Formulation and in vitro evaluation of cefpodoxime proxetil gastro retentive floating tablets

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Abstract
In the present research work floating matrix tablet formulation of Cefpodoxime Proxetil was prepared by using different polymers. Initially analytical method development was done for the drug molecule. An absorption maximum was determined based on the calibration curve developed by using different concentrations. Gas generating agent sodium bicarbonate concentration was optimized. Then the formulation was developed by using different concentrations of Sodium CMC, Methyl Cellulose, Carrageenan as polymeric substances. The formulation blend was subjected to various preformulation studies, flow properties and all the formulations were found to be good indicating that the powder blend has good flow properties. Among all the formulations, The formulation prepared with Sodium CMC released the drug up to 24 hours (F2= 99.78%). The optimized formulation dissolution data was subjected to release kinetics, from the release kinetics data it was evident that the formulation followed Higuchi mechanism of drug release.

Keywords: Cefpodoxime Proxetil, Sodium CMC, Methyl Cellulose, Carrageenan, Floating Tablets.

INTRODUCTION
Oral delivery of drugs is by far the most preferred route of drug delivery due to ease of administration, patient compliance, and flexibility in formulation. From immediate release to site-specific delivery, oral dosage form has really progressed. It is evident from the recent scientific and patented literature that an increased interest in novel dosage forms that are retained in the stomach for prolong and predictable period of time exist today in academic and industrial research groups. Various attempts have been made to develop Gastro retentive delivery systems [1].

Floating Drug Delivery Systems and Its Mechanism
Floating drug delivery systems
Floating systems are low density systems that have sufficient buoyancy to float over the gastric contents and remain in the stomach for a prolonged period. While the system floats over the gastric contents, the drug is released slowly at the desired rate, which results in increased gastro-retention time and reduces fluctuation. However, 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 reliably buoyant on the Surface of the meal. To measure the floating force kinetics, a novel apparatus for determination of resultant weight has been reported in the literature. The apparatus operates by measuring continuously the force equivalent to F (as a function of time) that is required to maintain the submerged object. The object floats better if F is on the higher positives ideas shown in fig. This apparatus helps in optimizing FDDS with respect to stability and durability of floating forces produced in order to prevent the drawbacks of unforeseeable intragastric buoyancy capability variations [2].

F = F buoyancy – F gravity
= (DF – Ds) g v--- (1)
Where, F= total vertical force, DF = fluid density,
Ds= object density, v = volume and g = acceleration due to gravity.

Classification of Floating Drug Delivery Systems (FDDS)
(A) Effervescent FDDS
(I) Gas generating system (II) volatile liquid containing system

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B) Non-Effervescent FDDS
(I) Colloidal gel barrier system
(II) Microporous compartment system
(III) Floating microsphere
(IV) Alginate floating beads.
(C) Raft forming system

Effervescent System FDDS
These are matrix type of system. Prepared with the help of sellable polymer such as methylcellulose and Chitosan and various effervescent compounds. Ex: sodium bicarbonate, tartaric acid, citric acid.
These are formulated in such a way that when they come in contact with gastric content, CO₂ is liberated and gets entrapped in swollen hydrocolloid which provides buoyancy to dosage form. The design of delivery system was based on swellable asymmetric triple layer tablet approach [3].

(I) Gas Generating Systems
These are low density FDDS is based on the formation of CO₂ within the device following contact with body fluids. The materials are fabricated so that upon arrival in stomach, CO₂ is liberated by acidity of the gastric content and is entrapped in the gellified hydrocolloid this produce upward motion of the dosage form and maintain its buoyancy. (Fig.1)

Volatile Liquid Containing Systems (Osmotically Controlled DDS)
As an Osmotically controlled floating system, the device comprised of a hallow deformable unit that was convertible from a collapsed position after an extended period of time. A housing was attached to the deformable unit and it was internally divided into a first and second chamber with the chambers separated by an impermeable, pressure responsive movable bladder. The first chamber contain an active drug, while the second chamber contain a volatile liquid, such as cyclopentane or ether that vaporises at physiological temperature to produce a gas, enabling the drug reservoir to float. To enable the unit to exit from the stomach, the device contained a bioerodible plug that allowed the vapour to escape [7].

