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### Design and evaluation studies on colon specific ciprofloxacin matrix tablets for Inflammatory Bowel Disease treatment

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#### ABSTRACT

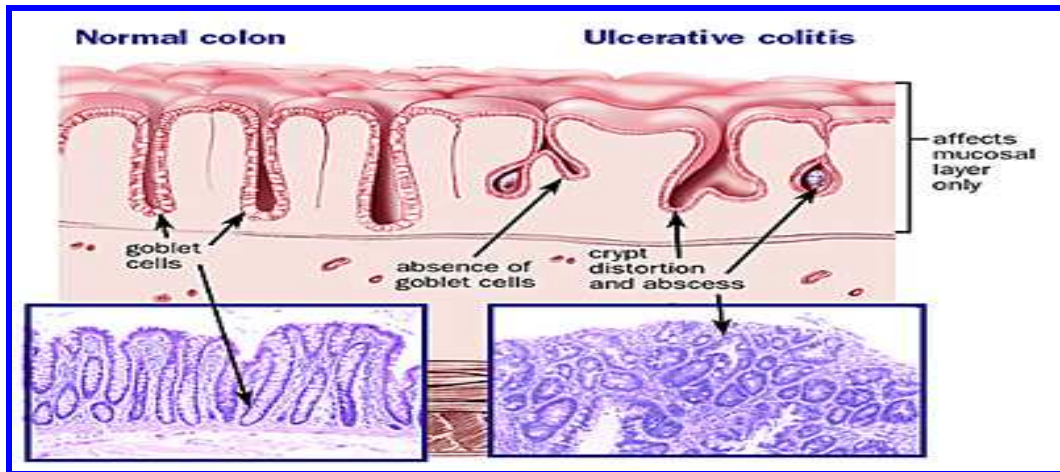
Matrix colon tablet formulation of Ciprofloxacin hydrochloride containing matrix carrier granules were prepared by wet granulation technology. The granular bed were evaluated for rheological properties indicated that, the granules were freely flowable and easily compressible. Granules were compressed in 10 station tablet punching machine and evaluated for post compressional characteristics of weight variation, thickness test, diameter test, hardness test, friability. The results showed that the pre formulation batches of tablets showed uniform and reproducible compressional characteristics. The drug content of tablet revealed that the drug is accurately and fairly distributed. The hardness ( $\text{Kg/cm}^2$ ) was found in the range of  $4.5 \pm 0.090 - 5.6 \pm 0.201 \text{ Kg/cm}^2$  with minimum friability. The colon targeted tablets were not disintegrated in 0.1N HCl. The in vitro drug release studies indicated that sterculia and almond gum could be used for development of colon matrix tablets of ciprofloxacin hydrochloride. The matrix tablet containing both gums was susceptible to bacterial degradation in presence of rat cecal content. The formulation containing more amount of sterculia gum is suitable as matrix carrier for colonic ciprofloxacin HCl matrix tablets.

**Keywords:** Ciprofloxacin hydrochloride, Matrix carrier, In vitro studies and Inflammatory bowel disease.

#### INTRODUCTION

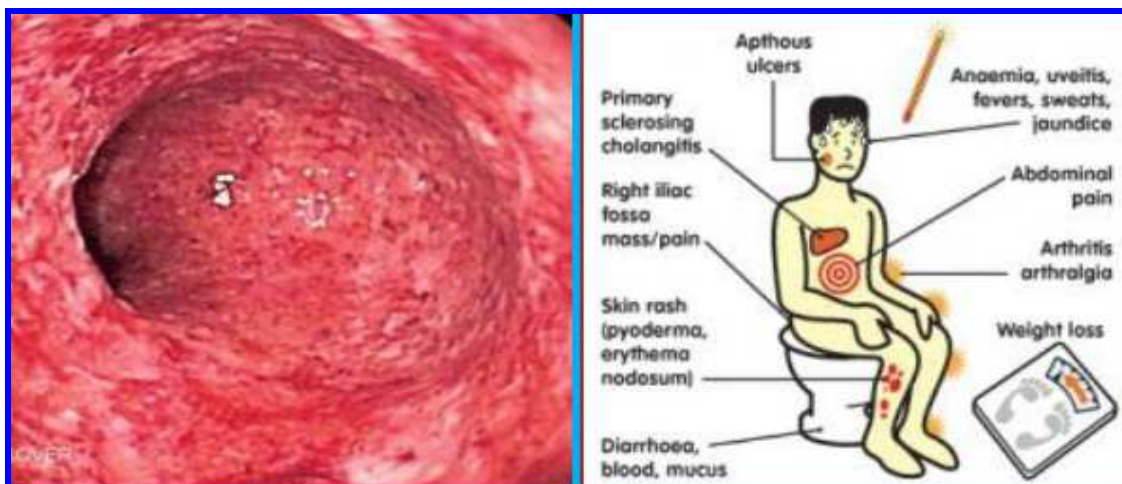
Ulcerative colitis is an inflammatory bowel disease (IBD), causes inflammation and sores (ulcers) in the lining of the rectum and colon. Ulcerative colitis (UC) is closely related to another condition of inflammation of the intestines called Crohn's disease. Together, they are frequently referred to as IBD. Ulcerative colitis can occur in people of any age, but it usually starts between the ages of 15 and 30, and less frequently between 50 and 70 years of age. It affects men and women equally. The most common symptoms of ulcerative colitis are

abdominal pain and bloody diarrhea due to inflammation triggered by the immune system. Ulcerative colitis likely involves abnormal activation of the immune system in the intestines. The continued abnormal activation of the immune systems causes chronic inflammation and ulceration. Ulcerative colitis is not caused by emotional distress or sensitivity to certain foods or food products, but these factors may trigger symptoms in some people. The stress of living with ulcerative colitis may also contribute to a worsening of symptoms [1-2].



