Research Article

# Formulation and *In-Vitro* Evaluation of Colon Targeted Matrix Tablets of Lornoxicam

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**ABSTRACT**

The aim of the present work was to develop colon targeted matrix tablets of lornoxicam using natural polymers such as Tamarind seed polysaccharide, Guar gum, Xanthan gum as carriers in various concentrations. Matrix tablets were prepared by direct compression method. Prepared formulations were subjected to various evaluation parameters like hardness, friability, thickness, % drug content, weight variation etc. The tablets were subjected to *in-vitro* drug release in 1.2 pH for first 2 hrs then in 7.4 pH for next 3hrs followed by 6.8pH phosphate buffer. *In-vitro* studies revealed that tablets formulated with the natural polymers have controlled the drug release in stomach and small intestine environment and released maximum amount of the drug in colonic environment. Results showed that tablets with higher binding concentration showed minimum drug release. Combination of polymers shows greater retarding of drug release. The compatibility of the drug and polymer were determined by FTIR spectroscopy. Results showed that the drug was compatible with all polymers. The release data was fitted to various mathematical models such as Higuchi, Korsmeyer-peppas, Hixson crowell, Zero order and first order to evaluate the kinetics of drug release. The drug release follows mixed order kinetics and mechanism was found to be non-Fickian diffusion. The stability studies were carried out according to the ICH guidelines which indicates the selected formulation (F10 & F12) were stable.

**Keywords:** Matrix tablets, Lornoxicam, Tamarind seed polysaccharide, Guar gum, Xanthan gum.

## INTRODUCTION

The oral route of drug administration is the most convenient and important method of administering drugs for systemic effect. These systems have more advantages due to patient acceptance and ease of administration[1]. Conventional dosage form release the drug instantaneously and showing large distribution to all organs, least concentration reaches to required site but in disease or disorder there is need to have more drug concentration at specific site it is problem in conventional dosage form. So, there is need to target the drug to specific site[2]. During the last decade there has been interest in developing site-specific formulations for targeting drug to the colon.

Colonic drug delivery has gained increased importance not just for the delivery of the drugs for the treatment of local diseases associated with the colon like Crohn's disease, ulcerative colitis, irritable bowel syndrome and constipation but also for the systemic delivery of proteins, therapeutic peptides, antiasthmatic drugs, antihypertensive drugs and antidiabetic agents.[1]The colon specific drug delivery system (CDDS) should be capable of protecting the drug in route to the colon i.e. drug release and absorption should not occur in stomach as well as small intestine, and neither the bioactive agent should be degraded at either of the dissolution sites, but only released and absorbed once the drug reaches the colon.[3]

Colon is concerned with number of diseases like IBD. Colon cancer etc., IBD covers group of disorders in which the intestines become inflamed. Two major types of IBD are described: Ulcerative colitis and Crohn's disease. As the name suggests, Ulcerative colitis is limited to the colon. Although crohn's disease can involve any part of the gastrointestinal tract from the mouth to the anus, it most commonly affects the small intestine and the colon[4].

Lornoxicam is a non-steroidal anti-inflammatory drug with analgesic property and belongs to the class Oxicams. Lornoxicam inhibits synthesis of prostaglandins via inhibition of cyclo-oxygenase enzyme. It is

used in the treatment of inflammatory bowel diseases and in colonic disorders. Lornoxicam undergoes extensive and highly variable hepatic first-pass metabolism following oral administration with a reported systemic bioavailability between 15% and 23%. Lornoxicam has half life of 3 to 5 hrs. So, patients are routinely asked to take Lornoxicam for several times in a day. Such frequent drug administration may reduce patient's compliance and therapeutic efficacy[2,5,6,7].

Colon targeted formulation is needed for the Lornoxicam overcome the above mentioned problems and also to minimize the GI disturbances such as peptic ulcer with or without bleeding if present in larger concentration in GI tract. The aim of the present research work was to develop matrix tablets of Lornoxicam targeted to colon.

## MATERIALS AND METHODS

### MATERIALS

Lornoxicam is a gift sample from Naprod Life Sciences P.LTD, India. Tamarind seeds from local market, Guar Gum, Xanthan Gum, Micro Crystalline Cellulose, Talc, Magnesium Stearate from S.D. Fine Chem. Ltd, Mumbai, India.

