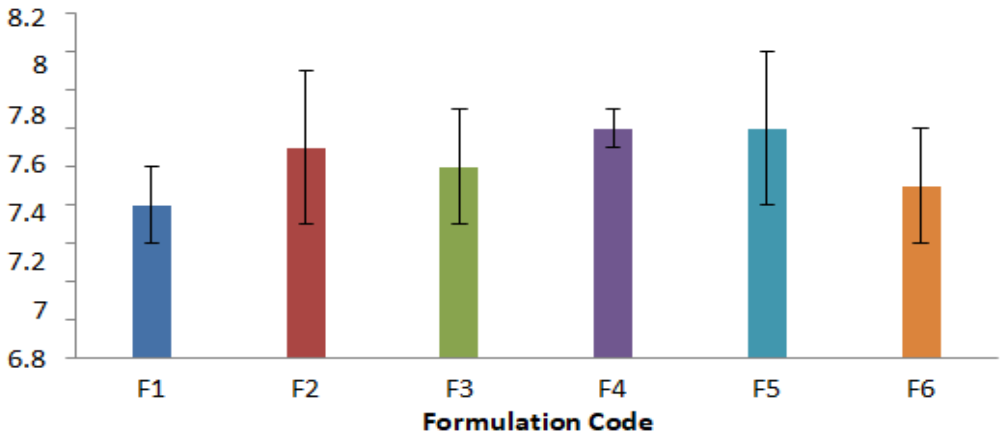

Figure 6.9: % Drug Content Studies of Cephalexin Floating Tablets Formulations.

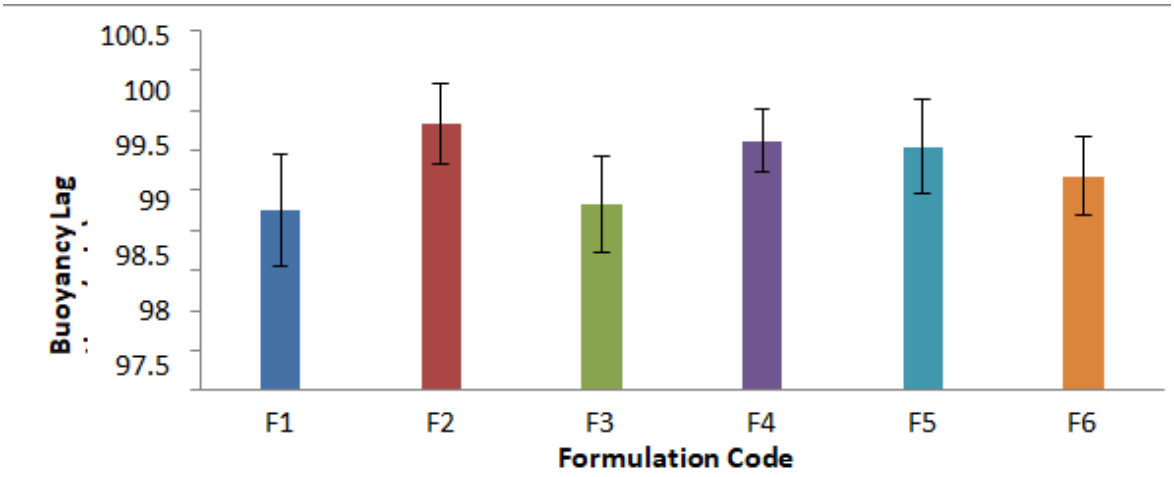

Figure 6.10: Buoyancy Lag Time (Min.) Studies of Cephalexin Floating Tablets Formulations.