**Figure 1: Ulcerative colitis of Colon mucosal lining with crypt distortion and abscession**

Ulcerative colitis is diagnosed by blood test, Stool sampling, colonoscopy or sigmoidoscopy with biopsy. There is some evidence that a stool test for a protein called calprotectin could be useful in identifying patients who would benefit from colonoscopy. Calprotectin seems to be a sensitive marker of intestinal inflammation. Ulcerative colitis is treated by using Aminosalicylates (mesalamine), Corticosteroids (Budesonide), Immunomodulators (azathioprine) etc. Colon cancer is a recognized complication of chronic ulcerative colitis. The risk for cancer begins to rise after eight to ten years of colitis.



**Figure 2: Inflammation, ulceration of colon in Ulcerative colitis and the symptoms of IBD**

Ciprofloxacin is an antibiotic that destroys bacteria, which may help control infection and inflammation in the intestines that developed due to crohn’s disease. Ciprofloxacin is effective against a broad range of bacteria. Ciprofloxacin and metronidazole may be used

together to treat Crohn's disease. The antibiotics under current investigation were ciprofloxacin, metronidazole, and doxycycline, which can treat postinfectious IBS, a disorder believed to be caused by alterations in intestinal microflora [3-4].

Ciprofloxacin hydrochloride (CH) is a broad-spectrum antibiotic that is active against both Gram-positive and Gram-negative bacteria used in ulcerative colitis and irritable bowel syndrome. A currently popular antibiotic for gastrointestinal infection is ciprofloxacin, which is employed successfully in UC and CD. Ciprofloxacin is a fluoroquinolone that is well absorbed and is active against Gram-negative facultative anaerobes and microaerophiles, such as salmonella, shigella and campylobacter, and it also has modest activity against Gram-positive organisms such as *Enterococcus faecalis* [5]. Ciprofloxacin HCl functions by inhibiting DNA gyrase, a type II topoisomerase, which is an enzyme necessary to separate replicated DNA, thereby inhibiting cell division. It is rapidly absorbed orally and shows 60-70% oral bioavailability and 3-4 h elimination half-life. Due to its elimination half-life, ciprofloxacin is administered twice to thrice daily [6]. The molecular formula is  $C_{17}H_{18}FN_3O_3$  and the molecular weight is 331.3415. CH is rapidly absorbed from the gastrointestinal tract after oral administration. CFH has a  $t_{1/2}$  of 4.0 h with an oral bioavailability of 70%. CFH chemical structure is given in figure-1 and its IUPAC name is *1-cyclopropyl-6-fluoro-4-oxo-7-piperazin-1-ylquinoline-3-carboxylic acid* [7].

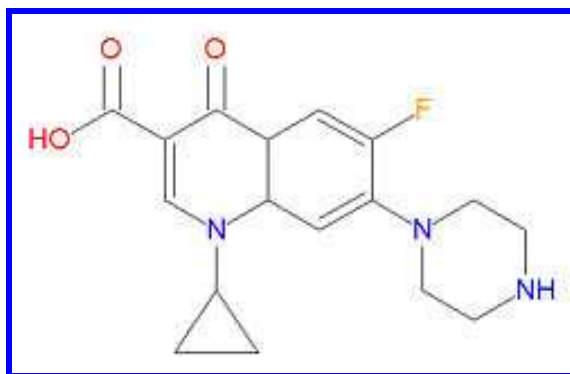


Figure 3: Chemical structure of Ciprofloxacin hydrochloride.

Abdul W. Basit et.al [8] developed Polysaccharide-based colonic drug delivery. The results show there was no drug release in the stomach or small intestine confirming the ability of the amylose in the coating and released 92% of the drug in the colon. Singhal AK et.al [9] developed colon targeted delivery by using guar gum as matrix carrier and Curcumin as a model drug. Forty percent guar gum-containing formulation showed better drug release of 91.1%, at the end of 24 hours in the presence of rat cecal contents. Chickpetty SM et.al [10] developed compression coated of combined time and pH dependent fast disintegrating colonic delivery system using diclofenac sodium as model drug. They reported core tablets compression-coated with HPMC and ED mixture in the ratio 6:4 was found to be suitable for targeting diclofenac sodium to the colon.