### METHOD

#### Standard Curve for Lornoxicam

100 mg of Lornoxicam was accurately weighed and dissolved in 100 ml of pH 1.2 to prepare first stock solution. 5ml of above solution was taken and diluted to 100 ml with the same solvent to prepare II stock solution. The aliquot amount of stock solution II was further diluted with pH 1.2 to get 2 µg, 4 µg, 6µg, 8µg, 10µg, 12µg, 14µg of drug per ml of the final solution. Then the absorbance was measured in a UV spectrophotometer at 373 nm against pH 1.2 as blank. The same procedure was repeated by using phosphate buffer pH 7.4 and pH 6.8.

#### Isolation of Tamarind seed polysaccharide

The seeds of Tamarindus indica were washed thoroughly with water to remove the adhering materials. Then, the reddish testa of the seeds was removed by heating seeds in sand in the ratio of 1:4 (Seed: Sand). The seeds were crushed lightly soaked in water separately for 24 h and then boiled for 1 h and kept aside for 2 h for the release of mucilage into water. The soaked seeds were taken and squeezed in a muslin bag to remove marc from the filtrate. Then, equal quantity of acetone was added to precipitate the mucilage. The mucilage was separated. The separated mucilage was dried at temperature 50°C, powdered and passed through sieve number 80 and stored in airtight container at room temperature[8].

**Table 1: Composition of formulations**

| Formulation code | Lornoxicam | Tamarind seed polysaccharide | Guar gum | Xanthan gum | Magnesium stearate | Talc | Micro Crystalline Cellulose | Total |
|---|---|---|---|---|---|---|---|---|
| F1 | 8 | 40 | - | - | 2.4 | 5 | q.s | 150 |
| F2 | 8 | 60 | - | - | 2.4 | 5 | q.s | 150 |
| F3 | 8 | 80 | - | - | 2.4 | 5 | q.s | 150 |
| F4 | 8 | - | 40 | - | 2.4 | 5 | q.s | 150 |
| F5 | 8 | - | 60 | - | 2.4 | 5 | q.s | 150 |
| F6 | 8 | - | 80 | - | 2.4 | 5 | q.s | 150 |
| F7 | 8 | - | - | 40 | 2.4 | 5 | q.s | 150 |
| F8 | 8 | - | - | 60 | 2.4 | 5 | q.s | 150 |
| F9 | 8 | - | - | 80 | 2.4 | 5 | q.s | 150 |
| F10 | 8 | 40 | 40 | - | 2.4 | 5 | q.s | 150 |
| F11 | 8 | - | 40 | 40 | 2.4 | 5 | q.s | 150 |
| F12 | 8 | 40 | - | 40 | 2.4 | 5 | q.s | 150 |

**EVALUATION OF PREFORMULATION PARAMETERS**

**Micromeritic properties**

**Angle of Repose**

The angle of repose of powder was determined by the funnel method. The accurately weighed powder was taken in a funnel. The height of the funnel was adjusted in such a way that the tip of the funnel just touched the apex of the heap of the granules. The powder was allowed to flow through the funnel freely onto the surface. The diameter of the powder cone was measured and angle of repose was calculated using the following equation.

$$\vartheta = \tan^{-1}\frac{h}{r}$$

Where ***h*** and ***r*** are the height and radius of the powder cone.

**Bulk Density**

bulk density was determined by pouring presieved drug excipient blend into a graduated cylinder and measuring the volume and weight "as it is". It is expressed in g/ml and is given by

$$D_b = \frac{Mass\ of\ powder}{Bulk\ volume\ of\ the\ powder}$$

**Tapped density**

The measuring cylinder containing a known mass of blend was tapped for a fixed time. The minimum volume occupied in the cylinder was measured. The tapped density was calculated using the formula:

$$D_t = \frac{Mass\ of\ powder}{Tapped\ volume\ of\ the\ powder}$$

**Carr's index**

It helps in measuring the force required to break the friction between the particles and the hopper. It is expressed in % and given by

$$Carr's\ index\ (\%) = \frac{Tapped\ density - Bulk\ density}{Tapped\ density} \times 100$$

**Hausner's Ratio**

Hausner's ratio was measured by the ratio of tapped density to bulk density.

$$Hausner's\ ratio = \frac{Tapped\ density}{Bulk\ density}$$

**Preparation of tablets**

All the formulations were prepared by direct compression method. The drug (8mg/tablet) and other excipients used in the formulations passed through sieve No. 60 prior to compression.