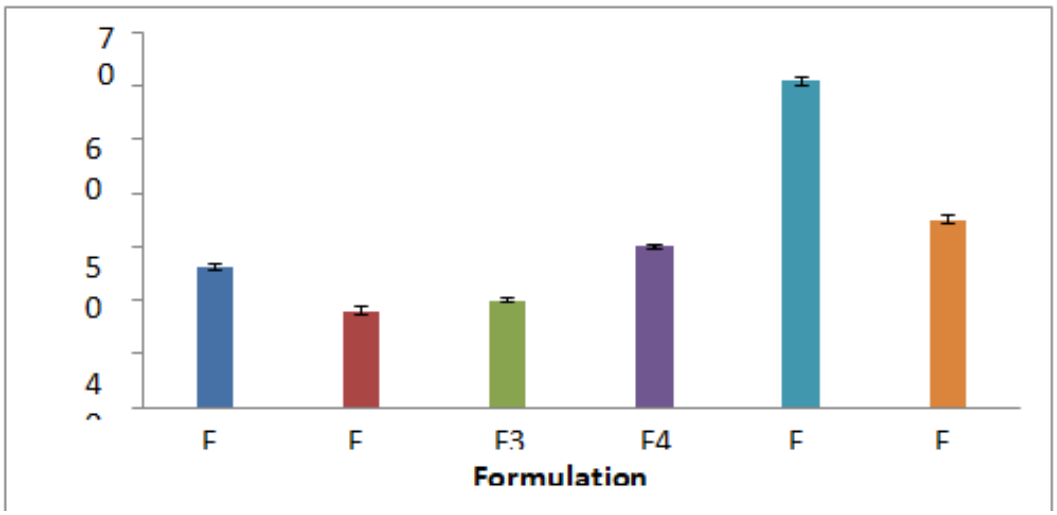

Figure 6.11: Friability Studies of Cephalexin Floating Tablets Formulations

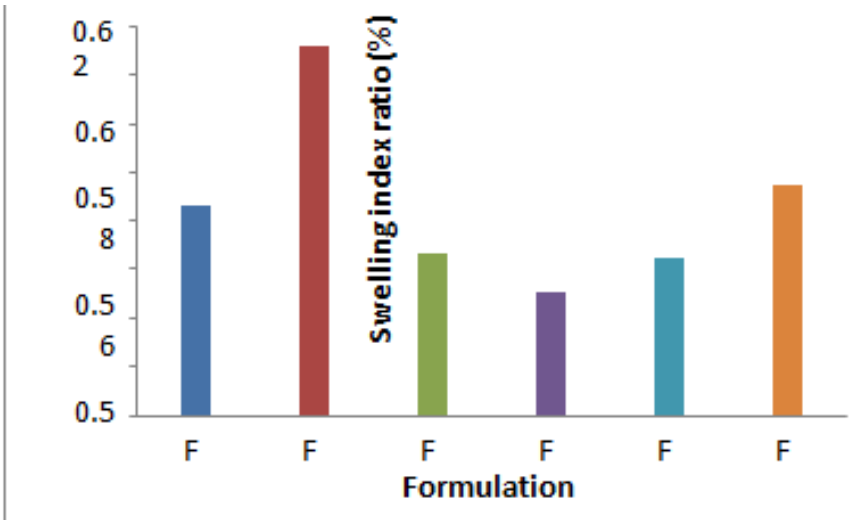

Figure 6.12: Total Floating Time Studies of Cephalexin Floating Tablets Formulations.

