ISSN: 0976-7126

INTERNATIONAL JOURNAL OF PHARMACY & LIFE SCIENCES

Studies on design and development of colon specific drug delivery using sesbania gum

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Abstract

The aim of present work was to develop colon targeted drug delivery systems based on polysaccharide, sesbania gum, were evaluated using in-vitro method. Sesbania gum, in the form of matrix, enteric-coated and compression-coated tablets, were evaluated for in-vitro drug release studies. Curcumin was used as a model drug to assess the ability of guar gum to deliver the drugs selectively to the colon by conducting in-vitro drug release studies. Sesbania gum, in the form of matrix and enteric-coated tablets failed to release the drug in the physiological environment of colon. In view of this result, fast disintegrating curcumin core tablets were compression coated with coat formulation containing different quantity of sesbania gum and the ability of sesbania gum to release the drug in the colon is demonstrated by in vitro dissolution testing. The sesbania gum as 265 mg coat weight was found insufficient to protect curcumin core till 5 hr dissolution study. The compression coated curcumin tablets coated with SG in 345 mg provided best degradation in colonic fluids. It found that compression coated tablet of curcumin coated with SG (345 mg) was most likely to provide targeted delivery of curcumin to the colon which showed good stability also. Thus, the results clearly demonstrate that sesbania gum is a potential colon-specific drug delivery carrier.

Keywords: Sesbania gum, Curcumin, Compression coated tablet.

Introduction

Colon-specific drug delivery has gained increased importance in the delivery of drugs for the treatment of local diseases associated with the colon, such as Crohn's disease, ulcerative colitis, colorectal cancer and amoebiasis. Amoebiasis is an infection of the large intestine caused by entamoeba histolytica, a single celled protozoan parasite that causes 34–50 million symptomatic infections each year and is responsible for up to 100,000 deaths[1,2]. Inflammatory bowel disease (IBD) is an umbrella term which includes Crohn's disease and ulcerative colitis. IBD can be seen most frequently in the early adult life. Most widely used classes of drugs for the therapy include 5-amino salicylic acid (5-ASA) drugs, steroids and immune suppressants (long term therapy)[3]. All these classes are potent enough but are not devoid of side effects. For example 5- ASA drugs causes anemia, skin rashes, heart burn, reduced sperm count during therapy and are to be taken in high doses. Corticosteroids are associated with hypertension, diabetes, insomnia, osteoporosis, muscle weakness, delayed healing, peptic ulcers, glaucoma, growth retardation, psychiatric disturbances and weight gain while immunosuppressant cause bone marrow suppression, blood problems, kidney and liver damage. The risk of reoccurrence of the disease and colon carcinoma is more if these diseases are not properly treated. So, curcumin was selected as a drug in order to treat these diseases because it has been found to be safe and effective molecule, which is also proved to be a potent anti-inflammatory [4, 5], anticancer[6] and antioxidant[7]. It can be used up to 8 gram per day in human volunteers[8]. Various approaches have been proposed for targeted colon drug delivery, namely pH and time-dependent systems, pressure-controlled release systems, osmotic systems, prodrugs and polysaccharide-based delivery systems. The pH approach has been shown to lack site-specificity because of inter/intra subject variation and the similarity of the pH between the small intestine and the colon. Timed-release systems depend on the relative consistency of the small intestinal transit times, but the high variability in gastric retention times makes prediction of the accurate location of drug release difficult. Prodrugs and polysaccharide-based delivery systems depend on the enzymatic degradation carried out by the inherent bacterial flora present in the colon, thereby resulting in drug release.

The enzyme trigger mechanism in such delivery systems makes them highly site-specific. Prodrugs, however, are considered as new chemical entities from a regulatory perspective which requires a detailed toxicological study to be performed, before being used as drug carriers. Natural polysaccharides are now extensively used for the development of solid dosage forms for delivery of drug to the colon. A large number of polysaccharides have already been studied for their potential as colon-specific drug carrier systems, such as chitosan, pectin, chondroitin sulphate, cyclodextrin, dextrans, guar gum, inulin, amylose and locust bean gum. Sesbania gum (SG) is derived from the endosperm of seeds of the plant sesbania grandiflora belonging to family Leguminosae (Papillionaceae). It contains high molecular weight hydrocolloidal polysaccharides composed of galactan and mannan units combined through glycosidic linkages. Commercially galactomannans of guar gum (Cyamopsis tetragonolobus L. Taub, Man:Gal 2:1), locust bean gum (Ceratonia siliqua, Man:Gal 2:1) and tara (Caesalpinea spinosa, Man:Gal 3:1) are used. The good swelling characteristics of treated SG can be of value in formulation of sustained release tablets whereby the drug release from matrices can be controlled with the swelling of the polymer. Also, treated SG shows pH dependent swelling characteristics and has better swelling in pH-7.6 phosphate buffer and distilled water as compared to 0.1 N HCL. These differences in swelling can be effectively explored in the formulation of intestinal/colonic drug delivery systems[9-15].