Kishore G et.al [11] developed colon targeted tablets of praziquantal using various proportions of xanthan gum and guar gum as matrix carrier. The matrix tablet containing 40% of xanthan gum and guar gum showed maximum drug release, praziquantal on inclusion complexation with  $\beta$ -CD released significantly in colonic environment. Sonia Gupta et.al [12] developed the colon targeted pectin matrix tablet containing 5 - Fluorouracil as model drug

coated with combination of Eudragit RS100 and inulin. Formulation F11 showed the release  $8.5 \pm 2.58\%$  of drug after 5 hrs, The complete drug release from formulation F11 in the presence of rat caecal contents was observed that  $87.1 \pm 3.5\%$  of drug was released after 24h. Surajit Das et.al [13] developed Zinc-pectin-chitosan composite microparticles containing resveratrol as model drug. Formulation prepared at pH 1.5, 1% chitosan, 120 min cross-linking time, and pectin: drug at 3:1 ratio demonstrated colon-specific drug release and *in vivo* colon-specific drug release from the zinc-pectin-chitosan composite particles only. Lai HM et.al [14] developed a novel colon-targeted drug delivery system using guar gum and Eudragit as enzyme-and pH-based materials. *In vitro* drug release was evaluated, using beta-mannanase, rat cecal content, and human fecal media to simulate the pH and enzyme during intestinal transit to the colon. The lansoprazole released in simulated small intestine fluid (pH 6.8) after 5 hours was less than 10% and in rat cecal content (pH 7.4) is  $80.01 \pm 0.3\%$ . The developed system could be a potential carrier to the colon.

Based on the above literature review it was evident that there is a scope for development and evaluation of colon specific tablets that could reduce inflammation during UC by using model drug like CH. This type of dosage form is useful in reducing symptomatic pain and helps patient to manage the disease condition. Hence in the present investigation colon targeted Ciprofloxacin hydrochloride tablets were developed by using wet granulation technology by employing various excipients, matrix carriers towards colon and the tablets were formulated with natural gums as carriers for their evaluation studies. Further various rheological properties of granular bed and compression characteristics of the compressed tablets were studied. Further the tablets were subjected for *In vitro* drug release studies in different pH of dissolution media to mimic the gastrointestinal tract conditions with and without rat cecal content.

## MATERIALS AND METHODS

### Active pharmaceutical ingredient and Reagents:

Ciprofloxacin hydrochloride was kindly supplied by Granules India Ltd, Hyderabad, India. Potassium dihydrogen ortho phosphate and Sodium hydroxide pellets from S.d. Fine chemicals limited, Mumbai were used in study. Insoluble Potato starch procured from S.d. fine chemicals limited, Mumbai. Sterculia gum, Almond gum supplied by Qualigens, Mumbai. HPMC K4M obtained from Yarrow Chemicals, Mumbai. Talc and Magnesium Sterate was obtained from S.d. Fine chemicals limited, Mumbai. Other solvents and chemicals used in the research study were of LR grade.

### Formulation design of Colon targeted tablet containing Ciprofloxacin Hydrochloride:

Table 1. Formulation of colon targeted matrix tablets of ciprofloxacin Hydrochloride

Sl.No	Ingredients	Formulation			
		SG25	SG30	AG25	AG30
1	Ciprofloxacin HCL	250	250	250	250
2	Starch paste 15%	90	90	90	90
3	Sterculia gum	150	180	-	-
4	Almond gum	-	-	150	180
5	HPMC K4 M	98	68	98	68
6	Talc 2%	8	8	8	8

7	Magnesium state 1%	4	4	4	4
8	Total Tablet weight (mg)	600	600	600	600

SG25 Matrix tablet containing sterculia gum of 25 % as carrier

SG30 Matrix tablet containing sterculia gum of 30 % as carrier

AG25 Matrix tablet containing almond gum of 25 % as carrier

AG30 Matrix tablet containing almond gum of 30 % as carrier

### Method of preparation of ciprofloxacin hydrochloride granules by wet granulation [15]:

All the powders as mentioned in formula and required to prepare a batch of 300 tablets were weighed accurately and passed through # 120 mesh sieve and uniformly blended in a cube mixer. Starch paste (15% w/w) was prepared by placing weighed quantity of starch in a beaker containing required volume of hot distilled water and further heated with continuous stirring on water bath till the starch swells and a thick paste was formed. The powder blend was taken in a mortar and was thoroughly triturated with starch paste (15 % w/v) to produce wet mass. Then wet mass was then passed through mesh # 14. The granules so obtained were dried at 40°C/ 30 % RH for 2 – 3 h. Dried granules again passed through mesh # 16. Later, talc and magnesium stearate as required were incorporated and blended. These granules were evaluated for pre-compression characteristics prior to and after incorporating lubricants (granules ready for compression).

### Preparation of ciprofloxacin hydrochloride colon targeted matrix tablet:

The dried granules ready for compression were compressed into tablet using 13 mm plain punches and at a pressure of 5 kg/cm<sup>2</sup> using a 10 station Tablet pilot press (Chamunda Pharma, India) The obtained tablets were evaluated for Compressional characteristics.