Non-Effervescent FDDS
Non-Effervescent FDDS use a gel forming (or) swellable cellulose type of hydrocolloids, Polysaccharide, matrix forming polymer like polycarbonate, polymethacrylate and polystyrene. One of the formulation methods involves the mixing of the drug with gel forming hydrocolloids which swell in contact with gastric fluid after oral administration and maintains integrity of shape and a bulk density barrier, the air trapped by swollen polymer confer buoyancy to the dosage forms [8].

Colloidal Gel Barrier Systems (Hydrodynamic Balanced Systems)
Such system contains drug with gel-forming hydrocolloids meant to remain buoyant on the stomach content. This prolongs GRT and maximizes the amount of drug that reaches its absorption site in the solution form for ready absorption, this system incorporates a high level of one or more gel-forming highly soluble cellulose type hydrocolloid e.g.(HPMC), polysaccharides and matrix forming polymer such as polycarbophil, polystyrene and polyacrylate. On coming in the contact with GI fluid, the hydrocolloid in the system hydrates and forms a colloid gel barrier around its surface [9]. Shown in fig 2.
Microporous Compartment Systems
This technology is based on the encapsulation of a drug reservoir inside a Microporous compartment with pores along its top and bottom walls. The peripheral wall of the drug reservoir compartment is completely sealed to prevent any direct contact of gastric surface with the undissolved drug. In the stomach, the floatation chamber containing entrapped air causes the floatation chamber containing entrapped air causes the delivery system to float over the gastric content. Gastric fluid enters through the aperture, dissolves the gastric fluid to an extent that it prevents their exist from the drug and carrier the dissolved drug for continuous transport across the intestine for absorption [10].

Floating Microspheres / Micro balloons
Hallow microspheres are considers as most promising buoyant system as they are more advantageous because of central hallow space inside the microsphere. Hallow microsphere is loaded with drug in their outer polymer shelf were prepared by a novel emulsion solvent Diffusion method [11] Fig.3.

Alginate Beads / Floating Beads
Multi-unit floating dosage forms have been developed from freeze calcium alginate. Spherical beads of approximately 2.5 mm in diameter can be prepared by dropping sodium alginate solution into aqueous solution of calcium chloride. Causing the precipitation of calcium alginate. The beads are then separated, snap-frozen in liquid nitrogen and freeze-dried at 400C for 24 h, leading to the formation of a porous system, this can maintain a floating force for over 12 h. these floating beads gave a prolonged residence time of more than 5.5 h.

Raft forming systems
Raft forming system have received much attention for the delivery of antacid and drug delivery for gastro infection and disorders on contact with gastric fluid a gel forming solution swells and forms a viscous cohesive gel containing entrapped co2 bubbles. Which forms raft layer on top of gastric fluid which releases drug slowly in stomach. (Often used for gastro esophageal reflux treatment [12].

Advantages of FDDS
FDDS is highly advantageous in the treatment of the disorders related to the stomach. As the prime objective of such systems is to produce a gastro retentive product or a product which has an enhanced retention time in the stomach [13].
Drugs with considerably short half life can be administered in this manner to get an appreciable therapeutic activity.

Enhancement of the bioavailability for drugs which can metabolized in the upper GIT.

They also have an advantage over the conventional system as it can be used to overcome the adversities of gastric retention time as well as the gastric emptying time.

The duration of treatment through a single dose, which releases the an active ingredient over an extended period of time.

The active entity is delivered specifically to the site of action, thus minimizing or eliminating the side effects.

Disadvantages of FDDS

The major disadvantage of floating system is requirement of a sufficient high level of fluids in the stomach for the drug delivery to float. However this limitation can be overcome by coating the dosage form with the help of bioadhesive polymers that easily adhere to the mucosal lining of the stomach [14].

