Original Article

# DESIGN AND FORMULATION OF NOVEL COLON TARGETED FENOPROFEN TABLET

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## Abstract

Fenoprofen is a propionic acid derivative and is a protypical NSAID used to reduce fever, mild to moderate pain, inflammatory diseases like rheumatoid, juvenile arthritis and ankylosing spondylitis, Fenoprofen Plasma half-life is approximately 3 hours, and having rapid absorption which requires frequent dose administration, So to avoid repeated frequent dose administration The colon targeted tablets of Fenoprofen tablets were prepared by direct compression method by using natural polymers like xanthan gum and guar gum, alone and in combinations in different concentrations. In the present work, total nine formulations were prepared and the detailed composition is shown in Table. The prepared colon targeted tablets of Fenoprofen were then subjected to FTIR, pre compression parameters like Angle of repose, Bulk density, Tapped density, Carr's index and Hausner's ratio. Then the tablets were evaluated for post compression parameters like Thickness, Hardness, average weight, friability, drug content, in vitro dissolution, and drug release kinetics. Among all the nine formulations formulated by using xanthan gum and guar gum. Formulation F7 containing xanthan gum and guar gum in 1:1 ratio shows sustained drug release by targeting the drug release at colon pH. when compared with all other formulations. So the drug release kinetics were performed for the F7 formulation containing xanthan gum and guar gum in 1:1 ratio. The diffusion exponent 'n' values of Korsemeyer-Peppas model was found to be in the range of 2.359 for the Fenoprofen colon targeted tablets prepared with xanthan gum and guar gum in 1:1 ratio indicating super case transport of drug through Fenoprofen colon targeted tablets.

**Keywords:** Fenoprofen, xanthan gum and guar gum, FTIR.

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## INTRODUCTION

Targeted drug delivery to the colon is highly desirable for local treatment of a variety of bowel diseases such as ulcerative colitis, crohan's disease amebiosis, colonic cancer, and for local treatment of local colonic pathologies, and the systemic delivery of protein and peptide drugs [1,2].

Dosage forms that deliver drugs in the colon rather than upper GIT has number of advantages. Oral delivery of drugs in the colon is valuable in the treatment of diseases of colon where by high local concentration can be achieved while minimizing side effects. The colon is attracting interest as a site where poorly absorbed drug molecule may have an improved bioavailability because the colon has a long retention time and appears highly responsible to agents that enhance the absorption of poorly absorbed drugs. The simplest method for targeting of drugs to the colon is to obtain slower release rates or longer release periods by the application of thicker layers of conventional enteric coating or extremely slow releasing matrices [3,4]. There are various methods or techniques through which colon drug targeting can be achieved, for example, formation of prodrug, coating with pHsensitive polymers, coating with biodegradable polymers, designing formulations using polysaccharides, timed released systems, pressure-controlled drug delivery systems, osmotic pressure controlled systems. Coating of the drugs with pH-sensitive polymers provides simple approach for colon-specific drug delivery [5,6].

Fenoprofen is highly bound to plasma proteins. Fenoprofen is a Cyclooxygenase (COX) inhibitor. An

anti-inflammatory analgesic and antipyretic highly bound to plasma proteins. [7,8] It is pharmacologically similar to aspirin, but causes less gastrointestinal bleeding.

Fenoprofen is a nonsteroidal anti-inflammatory drug used to treat inflammation and pain related to colon. The frequent intake of Fenoprofen leads to gastric ulceration, bleeding, and other gastric complications. Thus the development of colonic delivery of Fenoprofen is appropriate to reduce its side effects and achieve high local drug concentrations in the colon [9,10].