**Evaluation of Lornoxicam matrix tablets**

The matrix tablets prepared were evaluated for Weight variation**,** Hardness, Friability**,** Drug content**,** *In-vitro* Dissolution Studies**,** Stability Studies.

**Weight Variation Test**

To study weight variation, 20 tablets of each formulation were weighed using an electronic balance and the test was performed according to the official method.

**Hardness**

The resistance of tablet for shipping or breakage, under conditions of storage, transportation and handling, before usage, depends on its hardness. The hardness of tablet of each formulation was measured by using Pfizer hardness tester.

**Tablet thickness**

Thickness of tablets was important for uniformity of tablet size. Thickness was measured by using screw gauze on 3 randomly selected samples.

**Friability**

Friability is the measure of tablet strength. Roche Friabilator was used for testing the friability using the following procedure. Twenty tablets were weighed accurately and placed in the plastic chamber that revolves at 25 rpm for 4 mins dropping the tablets through a distance of six inches with each revolution. After 100 revolutions the tablets were reweighed and the percentage loss in tablet weight was determined.

$$\%\ Friability = \frac{Weight_{initial} - Weight_{final}}{Weight_{initial}} \times 100$$

**Drug Content**

Ten tablets were weighed and average weight is calculated. All tablets were crushed and powder equivalent to 8 mg drug was dissolved in 8 ml of 0.1N NaOH and the volume was made up to 100 ml with pH 6.8 phosphate buffer. The solution was shaken for 1 h and kept for 24 h. From the stock solution, 1ml solution was taken in 10 ml volumetric flask and the volume was made with pH 6.8

phosphate buffer. Solution was filtered and absorbance was measured spectrophotometrically at 379 nm against pH 6.8 phosphate buffer as a blank. Amount of drug present in one tablet was calculated[9].

### *In-vitro* dissolution studies

The *in-vitro* dissolution studies were performed using the USP-II (Paddle) dissolution apparatus at 50 rpm. Three dissolution medias-acidic buffer pH 1.2 for 2 hrs and phosphate buffer pH 7.4 for 3 hrs and phosphate buffer pH 6.8 for seven hrs. Medium is maintained at 37±0.5$^0$C. A 5ml was withdrawn at specific time intervals and drug content was determined by UV-Visible spectrometer at 373nm. The study was performed in triplicate.

### Stability Studies

The optimized formulation was subjected for two months stability study according to ICH guidelines**.** The selected formulations were packed in aluminium foil in tightly closed container. They were then stored at 40ºC / 75% RH for two months and evaluated for their permeation study.[10]

## RESULTS AND DISCUSSION

### IR Studies

Drug polymer interaction study was carried out for pure drug, Tamarind seed polysaccharide, Guar gum, Xanthan gum. The results showed that there is no significant change in the chemical integrity of the drug, indicating no interaction between the drug molecule and polymers.

**Table 2: Evaluation of Pre-Compression**

| Formulation code | Bulk density (gm/cc) | Tapped density (gm/cc) | Carr's Index (%) | Hausner's Ratio | Angle of Repose (θ) |
|---|---|---|---|---|---|
| F1 | 0.3813±0.0015 | 0.4493±0.0030 | 15.131±0.501 | 1.178±0.0069 | 25.84±0.723 |
| F2 | 0.3923±0.0025 | 0.4586±0.0011 | 14.462±0.361 | 1.169±0.0049 | 26.91±0.930 |
| F3 | 0.3886±0.0015 | 0.4603±0.0105 | 15.537±2.058 | 1.184±0.0287 | 25.07±0.760 |
| F4 | 0.3843±0.0015 | 0.4446±0.0030 | 13.564±0.920 | 1.157±0.0123 | 20.57±0.330 |
| F5 | 0.368±0.0017 | 0.433±0.0026 | 15.008±0.836 | 1.176±0.0115 | 20.80±0.767 |
| F6 | 0.3785±0.0012 | 0.448±0.004 | 15.495±0.510 | 1.183±0.0071 | 21.40±0.447 |
| F7 | 0.3816±0.0011 | 0.4113±0.0025 | 7.209±0.659 | 1.077±0.0076 | 19.43±0.465 |
| F8 | 0.3803±0.0005 | 0.412±0.0026 | 7.683±0.514 | 1.083±0.0060 | 18±0.445 |
| F9 | 0.3826±0.0015 | 0.413±0.005 | 7.338±0.760 | 1.079±0.0088 | 20.61±0.280 |
| F10 | 0.3658±0.0020 | 0.4293±0.0037 | 14.788±0.386 | 1.173±0.0053 | 22.82±0.557 |
| F11 | 0.376±0.0017 | 0.4603±0.0024 | 18.311±0.794 | 1.224±0.011 | 17.52±0.390 |
| F12 | 0.3813±0.0045 | 0.498±0.0065 | 23.426±0.120 | 1.305±0.0020 | 26.21±0.35 |

