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**Research**

# Formulation and Development of Gastro-Retentive Floating Matrix Tablets of Zaltoprofen by Direct Compression Method

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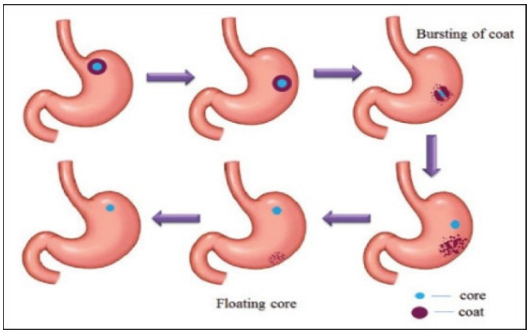
**Abstract**

Zaltoprofen inhibits the cyclooxygenase-2 (COX-2) enzyme, which is crucial for producing prostaglandins (like PGE2) that mediate pain, inflammation, and fever. It blocks the B2 bradykinin receptor-mediated signaling pathway in primary sensory neurons, effectively stopping bradykinin, a potent pain mediator, from activating pain signals. The Present study is aimed to develop a novel gastro retentive drug delivery system based on direct compression method for sustained delivery of active agent to improve the bioavailability, reduce the number of doses and to increase patient compliance. Gastro retentive floating tablets of Zaltoprofen were prepared by direct compression method using altered concentrations of Eudragit S100, Eudragit L100, Eudragit RSPO, MCC as Polymers. The prepared tablets of Zaltoprofen were evaluated for hardness, thickness, friability, weight variation, drug content uniformity, total floating time, in-vitro dissolution study, etc. in-vitro drug release of floating gastro retentive tablet of Zaltoprofen shown that the formulation F6 was found to be the best formulation as it releases 98% Lovastatin in a controlled manner for an extended period of time up to 10 hours. Prepared floating tablets of Zaltoprofen may prove to be a potential candidate for safe and effective controlled drug delivery over an extended period of time for gastro retentive drug delivery system.

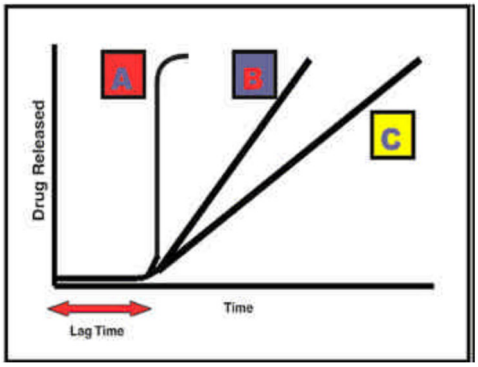
**Keywords:** Zaltoprofen, Gastro retentive, Eudragit, Floating tablet.

## INTRODUCTION

The oral route is the most preferred route of administration of drugs because of low cost of therapy, ease of administration, patient compliance and flexibility in formulation, etc. The current research addresses briefly about the FDDS that is one of the most leading methodologies in gastro retentive drug formulations[4]. The purpose of designing by which the drug is released from dosage form depends on the type of coating; insoluble coating under all physiological conditions, pH-dependent coating whose solubility changes dramatically at some point in GI tract, and slowly erodible coating.




The method of application and processing conditions may influence the porosity of the coating and consequently the release mechanism. The present work is aimed at formulating floating drug delivery of Zaltoprofen using various grades of HPMC polymers[2]. Oral controlled drug delivery systems represent the most popular form of controlled drug delivery systems for the obvious advantages of oral route of drug administration. Such systems release the drug with constant or variable release rates. These dosage forms offer many advantages[8], such as nearly constant drug level at the site of action, prevention of peak-valley fluctuations, reduction in dose of drug, reduced dosage frequency, avoidance of side effects, and improved patient compliance[14].




In this context, the aim of the research was to achieve a so-called sigmoidal release pattern (pattern A in Figure).The characteristic feature of the formulation was a defined lag time followed by a drug pulse with the enclosed active quantity being released at once. Thus, the major challenge in the development of pulsatile drug delivery system is to achieve a rapid drug release after the lag time. Often, the drug is released over an extended period of time (patterns B & C in Figure) [12].

### Formulation development of Floating Tablets:

### Preparation calibration curve:

100mg of Zaltoprofen pure drug was dissolved in 100ml of water(stock solution)10ml of solution was taken and make up with100ml of water (100µg/ml).from this 10ml was taken and make up with 100 ml of water (10µg/ml). The above solution was subsequently diluted with 0.1N HCl to obtain series of dilutions Containing 2, 4, 6, 8, 10, 20, 30, 40, 50, 60, 70, 80, 90 and 100µg/ml of Zaltoprofen per ml of solution[11].