The half-life following a single oral dose is approximately 3 hours. The success of a therapy depends on selection of the appropriate delivery system and the drug. Controlled release dosage forms are designed to complement the pharmaceutical activity of a medicament in order to achieve better selectivity and longer duration of action. Thus, Fenoprofen is chosen as a suitable candidate for colon targeted drug delivery system [11-19]

## MATERIALS AND METHOOLOGY

Fenoprofen Pharma grade is gifted from Cipla pharmaceuticals limited Pvt, ltd. Guar gum, Xanthan gum MCC, Mg-Stearate Talc, Mumbai Hydrochloric acid, Shreeji chemicals, Mumbai

Determination of Melting Point

Melting point of Fenoprofen was determined by capillary method. Fine powder of Fenoprofen was filled in glass capillary tube (previously sealed on one end). The capillary tube is tied to thermometer and placed in oil bath (light paraffin oil bath), The temperature at which it starts to melt was noted.

Solubility Studies:

Solubility of Fenoprofen was determined in pH 1.2 HCL, pH 6.8 and pH 7.4 phosphate buffers. Solubility studies were performed by taking excess amount of Fenoprofen in different beakers containing the solvents. The mixtures were shaken for 24 hrs at regular intervals. The solutions were filtered by using whattmann's filter paper grade no. 41. The filtered solutions were analyzed spectrophotometrically at 269 nm.

Determination of λmax of Fenoprofen using 0.1 N HCL

A solution of Fenoprofen containing the concentration 10µg/ml was prepared in 0.1 N HCL and UV spectrum was taken. The solution was scanned in the range of 200-400nm.

Standard Calibration Curve of Fenoprofen using 0.1 N HCL

Method

10 mg drug was accurately in 10ml volumetric flask. It was dissolved in 0.1N HCL to gives 1000 µg /ml. the standard stock solution stock solution was then serially diluted with 0.1 N HCL to get 1 to 10 µg/ml of Fenoprofen. The absorbance was measured against 0.1 N HCL as blank using UV spectrophotometer at 269 nm. The absorbance values were plotted against concentration (µg/ml) to obtain the standard calibration curve.

Standard Calibration Curve of Fenoprofen using 6.8pH Buffer

Method

10 mg drug was accurately in 10ml volumetric flask. It was dissolved in 6.8pH buffer to gives 1000 µg /ml. the standard stock solution stock solution was then serially diluted with 6.8pH buffer to get 1 to 10 µg/ml of Fenoprofen. The absorbance was measured against 6.8pH buffer as blank using UV spectrophotometer at 269 nm. The absorbance values were plotted against concentration (µg/ml) to obtain the standard calibration curve.

Compatibility studies:

Compatibility studies were performed through FTIR spectroscopy. The IR spectrum of pure drug and physical mixture of drug and polymer was studied. The characteristic absorption peaks of Fenoprofen obtained were obtained at 4000-500cm-1.

COMPOSITION OF FENOPROFEN COLON TARGETED TABLETS

Table: Composition of Fenoprofen colon targeted tablets

| Ingredients | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
|---|---|---|---|---|---|---|---|---|---|
| **Fenoprofen** | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Xanthan gum** | 30 | 45 | 60 | - | - | - | 30 | 30 | 60 |
| **Guar gum** | - | - | - | 30 | 45 | 60 | 30 | 60 | 30 |
| **MCC** | Q.S | Q.S | Q.S | Q.S | Q.S | Q.S | Q.S | Q.S | Q.S |
| **PVP K 30** | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 |
| **Talc** | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 |
| **Mg. stearate** | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 |
| **Total weight(mg)** | 400 | 400 | 400 | 400 | 400 | 400 | 400 | 400 | 400 |

## RESULTS & DISCUSSION

PREFORMULATION STUDIES

Melting Point Determination

The melting point of Fenoprofen was found to be 168-170o C, which was official melting point of the Fenoprofen as per monograph.