The results of bulk density and Tapped density ranged from 0.365±0.002 to 0.3923 ± 0.0020 and 0.4113±0.0125 to 0.498±0.0065 respectively and the compressibility index (%) ranged from 7.209±0.0.659 to 23.426±0.120. The Hausner's Ratio ranged from1.077±0.0079 to 1.305±0.002. The results of angle of repose ranged from 17.52±0.390 to 26.91±0.930 (º).

**Table 3: Results of post compression characteristics**

| Formulation | Weight Variation (mg) | Hardness (Kg/cm$^2$) | Friability (%) | Thickness (mm) | Drug content (%) |
|---|---|---|---|---|---|
| F1 | 150.08±0.244 | 6.7±0.11 | 0.2594±0.103 | 3.22±0.05 | 97.21±0.29 |
| F2 | 149.9±0.408 | 6.8±0.05 | 0.697±0.46 | 3.27±0.04 | 97.51±0.49 |
| F3 | 150.2±0.490 | 6.9±0.15 | 0.594±0.66 | 3.21±0.05 | 98.34±0.21 |
| F4 | 150.9±0.406 | 6.5±0.11 | 0.5855±0.66 | 3.16±0.02 | 98.11±0.82 |
| F5 | 150.3±0.340 | 6.6±0.05 | 0.1785±0.04 | 3.25±0.17 | 99.57±0.33 |
| F6 | 150.3±0.637 | 6.7±0.1 | 0.5505±0.301 | 3.10±0.01 | 99.56±0.83 |
| F7 | 150.5±1.01 | 6.5±0.05 | 0.2593±0.013 | 3.24±0.174 | 101.15±0.54 |
| F8 | 150.1±0.67 | 6.6±0.1 | 0.1802±0.076 | 3.22±0.01 | 97.51±0.49 |
| F9 | 150.7±0.63 | 6.7±0.1 | 0.1395±0.06 | 3.19±0.02 | 99.49±0.81 |
| F10 | 150.84±1.36 | 6.8±0.05 | 0.1474±0.01 | 3.10±0.01 | 98.37±0.67 |
| F11 | 150.8±0.71 | 6.6±0.1 | 0.365±0.24 | 3.22±0.15 | 100.7±0.52 |
| F12 | 150.7±0.72 | 6.7±0.1 | 0.154±0.04 | 3.16±0.01 | 98.32±0.061 |

The results of weight variation of tablets for all formulations were ranged from 149.9±0.408 to 150.9±0.406 (mg) indicating that the weight variation is within the pharmacopoeial limits. Hardness was ranged from 6.5±0.05 to 6.9±0.15 (kg/cm$^2$). friability ranged from

0.0133±0.003 to 0.097±0.0209(%) indicating that the friability of all formulations was less than 1%. thickness of all formulations ranged from 3.10±0.01 to 3.27±0.04 (mm). The percentage drug content of all formulations was ranged from 97.21±0.29 to 101.15±0.54 (%) which was all within the acceptable limits of official standards.

***In-vitro* drug release**

The *in-vitro* release study was carried out in three different dissolution media namely, in simulated gastric fluid (acidic buffer pH 1.2) for 2 hrs and then medium was replaced by simulated intestinal fluid for next 3 hrs (phosphate buffer 7.4pH) and then followed by simulated colonic fluid (phosphate buffer 6.8 pH) for next 7hrs.