Gastric retention is influenced by many factors such as gastric motility, pH and presence of food. These factors are never constant and hence the buoyancy cannot be predicted.

Drugs that cause irritation and lesion to gastric mucosa are not suitable to be formulated as floating drug delivery systems.

High variability in gastric emptying time due to its all (or) non-emptying process.

Patients should not be dosed with floating forms just before going to bed.

Floating system is not feasible for those drugs that have solubility (or) stability problem in gastric fluids.

The dosage form should be administered with a minimum of glass full of water (200-250 ml).

The drugs, which are absorbed throughout GIT, which under go first-pass metabolism (Nifedipine, Propranolol etc.), are not desirable candidate.

RESULTS AND DISCUSSION

Analytical Method

a. Determination of absorption maxima

The standard curve is based on the spectrophotometry. The maximum absorption was observed at 263 nm.

b. Calibration curve

Graphs of Cefpodoxime proxetil was taken in 0.1N HCL (pH 1.2). The data shown in Table 1 and Fig.5.

Standard graph of Cefpodoxime proxetil was plotted as per the procedure in experimental method and its linearity is shown in Table and Fig. The standard graph of Cefpodoxime proxetil showed good linearity with R² of 0.999, which indicates that it obeys "Beer- Lamberts" law.

Drug – Excipient compatibility studies by Fourier Transform-Infrared Spectroscopy

There was no disappearance of any characteristics peak in the FTIR spectrum of drug and the polymers used. (Fig 6). This shows that there is no chemical interaction between the drug and the polymers used. The presence of peaks at the expected range confirms that the materials taken for the study are genuine and there were no possible interactions. Cefpodoxime proxetil is also present in the physical mixture, which indicates that there is no interaction between drug and the polymers, which confirms the stability of the drug (Fig.7) & Table 2.

Preformulation parameters of powder blend

Tablet powder blend was subjected to various pre-formulation parameters. The angle of repose values indicates that the powder blend has good flow properties. The bulk density of all the formulations was found to be in the range of 0.42 to 0.55 (gm/ml) showing that the powder has good flow properties. The tapped density of all the formulations was found to be in the range of 0.49 to 0.65 showing the powder has good flow properties. The compressibility index of all the formulations was found to be below 18 which shows that the powder has good flow properties. All the formulations has shown the hausners ratio ranging between 1.12 to 1.22 indicating the powder has good flow properties Table 2.

Optimization of sodium bicarbonate concentration

Three formulations were prepared with varying concentrations of sodium bicarbonate by direct compression method and three more formulations were prepared by wet granulation method to compare the floating buoyancy in between direct and wet granulation methods. The formulation containing sodium bicarbonate in 15mg concentration showed less floating lag time in wet
granulation method and the tablet was in floating condition for more than 12 hours. (Fig.9,10,11,12 &13)

**Quality Control Parameters For tablets:**
Tablet quality control tests such as weight variation, hardness, and friability, thickness, Drug content and drug release studies were performed for floating tablets Table 3 & 4. From the dissolution data it was evident that the formulations prepared with Sodium CMC polymer showed better drug release. The formulation F2 prepared with Sodium CMC shows good drug release more than 12 hours in the concentration 100 mg. Whereas F1 and F3 formulations retards the drug release. The formulations F7, F9 prepared with Carrageenan as polymer releases the drug upto 12 hrs. But F8 formulation retards the drug release. Hence from the above dissolution data it was concluded that F2 formulation was considered as optimised formulation because good drug release (99.78%) in 24 hours (Fig13).