### Determination of Absorption Maxima:

The absorbance of the above dilutions was measured at 271 nm by using UV-Spectrophotometer taking 0.1N HCl as blank. Then a graph was plotted by taking Concentration on X-Axis and Absorbance on Y-Axis which gives a straight line. Linearity of standard curve was assessed from the square of correlation coefficient ($R^2$) which determined by least-square linear regression analysis[5].

### Preparation of Gastro-retentive Floating Matrix Tablets of Zaltoprofen:

1. Zaltoprofen and all other ingredients were individually passed through sieve no ≠ 60.
2. All the ingredients were mixed thoroughly by triturating up to 15 min.
3. The powder mixture was lubricated with talc.
4. The tablets were prepared by using direct compression method.

**Table 1:** Formulation composition for floating tablets:

| Formulation No. | Zaltoprofen | Eudragit S100 | Eudragit L100 | Eudragit RSPO | $NaHCO_3$ | Mag. Stearate | Talc | MCC pH 102 |
|---|---|---|---|---|---|---|---|---|
| F1 | 80 | 40 | ----- | ----- | 30 | 5 | 5 | QS |
| F2 | 80 | 80 | ----- | ----- | 30 | 5 | 5 | QS |
| F3 | 80 | 100 | ---- | ----- | 30 | 5 | 5 | QS |
| F4 | 80 | ----- | 40 | ----- | 30 | 5 | 5 | QS |
| F5 | 80 | ----- | 80 | ---- | 30 | 5 | 5 | QS |
| F6 | 80 | ----- | 100 | ----- | 30 | 5 | 5 | QS |
| F7 | 80 | ----- | ----- | 40 | 30 | 5 | 5 | QS |
| F8 | 80 | ----- | ----- | 80 | 30 | 5 | 5 | QS |
| F9 | 80 | ----- | ----- | 100 | 30 | 5 | 5 | QS |

All the quantities were in mg, total weight is 250 mg.

**Evaluation of post compression parameters for prepared Tablets:**

The designed formulation compression coated tablets were studied for their physicochemical properties like weight variation, hardness, thickness, friability and drug content.

**Weight variation test:**

Twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight. The weight variation test would be a satisfactory method of deter mining the drug content uniformity[8].

**Hardness:**

For each formulation, the hardness of three tablets was determined using Monsanto hardness tester and the average is calculated and presented with deviation[7].

**Thickness:**

Tablet thickness is an important characteristic in reproducing appearance. Average thickness for core and coated tablets is calculated and presented with deviation[9].

**Friability:**

Roche friabilator was used to determine the friability by following procedure. Pre weighed tablets were placed in the friabilator. The tablets were rotated at 25 rpm for 4 minutes (100 rotations). At the end of test, the tablets were re weighed, loss in the weight of tablet is the measure of friability[1].

**Determination of drug content:**

Ten tablets were finely powdered quantities of the powder equivalent to one tablet weight of Meloxicam were accurately weighed, transferred to a 100 ml volumetric flask containing 50 ml water and were allowed to stand to ensure complete solubility of the drug. The mixture was made up to volume with water. The solution was suitably diluted and the absorption was determined by UV – Visible spectrophotometer. The drug concentration was calculated from the calibration curve[8].

**In vitro Buoyancy studies:**

The in vitro buoyancy was determined by floating lag time, and total floating time. (As per the method described by Rosa et al) The tablets were placed in a 100ml beaker containing 0.1N HCl. The time required for the tablet to rise to the surface and float was determined as floating lag time (FLT) and duration of time the tablet constantly floats on the dissolution medium was noted as Total Floating Time respectively (TFT) [17].

**In vitro drug dissolution studies:**

900ml 0f 0.1 HCl was placed in vessel and the USP apparatus –II (Paddle Method) was assembled. The medium was allowed to equilibrate to temp of 37°c $\pm$ 0.5°c. Tablet was placed in the vessel and the vessel was covered the apparatus was operated for 12 hours and then the medium 0.1 N HCl was taken and process was continued from 0 to 12 hrs at 75 rpm. At definite time intervals of 5 ml of the receptors fluid was withdrawn, filtered and again 5ml receptor fluid was replaced. Suitable

dilutions were done with receptor fluid and analyzed by spectrophotometric ally at 271 nm using UV-spectrophotometer[18].