Solubility

Table No 1: Solubility Studies of Fenoprofen Pure

| Solvents | Solubility (mg/ml) |
|---|---|
| 0.1N HCL | 0.038 |
| 6.8 pH buffer | 0.141 |
| 7.4 PH buffer | 0.120 |

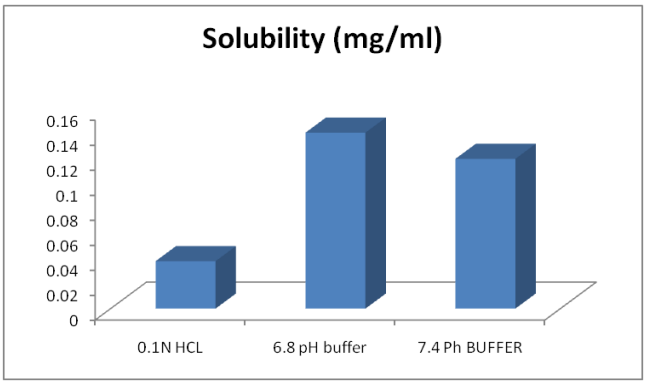


Fig 1: solubility Studies of Fenoprofen pure

Determination of UV Spectrum of Fenoprofen:

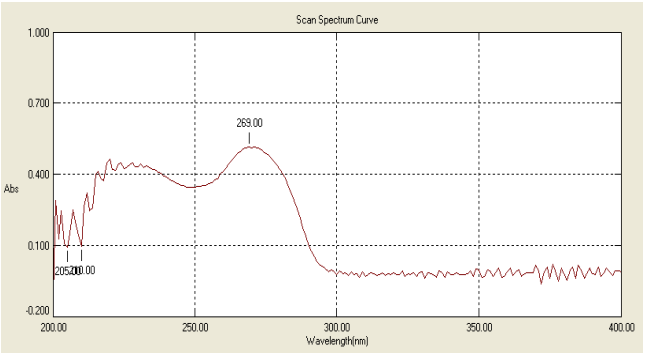


Fig 2: UV Spectra of Fenoprofen at 10 µg/ml Concentration

Table 1: Wavelength of Maximum Absorption of Fenoprofen in 0.1N HCL

| Sl. No. | Solvent | λmax |
|---|---|---|
| 1 | 0.1N HCL | 269nm |

Table 2: Standard Calibration Data of Fenoprofen in 0.1N HCL

| Concentration (µg/ml) | Absorbance |
|---|---|
| 0 | 0 |
| 2 | 0.079 |

| | |
|---|---|
| 4 | 0.181 |
| 6 | 0.271 |
| 8 | 0.376 |
| 10 | 0.468 |
| 12 | 0.573 |

EVALUATION OF FENOPROFEN COLON TARGETED TABLETS

Drug Polymer Interaction (FTIR) Study

From the spectra of Fenoprofen, physical mixture of Fenoprofen and polymer, i.e., optimized formulation, it was observed that all characteristic peaks of Fenoprofen were present in the combination spectrum, thus indicating compatibility of the Fenoprofen and polymer. IR Spectra shown in Figures