**Table 4: cumulative percentage drug release of F1 to F12**

| Time (min) | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 | F10 | F11 | F12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 15 | 4.89 | 6.07 | 5.60 | 4.89 | 5.36 | 4.77 | 6.19 | 5.21 | 4.02 | 4.77 | 3.86 | 3.86 |
| 30 | 6.26 | 8.08 | 7.68 | 7.84 | 8.20 | 7.60 | 8.48 | 8.39 | 7.83 | 6.04 | 4.44 | 6.53 |
| 60 | 8.90 | 11.48 | 9.46 | 9.78 | 8.91 | 9.77 | 11.48 | 11.83 | 9.06 | 8.49 | 6.67 | 7.99 |
| 120 | 13.72 | 13.08 | 12.00 | 15.47 | 13.50 | 13.06 | 14.43 | 15.41 | 12.43 | 10.22 | 9.47 | 11.43 |
| 180 | 17.44 | 15.26 | 14.87 | 18.50 | 15.50 | 16.64 | 20.10 | 17.26 | 16.33 | 13.29 | 12.89 | 12.26 |
| 240 | 18.76 | 18.62 | 18.16 | 21.48 | 19.16 | 19.90 | 25.63 | 24.25 | 23.65 | 14.69 | 15.95 | 15.83 |
| 300 | 20.96 | 20.64 | 19.59 | 23.62 | 23.51 | 21.75 | 27.69 | 26.97 | 25.67 | 15.99 | 17.77 | 17.94 |
| 360 | 25.33 | 24.51 | 23.64 | 28.55 | 26.93 | 26.51 | 33.70 | 31.76 | 30.91 | 19.32 | 21.43 | 21.41 |
| 420 | 27.51 | 27.18 | 25.89 | 31.88 | 30.99 | 29.44 | 36.93 | 33.02 | 32.58 | 22.50 | 23.92 | 23.82 |
| 480 | 30.91 | 28.79 | 28.16 | 33.51 | 32.41 | 31.90 | 40.84 | 40.24 | 35.18 | 25.29 | 27.26 | 26.16 |
| 540 | 32.57 | 32.07 | 31.48 | 37.19 | 35.21 | 34.07 | 47.23 | 46.00 | 37.99 | 27.18 | 30.03 | 27.67 |
| 600 | 35.46 | 34.12 | 33.52 | 40.93 | 38.36 | 36.84 | 55.52 | 49.58 | 46.11 | 29.99 | 32.07 | 30.70 |
| 660 | 38.57 | 37.22 | 36.54 | 44.15 | 42.11 | 39.91 | 59.37 | 55.31 | 50.24 | 32.15 | 34.16 | 33.11 |
| 720 | 42.56 | 41.25 | 39.94 | 49.80 | 47.71 | 44.58 | 63.06 | 60.69 | 54.51 | 33.83 | 36.38 | 35.62 |

Results showed that the drug release from the formulations decreased with increase in the amount of polymer added in each formulation. Formulation F10 and F12 shows slow release compared to all formulations and found to be good candidate for colonic drug delivery.