### Evaluation of rheological characteristics of ciprofloxacin hydrochloride granular bed:

#### Angle of repose ( $\theta^\circ$ ) [16]:

Angle of repose was determined by measuring the height and radius of the heap of the granule bed. A cylindrical two side open tube of 6 cm length is placed on graph paper. Granules were placed in the tube and slowly removed the tube vertically. With the help of scale the height and radius of the heap were measured and noted. Average of triplicate reading were noted (n = 3).

$$\theta = \tan^{-1} (h/r)$$

h = height of heap of granular bed.

r = radius of heap of granular bed.

#### Bulk density [17]:

Bulk density was determined (Konark instruments, India) by placing the granules blend in a measuring cylinder and the total volume was noted. The weight of granule bed was determined in a Dhona 200 D electronic balance. Bulk density was calculated by using the formula. Average of triplicate reading were noted (n = 3).

$\text{Bulk density} = \frac{\text{Total weight of granules}}{\text{Total volume of granules.}}$
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**Tapped density [17]:**

Tapped density was determined (Tapped density apparatus, Konark instruments, India) by taking the dried granules in a measuring cylinder and measuring the volume of granules after 100 tappings and weight of the total granules. Average of triplicate reading were noted (n = 3).

$$\text{Tapped density} = \frac{\text{Total weight of granules}}{\text{Total volume of granules after 100 tappings.}}$$

**Compressibility index [16]:**

Compressibility index was determined by placing the granules in a measuring cylinder and the volume ( $V_0$ ) was noted before tapping. After 100 tapings again volume ( $V$ ) was noticed. Average of triplicate compressibility indices of granule readings were taken and tabulated (n = 3).

$$\text{Compressibility index} = (1 - V / V_0) \times 100$$

$V_0$  = volume of powder/granules before tapping.  
 $V$  = volume of powder/granules after 100 tappings.

**Evaluation of Compressional characteristics of ciprofloxacin hydrochloride colon targeted matrix tablet:****Weight Uniformity [18]:**

Twenty tablets were taken and weighed individually. Average weight was calculated standard deviation and percent coefficient of variance was computed.

**Thickness test [18-19]:**

The tablets were evaluated for their thickness using a micrometer (Mitutoyo, Japan). Average of three readings were taken and the results were tabulated (n = 3).

**Diameter test [18]:**

The tablets were evaluated for diameter using a micrometer (Mitutoyo, Japan). Average of three readings were taken and tabulated (n = 3)

**Hardness test [20]:**

The tablets were evaluated for their hardness using Pfizer hardness tester. Average of three reading were taken and tabulated (n = 3).

**Disintegration test [21]:**

The disintegration time of tablet was determined by placing one tablet in each of the six tubes of the basket and operated the apparatus, using pH 1.2 buffer solution maintained at  $37 \pm 0.5^\circ\text{C}$ . Then the disintegration time of tablet is recorded. The experiment was repeated for three times and average was noted.

**Friability test [22]:**

The friability of the tablets was determined in Roche Friabilator. Five tablets were weighed accurately and placed in the tumbling chamber and rotated at 25 rpm for a period of 4 min.

Tablets were taken and again weighed. The percentage weight loss was determined by using formula given below. The experiment was repeated for three times and average was noted.

$$\% \text{ Friability} = \frac{\text{Initial weight of tablets} - \text{Final weight of tablets}}{\text{Initial weight of tablets}} \times 100$$

**Determination of drug content [19]:**

Five ciprofloxacin tablets were crushed into powder in a mortar and powdered equivalent to 250 mg of ciprofloxacin was taken in a volumetric flask containing distilled water and kept aside with constant shaking on a rotary shaker for 24 hours to extract the total drug present in the tablet. Then the absorbance of the solutions was measured after suitable dilution at 271 nm against drug devoid distilled water as blank. Averages of triplicate readings were taken. The content of drug was calculated using slope from calibration curve.

**Accuracy and Precision study [23]:**

The accuracy and recovery studies were carried out by adding a known amount of drug from the pre analyzed tablet powder and percentage recoveries were calculated. The reproducibility of estimation was determined by performing the tablet drug content of different samples. The results of precisions were expressed in % SD.

***In vitro* dissolution study [24]:****Drug release study in phosphate buffer of pH 1.2 and Sorenson's phosphate of pH 7.4.**

To access the integrity of matrix tablet, tablets were evaluated for drug release in the physiological environment of stomach, small intestine and colon. The conditions of GI transit were mimicked from stomach to colon. The drug release study were carried out in pH 1.2 in USP dissolution test apparatus of 900 ml fluid (Apparatus 1, 100 rpm, 37°C) for 2 h as the gastric emptying time of stomach is 2 h and at the end of gastric emptying time the dissolution medium were replaced with Sorenson phosphate buffer of pH 7.4 and continued the drug release study for 3 h as the small intestine transit time is 3 h and the samples were withdrawn at regular intervals and diluted with respective dissolution medium and estimated the drug release by measuring the sample absorbance at  $\lambda$  max of the drug in UV spectrophotometer.