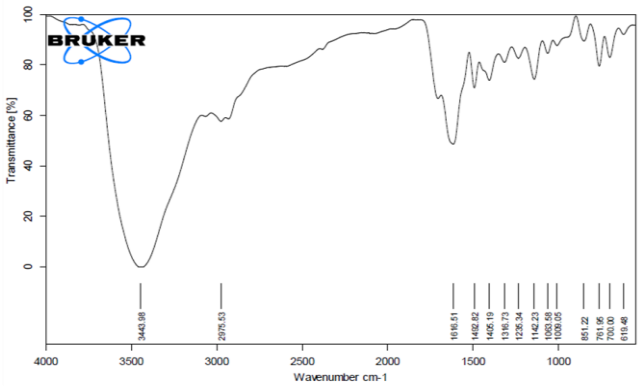


Fig 3: IR Spectra of Fenoprofen

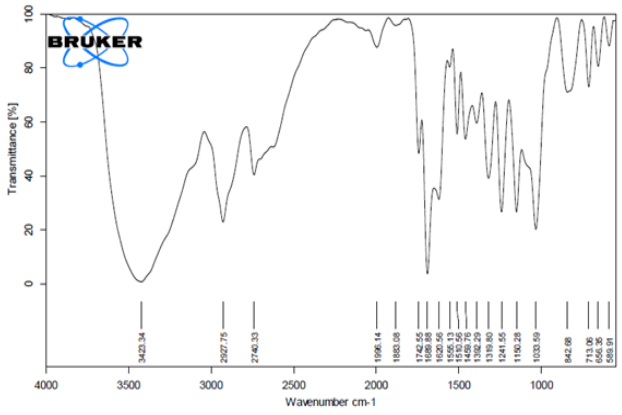


Fig 4: IR Spectra of Fenoprofen Optimized Formulation.

Pre Compression Parameters of Fenoprofen Colon Targeted Tablets:

Table 3: Pre Compression Parameters of Fenoprofen Colon Targeted Tablets

| FC | Angle of Repose | Bulk density | Tapped density | Hausner's ratio | Carr's Index |
|---|---|---|---|---|---|
| F1 | 22.21±0.84 | 0.324±0.04 | 0.282±0.10 | 1.14±0.24 | 12.96±0.48 |
| F2 | 21.84±0.62 | 0.316±0.12 | 0.270±0.02 | 1.17±0.10 | 14.55±0.12 |
| F3 | 22.96±0.22 | 0.327±0.16 | 0.266±0.56 | 1.22±0.62 | 18.65±0.46 |
| F4 | 22.85±0.14 | 0.330±0.54 | 0.270±0.84 | 1.22±0.58 | 18.18±0.28 |
| F5 | 22.46±0.58 | 0.325±0.28 | 0.264±0.52 | 1.20±0.42 | 18.76±0.46 |
| F6 | 22.64±0.02 | 0.334±0.22 | 0.268±0.46 | 1.24±0.48 | 19.76±0.28 |
| F7 | 23.64±0.42 | 0.320±0.46 | 0.252±0.12 | 1.26±0.26 | 21.25±0.64 |
| F8 | 22.85±0.23 | 0.330±0.28 | 0.268±0.28 | 1.23±0.22 | 18.78±0.22 |
| F9 | 21.54±0.14 | 0.320±0.54 | 0.266±0.66 | 1.20±0.10 | 16.87±0.84 |

Based upon the post compression parameters like bulk density, tapped density, carr's index and Hausner's ratio it was concluded that the flow properties of Fenoprofen colon targeted tablets were found to be within the range indicates better flow property.

Post Compression Parameters of Fenoprofen Colon Targeted Tablets:

Table 4: Post Compression Parameters of Fenoprofen Colon Targeted Tablets

| FC | Avg.Wt (mg) | Thickness (mm) | Hardness ($kg/cm^2$) | Friability (%) | Drug Content (%) |
|---|---|---|---|---|---|
| F1 | 401.28±0.54 | 4.12±0.10 | 8.54±0.48 | 0.22±0.48 | 86.14±0.14 |
| F2 | 400.02±0.16 | 4.02±0.26 | 8.92±0.26 | 0.16±0.54 | 90.54±0.28 |
| F3 | 398.56±0.22 | 4.22±0.54 | 9.12±0.22 | 0.54±0.22 | 94.26±0.26 |
| F4 | 400.28±0.54 | 4.28±0.67 | 8.26±0.48 | 0.28±0.01 | 93.64±0.24 |
| F5 | 399.64±0.68 | 4.10±0.89 | 8.54±0.22 | 0.10±0.26 | 92.41±0.58 |
| F6 | 402.14±0.46 | 4.02±0.46 | 9.20±0.16 | 0.46±0.28 | 88.26±0.66 |
| F7 | 400.01±0.22 | 4.98±0.22 | 8.86±0.28 | 0.29±0.54 | 96.14±0.59 |
| F8 | 399.87±0.10 | 4.52±0.18 | 8.24±0.29 | 0.84±0.42 | 96.20±0.54 |
| F9 | 398.54±0.48 | 4.26±0.62 | 8.26±0.18 | 0.12±0.68 | 95.61±0.22 |