**Table 1. Calibration graph of Cefpodoxime proxetil**

<table>
<thead>
<tr>
<th>Concentration [µg/mL]</th>
<th>Absorbance</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>5</td>
<td>0.179</td>
</tr>
<tr>
<td>10</td>
<td>0.346</td>
</tr>
<tr>
<td>15</td>
<td>0.573</td>
</tr>
<tr>
<td>20</td>
<td>0.692</td>
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<tr>
<td>25</td>
<td>0.822</td>
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**Table 2. Pre-formulation parameters of blend**

<table>
<thead>
<tr>
<th>Formulation Code</th>
<th>Angle of Repose</th>
<th>Bulk density (gm/mL)</th>
<th>Tapped density (gm/mL)</th>
<th>Carr’s index (%)</th>
<th>Hausner’s Ratio</th>
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<tbody>
<tr>
<td>F1</td>
<td>23.78</td>
<td>0.42</td>
<td>0.49</td>
<td>14.28</td>
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<tr>
<td>F2</td>
<td>24.17</td>
<td>0.45</td>
<td>0.53</td>
<td>15.09</td>
<td>1.17</td>
</tr>
<tr>
<td>F3</td>
<td>25.62</td>
<td>0.51</td>
<td>0.59</td>
<td>13.55</td>
<td>1.15</td>
</tr>
<tr>
<td>F4</td>
<td>24.83</td>
<td>0.48</td>
<td>0.57</td>
<td>15.78</td>
<td>1.18</td>
</tr>
<tr>
<td>F5</td>
<td>24.14</td>
<td>0.53</td>
<td>0.65</td>
<td>18.46</td>
<td>1.22</td>
</tr>
<tr>
<td>F6</td>
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<td>0.56</td>
<td>0.63</td>
<td>11.11</td>
<td>1.12</td>
</tr>
<tr>
<td>F7</td>
<td>23.87</td>
<td>0.47</td>
<td>0.55</td>
<td>14.54</td>
<td>1.17</td>
</tr>
<tr>
<td>F8</td>
<td>25.95</td>
<td>0.43</td>
<td>0.52</td>
<td>17.30</td>
<td>1.20</td>
</tr>
<tr>
<td>F9</td>
<td>24.66</td>
<td>0.55</td>
<td>0.62</td>
<td>11.29</td>
<td>1.21</td>
</tr>
</tbody>
</table>

**Table 3. In vitro quality control parameters**

<table>
<thead>
<tr>
<th>Formulation codes</th>
<th>Average Weight (mg)</th>
<th>Hardness (kg/cm2)</th>
<th>Friability (%loss)</th>
<th>Thickness (mm)</th>
<th>Drug content (%)</th>
<th>Floating lag time (min)</th>
<th>Total Floating Time(Hrs)</th>
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<tbody>
<tr>
<td>F1</td>
<td>300.7</td>
<td>5.0</td>
<td>0.46</td>
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<td>99.24</td>
<td>5.8</td>
<td>5</td>
</tr>
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<td>300.1</td>
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<td>0.49</td>
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<td>99.52</td>
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<td>12</td>
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<tr>
<td>F3</td>
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<td>3.1</td>
<td>98.42</td>
<td>5.0</td>
<td>8</td>
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<td>F4</td>
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<td>98.27</td>
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<td>11</td>
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<td>99.74</td>
<td>5.4</td>
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<td>F8</td>
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<td>F9</td>
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<td>0.60</td>
<td>3.6</td>
<td>98.77</td>
<td>4.4</td>
<td>12</td>
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</table>

All the parameters such as weight variation, friability, hardness, thickness, drug content were found to be within limits.
Table 4. Dissolution data of Floating Tablets

<table>
<thead>
<tr>
<th>Time (hr)</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>F4</th>
<th>F5</th>
<th>F6</th>
<th>F7</th>
<th>F8</th>
<th>F9</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>8.54</td>
<td>20.23</td>
<td>15.96</td>
<td>12.87</td>
<td>7.61</td>
<td>5.31</td>
<td>19.32</td>
<td>10.78</td>
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<td>2</td>
<td>14.69</td>
<td>28.45</td>
<td>25.77</td>
<td>28.71</td>
<td>22.31</td>
<td>14.82</td>
<td>33.7</td>
<td>21.37</td>
<td>24.9</td>
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<tr>
<td>4</td>
<td>28.48</td>
<td>33.62</td>
<td>30.02</td>
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<td>85.73</td>
<td>97.76</td>
<td>83.32</td>
<td>79.46</td>
<td>99.18</td>
<td>78.64</td>
<td>98.96</td>
</tr>
</tbody>
</table>