**Drug release study in Sorenson phosphate buffer of pH 6.8:**

The susceptibility of matrix tablet to colonic enzymatic degradation was assessed by conducting drug release studies by modify USP dissolution apparatus. A 150 ml beaker containing 100 ml of 4 % w/v rat cecal content was placed and the basket was manipulated to the centre of the beaker. The rat cecal content was prepared by male albino rats. The rats of 150-200 kg were selected and kept for fasting for one day with intermittent administering water before the drug release was conducted. The rats were taken from cage and anesthetized by spinal cord traction before 30 min prior to the experiment. Abdomen of rat was opened and the cecum was ligated at both ends and then suspended in saline phosphate buffer of pH 6.8 with the continuous supply of CO<sub>2</sub> in order to maintain the anaerobic condition. The cecum were opened and the cecal contents were weighed, transferred into 100 ml of Sorenson phosphate buffer of pH 6.8 to make 4 % w/v of rat cecal content solution, the cecal enzymes

are active in anaerobic condition, to mimic the anaerobic condition, the solution was continuously bubbled with CO<sub>2</sub>.

The drug release study of matrix tablet was conducted by slight modification of dissolution apparatus, by placing the tablet in basket and immersed in 100 ml of 4% rat cecal content in Sorenson phosphate buffer of pH 6.8 in 150 ml beaker. The beaker was immersed in water containing 1000 ml jar and in turn immersed in water bath (Apparatus 1, 100 rpm, 37°C) with continuous supply of CO<sub>2</sub>, studied the drug release up to 19 - 20 h as the colonic transit time 24 h. The sample were withdrawn at regular intervals without pre-filter and replaced with fresh buffer. Absorbance of the sample was measured in UV spectrophotometer at absorption maxima of the drug and concentration was calculated by regression equation.

## RESULTS

**Table 1. Evaluation of rheological characteristics of ciprofloxacin hydrochloride granular bed**

Formulation	Bulk density gm/cc	Tapped density gm/cc	Compressibility Index %	Angle of repose (°θ)	
				Before glidant	After glidant
SG 25	0.5 ± 0.04	0.58 ± 0.00	13.3 ± 0.58	23.68 ± 0.73	22.00 ± 0.80
SG 30	0.45 ± 0.01	0.50 ± 0.18	9.9 ± 0.02	25.60 ± 0.16	24.21 ± 0.06
AG 25	0.41 ± 0.01	0.44 ± 0.01	10.33 ± 0.58	26.28 ± 0.78	23.05 ± 0.34
AG 30	0.50 ± 0.005	0.59 ± 0.01	15.33 ± 0.47	25.16 ± 0.14	23.09 ± 0.06

**Table 2. Evaluation of compressional characteristics of ciprofloxacin hydrochloride tablets (n= 3).**

Formulation	Weight variation (mg)	Thickness (mm)	Diameter (mm)	Hardness (kg/cm <sup>3</sup> )	Disintegration Time (min)	Friability %	Drug content (mg)
SG 25	602± 0.940	4.11± 0.030	13.16± 0.040	5.6 ± 0.201	ND	0.41± 0.210	249.81± 0.510
SG 30	601 ± 0.920	4.09 ± 0.040	13.38± 0.180	4.50± 0.090	ND	0.40± 0.090	250 ± 0.500
AG 25	601± 0.990	4.20± 0.030	13.17± 0.090	5.0 ± 0.202	ND	0.49± 0.170	250.13± 1.000
AG 30	602 ± 2.210	4.16 ± 0.030	13.09 ± 0.020	4.60± 0.160	ND	0.34 ± 0.010	248.66± 0.4700

\* ND → Not disintegrated till 6 h.

**Table 3. Accuracy and precision studies of colon matrix tablets of ciprofloxacin HCl (n= 3).**

Drug	Formulation	Amount of drug added (mg)	Amount of drug recovered (mg)	Accuracy	Precision
Ciprofloxacin Hcl	SG25	250	250.00	100.0%	0.40
	SG30	250	250.00	100%	0.50
	AG25	250	249.81	99.2%	0.51
	AG30	250	248.66	99.48%	0.47