## RESULTS AND DISCUSSION

**Table 2:** Observations for graph of Zaltoprofen in 0.1 N HCl (271 nm)

| Concentration [µg/l] | Absorbence |
|---|---|
| 0 | 0 |
| 2 | 0.172 |
| 4 | 0.310 |
| 6 | 0.438 |
| 8 | 0.563 |
| 10 | 0.719 |

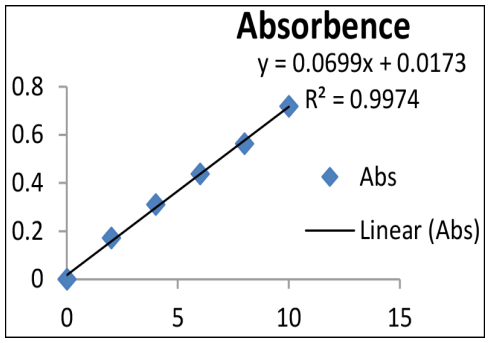



**Fig 1:** Standard graph of Zaltoprofenin 0.1N HCl

### Preformulation parameters of powder blend

**Table 3:** Pre-formulation parameters of blend

| Formulation Code | Angle of Repose | Bulk density (gm/ml) | Tapped density (gm/ml) | Carr's index (%) | Hausner's Ratio |
|---|---|---|---|---|---|
| F1 | 26.01 | 0.49±0.07 | 0.57±0.01 | 16.21±0.06 | 0.86±0.06 |
| F2 | 24.8 | 0.56±0.06 | 0.62±0.05 | 16.87±0.05 | 0.98±0.05 |
| F3 | 22.74 | 0.52±0.03 | 0.68±0.07 | 17.11±0.01 | 0.64±0.03 |
| F4 | 25.33 | 0.54±0.04 | 0.64±0.08 | 17.67±0.08 | 1.12±0.04 |
| F5 | 26.24 | 0.53±0.06 | 0.67±0.03 | 16.92±0.04 | 1.2±0.08 |
| F6 | 26.12 | 0.56±0.05 | 0.66±0.06 | 17.65±0.09 | 1.06±0.09 |
| F7 | 27.08 | 0.58±0.06 | 0.69±0.04 | 16.43±0.05 | 0.76±0.03 |
| F8 | 25.12 | 0.48±0.05 | 0.57±0.02 | 17.97±0.02 | 1.15±0.09 |
| F9 | 25.45 | 0.54±0.08 | 0.62±0.03 | 17.54±0.09 | 1.17±0.02 |

### Quality Control Parameters For tablets:

Tablet quality control tests such as weight variation, hardness, and friability, thickness, and drug release studies in different media were performed on the tablets.

**Table 4:** Invitro quality control parameters for tablets

| Formulation codes | Weight variation(mg) | Hardness ($kg/cm_2$) | Friability (%loss) | Thickness (mm) | Drug content (%) | Flaoting lag time |
|---|---|---|---|---|---|---|
| F1 | 202.5 | 3.5 | 0.52 | 4.8 | 99.76 | 4.0 |
| F2 | 205.4 | 3.2 | 0.54 | 4.9 | 99.45 | 4.2 |
| F3 | 198.6 | 3.4 | 0.51 | 4.9 | 99.34 | 4.5 |
| F4 | 210.6 | 3.5 | 0.55 | 4.9 | 99.87 | 4.1 |
| F5 | 209.4 | 3.4 | 0.56 | 4.7 | 99.14 | 4.0 |
| F6 | 210.7 | 3.2 | 0.45 | 4.5 | 98.56 | 4.4 |
| F7 | 202.3 | 3.1 | 0.51 | 4.4 | 98.42 | 4.5 |
| F8 | 201.2 | 3.3 | 0.49 | 4.7 | 99.65 | 4.6 |
| F9 | 198.3 | 3.5 | 0.55 | 4.6 | 99.12 | 4.7 |

In-Vitro Drug Release Studies

**Table 5:** Dissolution Data of Zaltoprofen Tablets

| TIME (hr) | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.5 | 18.81 | 19.89 | 14.21 | 19.62 | 18.42 | 19.62 | 21.73 | 18.52 | 19.53 |
| 1 | 29.02 | 28.04 | 18.87 | 27.86 | 27.73 | 27.86 | 30.23 | 37.47 | 28.97 |
| 2 | 35.70 | 35.43 | 27.19 | 36.35 | 35.63 | 36.35 | 44.9 | 59.93 | 35.89 |
| 3 | 43.32 | 41.65 | 35.66 | 41.45 | 42.04 | 41.45 | 50.87 | 65.85 | 45.7 |
| 4 | 49.25 | 47.18 | 43.32 | 47.80 | 57.25 | 47.80 | 54.73 | 77.54 | 54.38 |
| 5 | 55.28 | 53.81 | 51.06 | 55.25 | 64.33 | 55.25 | 66.37 | 89.55 | 61.2 |
| 6 | 60.92 | 58.89 | 57.13 | 60.24 | 75.41 | 60.24 | 70.84 | 96.67 | 67.06 |
| 7 | 66.08 | 64.53 | 63.63 | 66.73 | 83.84 | 66.73 | 73.17 | 104.28 | 72.52 |
| 8 | 70.44 | 69.43 | 69.71 | 71.34 | 102.80 | 76.34 | 79.01 | | 77.88 |
| 9 | 80.90 | 79.98 | 79.27 | 80.17 | | 88.52 | 84.23 | | 86.6 |
| 10 | 87.27 | 83.98 | 89.02 | 93.28 | | 98.17 | 90.18 | | 89.09 |