The average weight of the Fenoprofen colon targeted tablets were found to be in the range of 398.54 to 402.14mg. Thickness of the Fenoprofen colon targeted tablets were found to be in the range of 4.00 to 4.52mm. Hardness of the Fenoprofen colon targeted tablets were found to be in the range of 5.98 to 6.52 kg/cm2. Friability of the Fenoprofen colon targeted tablets were found to be in the range of 0.10 to 0.84% Drug content of the Fenoprofen colon targeted tablets were found to be in the range of 86.14 to 96.20%.

In vitro Dissolution Studies of Fenoprofen Colon Targeted Tablets:

Table 5: In vitro Release Data of Fenoprofen Colon Targeted Tablets of Formulations F1-F9

| Time (hrs) | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1 | 9.36±0.18 | 7.82±1.02 | 3.24±0.48 | 14.77±0.08 | 10.03±0.48 | 6.46±0.18 | 0.26±0.58 | 0.20±0.48 | 0.54±0.64 |
| 2 | 24.26±0.32 | 20.26±0.54 | 5.24±0.52 | 36.42±0.28 | 26.93±0.52 | 10.54±0.15 | 0.62±0.42 | 0.38±0.22 | 0.62±0.24 |
| 3 | 48.61±0.42 | 35.24±0.26 | 36.64±0.62 | 54.41±0.69 | 39.07±0.66 | 19.08±0.28 | 2.26±0.12 | 1.94±0.16 | 1.69±0.58 |
| 4 | 64.65±0.26 | 49.84±0.58 | 48.81±0.28 | 67.92±0.24 | 48.26±0.58 | 33.03±0.36 | 3.41±0.36 | 2.68±0.24 | 3.52±0.36 |
| 5 | 78.96±0.28 | 57.86±0.22 | 56.6±0.10 | 79.72±0.58 | 56.19±0.24 | 47.52±0.58 | 6.32±0.28 | 5.81±0.58 | 10.92±0.25 |
| 6 | 82.26±0.39 | 71.92±0.16 | 68.98±0.49 | 88.35±0.12 | 67.93±0.18 | 58.10±0.29 | 27.87±0.14 | 22.87±0.26 | 16.68±0.22 |
| 7 | 98.62±0.86 | 86.29±0.59 | 74.89±0.58 | 99.08±0.69 | 77.73±0.01 | 67.54±0.30 | 44.51±0.22 | 34.82±0.42 | 24.84±0.48 |
| 8 |  | 99.86±0.69 | 82.21±0.01 |  | 86.54±0.36 | 75.95±0.48 | 57.35±0.38 | 55.46±0.28 | 33.62±0.52 |
| 9 |  |  | 90.64±0.68 |  | 99.62±0.48 | 86.81±0.52 | 68.62±0.54 | 68.84±0.64 | 66.86±0.10 |
| 10 |  |  | 98.62±0.54 |  |  | 90.54±0.10 | 76.86±0.26 | 76.76±0.52 | 78.42±0.26 |
| 11 |  |  |  |  |  | 98.22±0.36 | 84.19±0.68 | 85.92±0.10 | 80.98±0.24 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 12 | | | | | | | 92.36±0.74 | 90.28±0.92 | 86.63±0.22 |

IN VITRO DRUG RELEASE STUDIES:

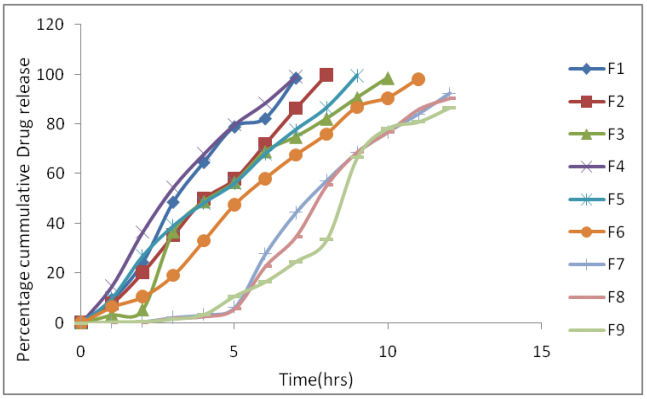


Fig 5: In Vitro Drug Release Studies of F1-F9 Formulation

The in vitro performance of Fenoprofen colon targeted tablets showed prolonged and controlled release. The results of the in vitro dissolution studies shows controlled and predictable manner as the polymer concentration increases the drug release from the colon targeted tablets decreases. Among all the nine formulations formulated by using xanthan gum, guar gum, alone and in combinations with different ratios. Formulation F7 containing xanthan gum and guar gum in 1:1 ratio shows sustained drug release of Fenoprofen tablets by targeting the drug release at the colon. Remaining formulations failed to sustained the drug release in colon region.

Xanthan gum in three different ratios of 30,45 and 60mg alone in the formulations of F1-F3 fails to release the drug at colon region. While F4-F6 formulations were prepared by using guar gum as same as the above concentrations, but none of the trails satisfy our aim and objective.

So further trails were formulated by using xanthan gum and guar gum in combinations in 1:1, 1:2 ratios of xanthan gum and guar gum, whereas F9 formulation was prepared by using 1:2 ratio of guar gum and xanthan gum. From the in vitro dissolution studies it was clearly observed that xanthan gum plays a vital role in retarding the drug release along with guar gum in 1:1 ratio. So the drug release kinetics were performed for the F7 formulation containing xanthan gum and guar gum in 1:1 ratio.

Table 6: Drug Release Kinetics of Optimized Formulation(F7)

| **$R^2$ values** | | | | | **n values** |
|---|---|---|---|---|---|
| **Formulation** | **Zero order** | **First order** | **Higuchi** | **Korsmeyer - Peppas** | **Korsmeyer-Peppas (n)** |
| **F7** | **0.921** | **0.835** | **0.740** | **0.919** | **2.359** |

The plots of cumulative percentage drug release V/s. time, cumulative percent drug retained V/s. root time, log cumulative percent drug retained V/s. time and log cumulative percent drug release V/s. log time were drawn and represented graphically as shown in Fig respectively. The slopes and the regression co-efficient of determinations (r2) were listed in Table 5.13. The co-efficient of determination indicated that the release data was best fitted with zero order kinetics. Higuchi equation explains the diffusion controlled release mechanism. The diffusion exponent 'n' values of Korsemeyer-Peppas model was found to be in the range of 2.359 for the Fenoprofen colon targeted tablets prepared with xanthan gum indicating super case transport of drug through Fenoprofen colon targeted tablets.

## CONCLUSION

In the present work, total nine formulations were prepared and the detailed composition is shown in Table. The prepared colon targeted tablets of Fenoprofen were then subjected to FTIR, pre compression parameters like Angle of repose, Bulk density, Tapped density, Carr's index and Hausner's ratio. Then the tablets were evaluated for post compression parameters like Thickness, Hardness, average weight, friability, drug content, in vitro dissolution, and drug release kinetics. Among all the nine formulations formulated by using xanthan gum and guar gum. Formulation F7 containing xanthan gum and guar gum in 1:1 ratio shows sustained

drug release by targeting the drug release at colon pH. when compared with all other formulations. So the drug release kinetics were performed for the F7 formulation containing xanthan gum and guar gum in 1:1 ratio. The diffusion exponent 'n' values of Korsemeyer-Peppas model was found to be in the range of 2.359 for the Fenoprofen colon targeted tablets prepared with xanthan gum and guar gum in 1:1 ratio indicating super case transport of drug through Fenoprofen colon targeted tablets. Thus Fenoprofen is a suitable candidate for treating colon inflammations and to reduce pain, by formulating as a colon targeted tablet by using xanthan gum and guar gum in 1:1 ratio.

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