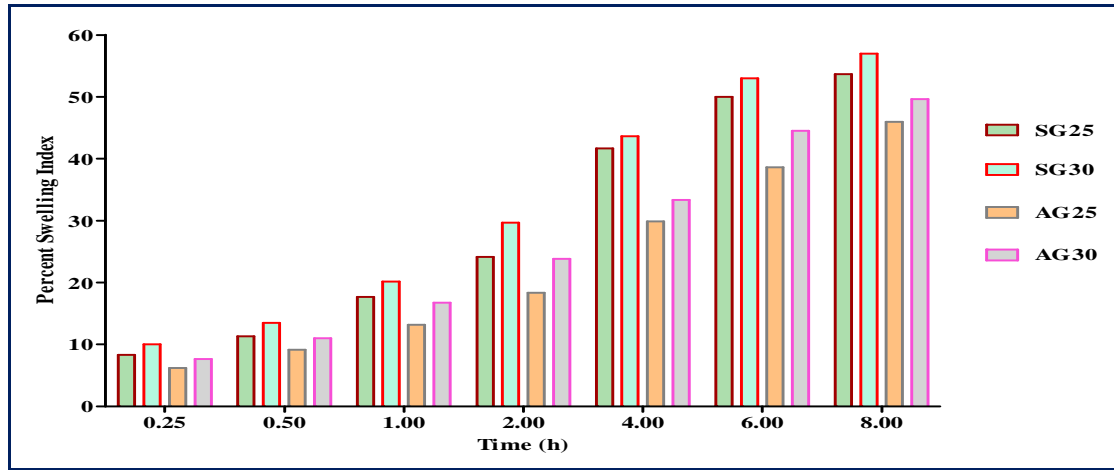


Figure 4. Swelling studies of Ciprofloxacin colon targeted tablets with sterculia gum and almond gum as matrix carriers at 25 and 30 %.

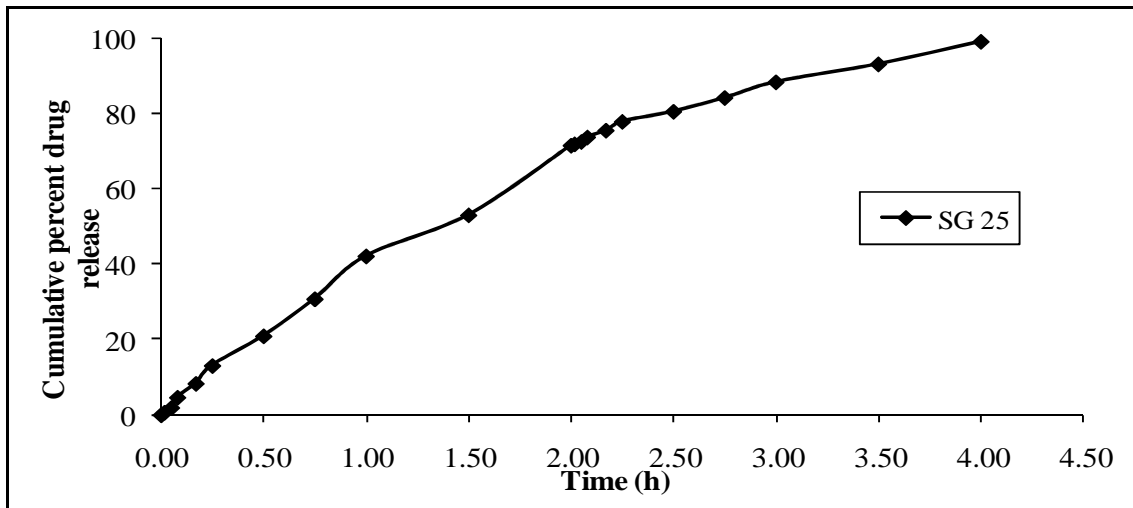


Figure 5. *In vitro* release of ciprofloxacin HCl from colon targeted matrix tablet containing 25% of Sterculia gum without rat cecal content

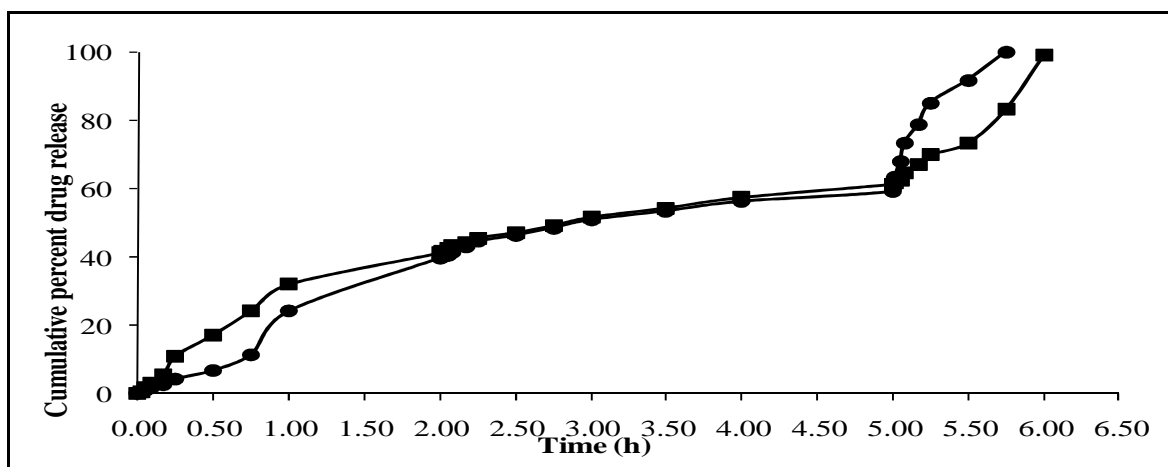


Figure 6. *In vitro* release of ciprofloxacin Hcl from colon targeted matrix tablet containing 30% of Sterculia gum with out and with rat cecal content