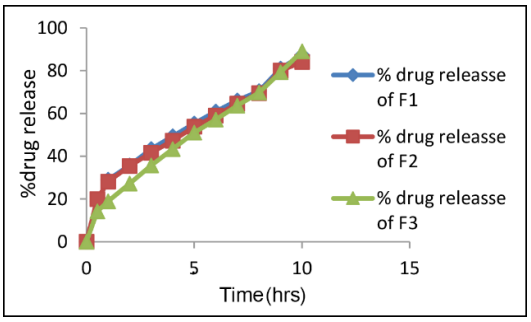



**Fig 2:** Dissolution profile of ZALTOPROFEN floating tablets (F1, F2, F3 formulations).

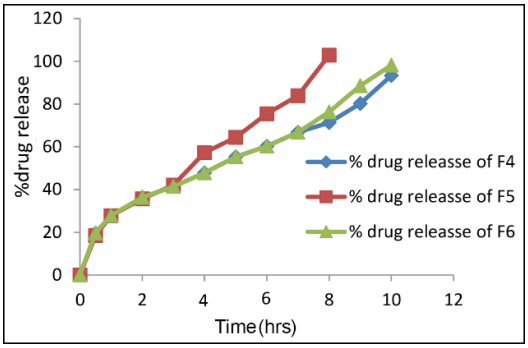



**Fig 3:** Dissolution profile of Zaltoprofen HCl floating tablets (F4, F5, F6 formulations).

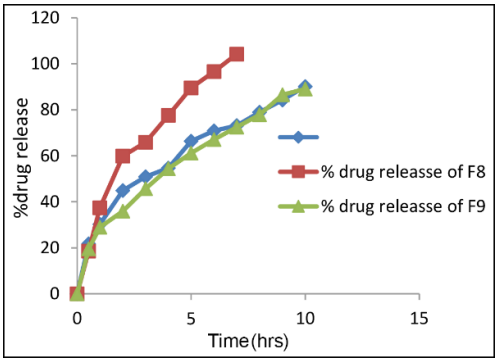



**Fig 4:** Dissolution profile of Zaltoprofen floating tablets (F7, F8, F9 formulations)

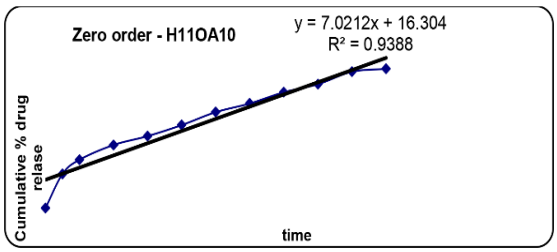



**Fig 5 :** Zero order release kinetics graph

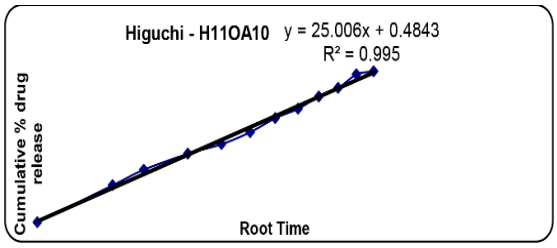



**Fig 6 :** Higuchi release kinetics graph

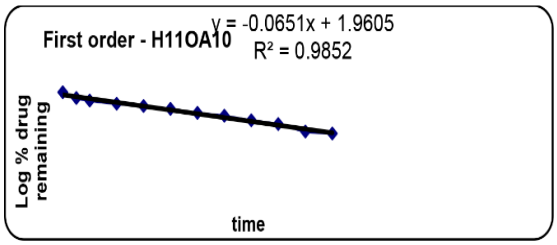



**Fig 7:** First order release kinetics graph

## CONCLUSION:

The present research focuses on the development of a gastro-retentive floating matrix formulation of Zaltoprofen using various hydrophilic polymers. Initially analytical method development was done for the drug molecule. Absorption maxima was determined based on that calibration curve was developed by using different concentrations. Gas generating agent sodium bicarbonate concentration was optimized. Then the

formulation was developed by using different concentrations of polymers of various grades of Eudragit. The formulation blend was subjected to various preformualation 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 formulations prepared by using Guar gum were unable to produce desired drug release, they were unable to retard drug release up to 10 hours. The formulations prepared with Eudragit L100 retarded the drug release up to 10 hours in the concentration of 100 mg (F6). Hence they were not considered. 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.

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