Table 5. Application kinetics for optimised formulation

<table>
<thead>
<tr>
<th>CUMULATIVE % RELEASE Q</th>
<th>TIME (T)</th>
<th>ROOT (T)</th>
<th>LOG(%) RELEASE</th>
<th>OG (T)</th>
<th>LOG(%) REMAIN</th>
<th>RELEASE RATE (CUMULATIVE % RELEASE / t)</th>
<th>1/CUM% RELEASE</th>
<th>PEPPAS log Q/100</th>
<th>% Drug Remaining</th>
<th>Q01/3</th>
<th>Qt1/3</th>
<th>Q01/3-Qt1/3</th>
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<tr>
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<td>0</td>
<td>0</td>
<td>2.000</td>
<td>0.00</td>
<td>1.902</td>
<td>20.230</td>
<td>0.0494</td>
<td>-0.694</td>
<td>79.77</td>
<td>4.642</td>
<td>4.642</td>
<td>0.000</td>
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<td>1.000</td>
<td>1.306</td>
<td>0.00</td>
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<td>20.230</td>
<td>0.0494</td>
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<td>4.642</td>
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<td>7.942</td>
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<td>1.302</td>
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<td>0.0100</td>
<td>-0.001</td>
<td>0.22</td>
<td>4.642</td>
<td>0.604</td>
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Fig 5. Standard graph of Cefpodoxime proxetil in 0.1N HCl

\[ y = 0.035x + 0.016 \]
\[ R^2 = 0.999 \]

Fig 6. FTIR Spectrum of pure drug

Fig 7. FTIR Spectrum of optimized formulation
Fig 8. Formulation Vs Floating Lag Time

Fig 9. Formulations Vs Total Floating Time

In Vitro Drug Release Studies

Fig 10. Dissolution data of Cefpodoxime proxetil Floating tablets containing Sodium CMC
Fig 11. Dissolution data of Cefpodoxime proxetil Floating tablets containing Methyl cellulose

Fig 12. Dissolution data of Cefpodoxime proxetil Floating tablets containing Carrageenan

Fig 13. Dissolution data of Cefpodoxime proxetil Floating tablets containing all formulations (Sodium CMC, Methyl cellulose, Carrageenan)
Fig 14. Zero order release kinetics

Fig 15. Higuchi release kinetics

Fig 16. Kors mayer peppas release kinetics
Fig 17. First order release kinetics

Optimised formulation F2 was kept for release kinetic studies. From the above graphs it was evident that the formulation F2 was followed Higuchi release kinetics.

CONCLUSION
Development of floating drug delivery of Cefpodoxime Proxetil tablets is to provide the drug action up to 24 hours. Floating tablets were prepared by direct compression method using various polymers like Sodium CMC, Methyl cellulose, Caragennan. The formulated Floating tablets were evaluated for different parameters such as Drug Excipient compatbability studies, Weight Variation, Thickness, Hardness, Content uniformity, In vitro Buoyancy studies, In vitro drug release studies performed in 0.1N HCL for 24 hrs and the data was subjected to zero order, first order, Higuchi release kinetics and karsmayer peppas graph.
The following conclusions could be drawn from the results of various experiments. FTIR studies concluded that there was no interaction between drug and excipients. The physico-chemical properties of all the formulations prepared with different polymers Sodium CMC, Methyl cellulose, Caragennan were shown to be within limits. Quality control parameters for tablets such as weight variation, Hardness, Friability, thickness, drug content and floating lag time were found to be within limits. In-vitro drug release studies were carried out for all prepared formulation and from that concluded F2formulation has shown good results. Finally concluded release kinetics to optimized formulation (F2) has followed Higuchi kinetics. Present study concludes that Floating system may be a suitable method for Cefpodoxime Proxetil administration.

ACKNOWLEDGEMENT
None

CONFLICT OF INTEREST
No Conflict of Interest.

REFERENCES