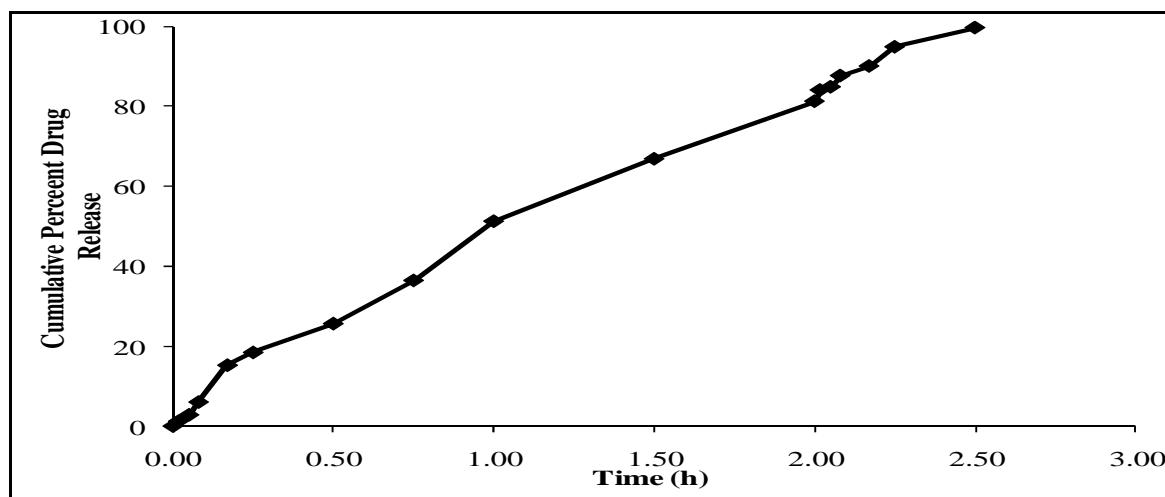


Figure 7. *In vitro* release of ciprofloxacin HCl from colon targeted matrix tablet containing 25% of Almond gum without rat cecal content

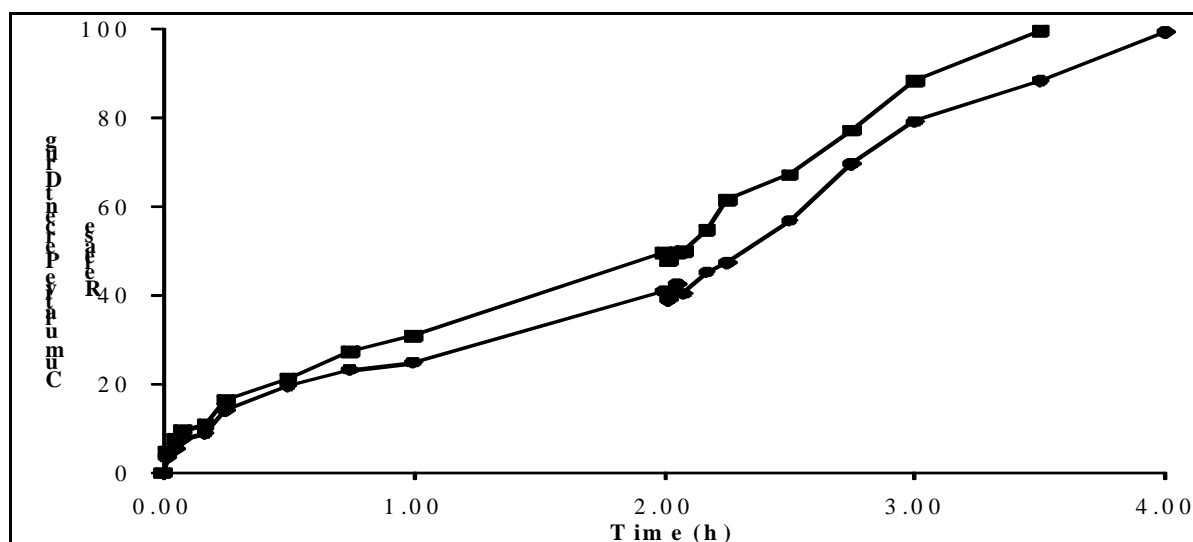


Figure 8. *In vitro* release of ciprofloxacin HCl from colon targeted matrix tablet containing 30% of Almond gum with out and with rat cecal content

## DISCUSSION

The micromeritic properties of the formulation observed indicated that the powder beds were suitable for compression and also free flowing. The angle of repose of all formulations were found in the range of  $23.68^{\circ}$  to  $26.28^{\circ}$  before adding glidants and after addition of glidants, the angle of repose was found to be  $22.0^{\circ}$  –  $24.21^{\circ}$  indicating the angle of repose was reduced after adding glidant and the granules are freely flowable. Bulk density of sterculia and almond gum formulations were found to be  $0.41 \pm 0.001$  to  $0.50 \pm 0.004$  and the tapped density is in range of  $0.44 \pm 0.001$  to  $0.59 \pm 0.001$ . Bulk density of less than 1 was found for all formulations developed during this phase. Carr's Compressibility index of granular bed was found to be less than 15 % indicating good to excellent flow of granules.