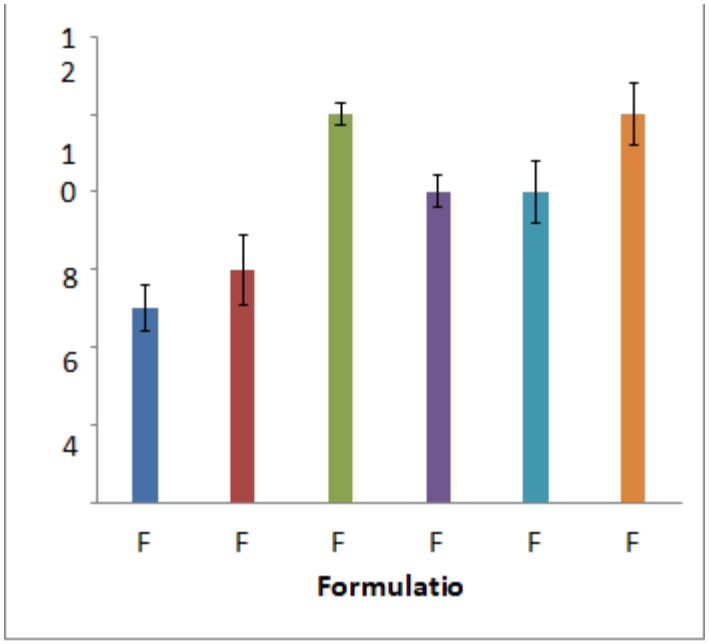

Figure 6.13: Swelling index ratio (%) Studies of Floating Tablets Formulations Table 6.10: % of Drug Release Studies of Floating Tablets Formulations.

Time (hr)	Swelling index ratio (%)					
	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
2	32	35	42	46	50	55
4	46	48	50	51	58	60
6	52	55	58	65	67	72
8	49	50	52	54	59	64

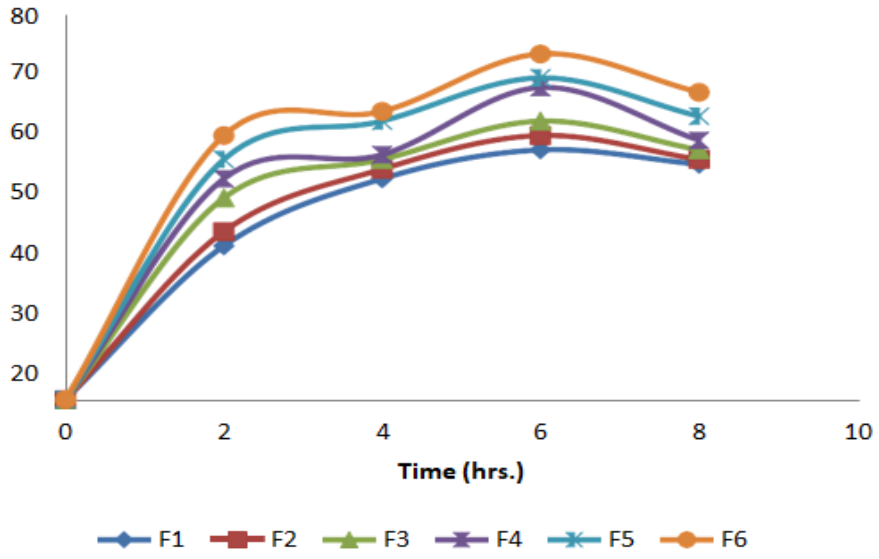

Figure 6.14: Photographic representation of Swelling index ratio (%) Studies.

TIME (hr)		% of Drug Release				
	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	
1	18.8	14.3	11.3	16.5	12.4	9.2
2	39.9	22.2	21.4	29.8	30.8	19.3
3	52.3	37.6	32.8	41.9	42.3	26.9
4	76.9	46.8	46.1	50.2	49.4	38.2
5	92.8	76.8	58.4	61.1	60.3	46.8
6	92.8	96.3	69.5	72.7	76.4	58.3
8	92.8	96.3	79.9	96.3	90.2	71.4
10	92.8	96.3	90.4	96.3	97.4	84.9