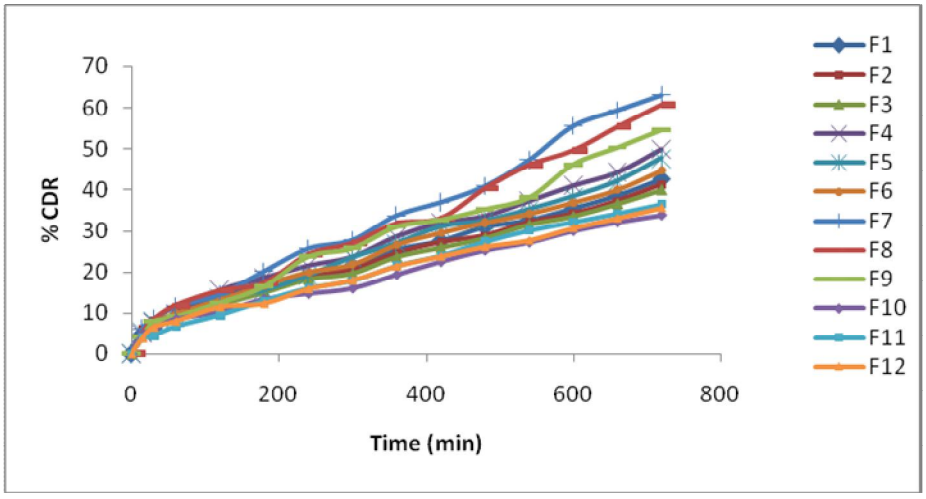


**Fig. 2: Comparision of cumulative% releaseVsTime profile of formulations F1-F12**

**Release kinetics of Lornoxicam**

**Table 5: Mathematical modeling and drug release kinetics of formulation F1 toF12**

| FORMULATION CODE | KINETIC MODELS | | | | | |
|---|---|---|---|---|---|---|
| | Zero order | First order | Higuchi | Hixson | Korsmeyer-pappas | |
| | $R^2$ | $R^2$ | $R^2$ | $R^2$ | n | $R^2$ |
| F1 | 0.979 | 0.993 | 0.979 | 0.993 | 0.504 | 0.996 |
| F2 | 0.976 | 0.992 | 0.966 | 0.994 | 0.409 | 0.989 |
| F3 | 0.982 | 0.995 | 0.968 | 0.997 | 0.439 | 0.993 |
| F4 | 0.983 | 0.988 | 0.972 | 0.991 | 0.496 | 0.990 |
| F5 | 0.986 | 0.988 | 0.963 | 0.992 | 0.474 | 0.989 |
| F6 | 0.982 | 0.994 | 0.976 | 0.995 | 0.490 | 0.991 |
| F7 | 0.991 | 0.967 | 0.945 | 0.980 | 0.483 | 0.994 |
| F8 | 0.989 | 0.969 | 0.944 | 0.980 | 0.502 | 0.987 |
| F9 | 0.987 | 0.977 | 0.956 | 0.984 | 0.568 | 0.976 |
| F10 | 0.983 | 0.994 | 0.961 | 0.995 | 0.478 | 0.992 |
| F11 | 0.990 | 0.998 | 0.975 | 0.998 | 0.61 | 0.996 |
| F12 | 0.983 | 0.996 | 0.973 | 0.996 | 0.528 | 0.983 |

All the formulations show linearity with respect to zero order and first order kinetics. The regression values of Zero order kinetics of Formulations ranges from 0.976 to 0.991 and the regression values of first order kinetics of Formulations ranges from 0.967 to 0.998. From the regression values was found that the drug release follows mixed order kinetics. To ascertain the drug release mechanism, the *in-vitro* data were also subjected to Higuchi's model. $R^2$ values of all formulations ranges from 0.945 to 0.979.The formulations were subjected to Peppas plots, 'n' value ranges from 0.409 to 0.61 indicating that the drug release was by non-Fickian diffusion mechanism.

## STABILITY STUDIES

The best formulations F10 and F12 subjected to stability studies at 40°C/75 RH and room temperature for 2 months. Then the tablets were analysed for physical change, drug content estimation and *in-vitro* dissolution studies at an interval of 15 days. Results show that after analyzing there was no change in case of physical appearance, no significant differences in the drug content and dissolution study. Comparison of drug release profile of formulations before stability and after stability the formulations found to be stable throughout the study period.

## SUMMARY

The present study was carried out to develop colon targeted matrix tablets of lornoxicam using natural polymers such as Tamarind seed polysaccharide, Guar gum, Xanthan gum alone and in combinations by direct compression method. Based on the IR studies there is no possibility of interaction between Lornoxicam and Tamarind seed polysaccharide, Guar gum and Xanthan gum.

All the prepared formulations were evaluated for both pre-compressive and post-compressive parameters such as melting point, solubility studies, compatibility studies, angle of repose, bulk density, tapped density, carr's index, hausner's ratio, tablet thickness, hardness, friability, weight variation and drug content uniformity, the values obtained were found to be satisfactory and they complies with pharmacopoeial standards.

The tablets were subjected to *in-vitro* drug release in 1.2 pH for first 2 hrs then in 7.4 pH for next 3hrs followed by 6.8pH phosphate buffer. *In-vitro* studies revealed that tablets formulated with the natural polymers have controlled the drug release in stomach and small intestine environment and released maximum amount of the drug in colonic environment. Results showed that tablets with higher binding concentration showed minimum drug release. Combination of polymers shows greater retarding of drug release. The formulations F10 and F12 produced better controlled in colonic conditions with 33.832 and 35.629% of drug release over a period of 12hrs in comparison to other formulations.

The release data was fitted to various mathematical models such as Higuchi, Korsmeyer-peppas, Hixson crowell, Zero order and first order to evaluate the kinetics of drug release. The drug release follows mixed order kinetics and mechanism was found to be non-Fickian diffusion.

## CONCLUSION

Present study revealed that tablets formulated with the natural polymers have controlled the drug release in stomach and small intestinal environment and released maximum amount of the drug in colonic environment. Results showed that tablets with higher binding concentration showed minimum drug release. Combination of polymers shows greater

retarding of drug release. It can be concluded that polysaccharides capable of retarding the drug release. Thus the approach polysaccharide based microbial degradation is potential system for the colonic delivery of lornoxicam for the treatment of IBD.

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