The matrix tablet was evaluated for post compressional characteristics like weight variation, thickness, diameter, hardness, disintegration time and swelling studies. The weight variation

study of all the formulation were found to be  $601 \pm 0.940$  to  $602 \pm 0.920$  indicating that, the tablets weight variation are acceptable within the I.P. limit  $600 \pm 5\%$ . Thickness of the tablet SG25 to AG30 were found to be  $4.09 \pm 0.40$  mm and  $4.20 \pm 0.30$  mm, and the diameter of tablets were found to be in the range of  $13.38 \pm 0.180$  mm and  $13.09 \pm 0.020$  mm, batches of different formulation are uniform and reproducible. The hardness of the tablets were found to be  $4.5 \pm 0.090$  -  $5.6 \pm 0.201$  Kg/cm<sup>2</sup> indicating tablets possess sufficient strength. Further disintegration test was conducted to understand the actual behaviour of the tablets *In vitro*. It was found that, the ciprofloxacin colon targeted tablet did not disintegrate for 6 h in 0.1N HCl but gradual swelling of the tablet was observed. There was no loss of integrity. The friability of formulations was found to be minimum (0.34 % and 0.49 %). Tablet can withstand stress during transport. The drug content of tablet formulations was found to be 248.66 to 250.13 mg indicating drug content was uniform.

The tablets of formulation SG25, SG30, Ag25 and AG30 were evaluated for swelling study, the % swelling index were found to be 53.66%, 57%, 45.96% and 49.63% the results indicated that, as the content of the polymer increases, the hydration of polymer increases due to more amount of water diffusion in the polymer, as a result the % of swelling index increased. The accuracy and precision studies indicates the uniform distribution of drug in all the formulations with good reproducibility.

The *In vitro* drug release study was carried in three different pH medium in order to mimic the GIT condition. First the drug release was carried in stomach pH 1.2 for 2 h and then the medium was replaced with Sorensen phosphate buffer of pH 7.4 for later 3 h to mimic small intestine environment, further the drug release in continued by replacing the medium with Sorenson phosphate buffer of pH 6.8 for 19 h (Control release). In order to study the susceptibility of matrix tablet to colonic enzymes, the medium were replaced with phosphate buffer saline of pH 6.8 containing 4% rat cecal content and studied for 19 h. With this step it would be fair to understand whether the drug release is influenced by dissolution medium or the rat cecal contents medium.

The drug release study was performed with and without rat cecal content. The formulation SG25 containing 25% of matrix carrier released 247.8 mg of drug within 4 h indicating drug released in stomach and small intestine. During the study observed that, tablet swelled after 15 minutes and remained intact throughout the 24 h dissolution study. Since complete drug release was observed only in stomach and small intestine media it was ascertained that 25 % sterculia gum as matrix carrier would not be adequate to target to colon. Hence further studies with rat cecal content was not continued. The formulation SG30 containing 30% of matrix carrier released 207.19 mg of drug in 5.75 h, it was observed that, tablet swelled after 15 min and remained intact throughout the 24 h dissolution study. The same formulation SG30 containing 30% of matrix carrier in presence of 4% rat cecal content released 249.7 mg in 5.75 h. From the above results it could be ascertained that additional amount of drug released due to rat cecal enzymatic break down of matrix tablet is 42.54 mg within 5.75 h and at the end of 24 h the matrix tablet integrity did not retained. The polymer matrix was susceptible to anaerobic enzymes, the viscous gel of the matrix weakens to release the drug.

The drug release study was performed with and without rat cecal content. The formulation AG25 containing 25% of matrix carrier released 249.08 mg of drug within 2.5 h due to swellind and leaching behaviour of almond gum. The formulation AG30 containing 30% of matrix carrier released 248.55 mg of drug in 4 h, it was observed that, tablet swelled and

remained intact throughout the 24 h dissolution study. The same formulation AG30 containing 30% of matrix carrier in presence of 4% rat cecal content released 249.34 mg in 3.5 h.

The results has given an insight that sterculia and almond gum could be used for development of colon matrix tablets of ciprofloxacin hydrochloride with gradual increments in their amount to optimize the formulation of colon tablets.

### CONCLUSION

The pre compressional and post compressional characteristics study of formulations indicate the granules are freely flowable and easily compressible, the tablets of all batches of different formulations are uniform and reproducible for their compressional parameters from batch to batch. The swelling study of colon targeted matrix tablet containing sterculia gum and almond gum as carriers with high swelling index due to their hydrophilic nature. The matrix tablet containing the lower percent sterculia gum and almond gum didn't retained the drug release in stomach and small intestine and remained intact during the 24 h study in absence of rat cecal content and on increasing the concentration of matrix carrier the drug release in stomach and small intestine is somewhat reduced. The matrix tablet containing both gums was susceptible to bacterial degradation in presence of rat cecal content. The formulation containing more amount of sterculia gum is suitable as matrix carrier for colonic ciprofloxacin HCl tablets as it might release small amount of drug in stomach and small intestine and the remaining amount could be dumped in colon due to break down by rat cecal content enzymes. Although the erratic results seen, which attribute to colon targeting in general, would indicate the tablets could not target to the colon but further improvement could possibly made by increasing the percent w/w of polymer content.

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