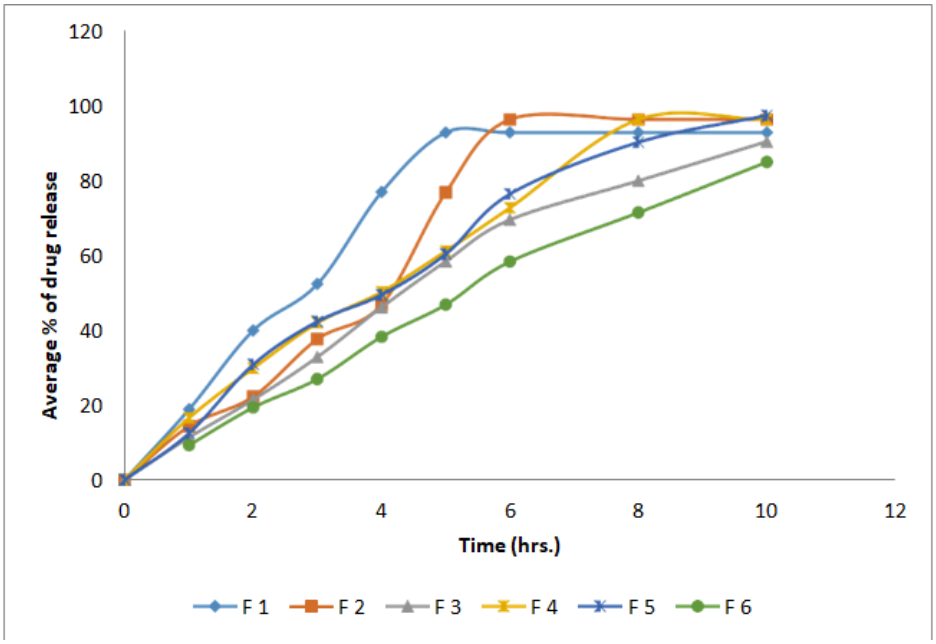

Figure 6.15: % of Drug Release Studies of Floating Tablets Formulations Figure.

6.7 Stability Studies of Tablets

Stability testing was conducted to know how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors. In the present stability study of the optimized batch, all the results were found to be satisfactory and within limits. There were no significant changes after the period of study. (Table 6.14)

S. No	Time points (hr)	Initial	Cumulative % Drug Release			
			25˚C/60%RH		40˚C/75%RH	
			1st Month	3rd Month	1stMonth	3rdMonth
1	1	12.4	12.2	11.7	11.2	10.7
2	2	30.8	30.4	30.1	29.4	29.1
3	3	42.3	42.1	41.8	39.6	39.2
4	4	49.4	49.0	48.6	47.8	47.4
5	5	60.3	58.3	59.4	59.1	58.6

6	6	76.4	76.1	75.5	75.1	74.9
7	8	90.2	89.8	89.2	88.7	88.1
8	10	97.4	97.1	96.5	96.1	95.8
9	Assay	99.5	99.2	99.1	98.7	98.5

Formulation and evaluation of Gas Powered Systems of Cephalexin Tablets was carried out by performing the preformulation studies, formulation of tablets, evaluation parameters, *in vitro* drug release studies and stability studies..

6.8 RESULT DISCUSSION

The preformulation studies of API and drug excipients compatibility studies were carried out.

- IR spectroscopic analysis of drug with excipients was showed that the drug was compatible with excipients which were used in the formulation.
- Cephalexin Floating tablets were prepared by direct compression method.
- The prepared powder blend was evaluated for parameters like angle of repose, bulk density, tapped density, compressibility index and Hausner ratio. The obtained results indicated that it has good flow property for direct compression method.
- The prepared tablets were evaluated for hardness, weight variation, friability, assay, Swelling Index and Buoyancy Study. All these parameters were found to be within the pharmacopoeial limits**. Formulation F5** was selected for drug release and stability study on the basis of appropriate results of post compression stdy.
- *In vitro* dissolution study was carried out for **F-5 formulation**. The drug release was found to be 97.4 % at 10 hrs and showed controlled release pattern.
- *in vitro* Buoyancy Study of formulation showed good results.
- The accelerated stability studies of F-5 formulation at 40^{o}C/75% RH for a period of 3 months indicated that there was no significant change in description, drug content and *in vitro* dissolution profiles. The result shows that the F-5 formulation was stable.

7. CONCLUSION AND SUMMARY

Formulation and evaluation of Gas Powered Systems of Cephalexin Tablets was carried out by performing the preformulation studies, formulation of tablets, evaluation parameters, *in vitro* drug release studies and stability studies.

The preformulation studies of API and drug excipients compatibility studies were carried out.

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