Material and methods

Materials

All the following materials were used as received as a gift sample from Sehat Pharma Pvt.Ltd. Himatnagar: Curcumin, Sesbania gum, PVP-K30, DCP, Eudragit S100, Eudragit L100, Sodium starch glycolate, magnesium stearate and talc.

Methods

Modification of sesbania gum:

The untreated sesbania gum was suspended in 9:1 acetone: chloroform mixture for 6 hr with intermittent stirring and supernatant which contain extraneous impurities (organic solvent soluble impurities) was removed. The precipitated gum was filtered, washed two times with organic solvent mixture and dried in a hot air oven at 45°C. The dried powder was passed through a 150 # sieve and used for further investigations[16].

Physicochemical properties of treated sesbania gum powder:

Treated SG powder was studied for physicochemical properties like microscopic characteristics, loss on drying (moisture content), viscosity, specific gravity, density, ash value, solubility, microbial load, and pH etc. The results of physicochemical properties are shown in Table 1.

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ISSN: 0976-7126

Preparation of curcumin matrix tablets using sesbania gum:
Matrix tablets of curcumin were prepared by wet granulation method using PVP-K30 solution (5% in IPA) as the binder. DCP was used as diluent and a mixture of talc- magnesium stearate (2:1) was used as lubricant. Sesbania gum was included in the formulations in various proportions. The composition of different formulations used in the study containing 450 mg of curcumin in each case is shown in the Table 2. In all the formulations, SG was sieved separately and mixed with curcumin, tartaric acid and DCP. The powders were blended and granulated with PVP-K30 solution. The wet mass was forced through 16 mesh sieve and the granules so obtained were dried at 40 °C for 2 hr in the oven. Dried granules were passed through 20 mesh sieve and the fines were separated using 40 mesh sieve to obtain 20-40 mesh granules. These granules were lubricated with mixture of talc and magnesium stearate (2:1). The lubricated granules were compressed into tablets using multipunch tablet compression machine. The compressed matrix tablets were tested for hardness, friability, drug content, weight variation, and drug release characteristics[17].

Preparation of enteric-coated curcumin matrix tablets[18]:

Preparation of coating solutions:
Eudragit S100 and Eudragit L100 were used as enteric coating polymers. The composition of the different coating solutions is shown in the Table 5.4. The coating solutions consisted of 10 %w/v polymer, 1 %w/v of castor oil and 0.5 %w/v talc. IPA- acetone (70:30) mixture was used as solvent. The castor oil was used as plasticizer and talc as antiadherent. Required quantity of the polymers was dissolved in the IPA-acetone mixture by shaking. Then 1 %w/v of castor oil was added and finally talc was dispersed in the solution. Final volume was adjusted to 25 ml with the IPA-acetone mixture.

Method used for coating of the tablets:
In the present study, dip coating method was used to coat the tablets because of the availability of the limited quantity of the active components. The formulation SG3 was used as the core tablets. The weighed core tablets were dipped into coating solutions by holding with forcep and after dipping were placed on a glass plate (smeared with castor oil) for drying in air for 15 minutes at room temperature. The tablets were then dried at 60°C in an oven for 30 minutes. During drying, the tablets were rotated occasionally. Additional coats were applied by repeating the above-described process till the desired amount of coat weight was obtained. Formulation codes for the enteric-coated tablets were ES1, ES2, and ES3 according to application of different coating solution 1:0, 1:1, and 0:1 respectively.

Preparation of curcumin compression coated tablets using sesbania gum[19]:

Preparation of curcumin core tablets:
The core tablets (average weight 450 mg) of curcumin, for compression coating with Sesbania gum, were prepared by wet granulation technique using PVP-K30 as binder. The composition of core tablets is given in Table 3. DCP was used as a diluent and SSG (20 mg) was added to obtain a fast disintegrating tablet. Curcumin, DCP and SSG were passed through the 100 mesh sieve and thoroughly mixed then granulated using PVP-K30 solution as the binder. The granules so obtained were dried at 40 °C for 2 hr in the oven. Dried granules were passed through 20 mesh sieve and the fines were separated using 40 mesh sieve to obtain 20-40 mesh granules. These granules were lubricated with mixture of talc and magnesium stearate (2:1). The lubricated granules were compressed into tablets using multipunch tablet compression machine. Weight variation, hardness, friability, and disintegration test were performed for the core tablets.

Preparation of curcumin compression coated tablets:
The core tablets of curcumin were compression coated with different coat formulation. The compression coat formulations were prepared using varying concentration of SG (Table 4). Granules of the above material were prepared using PVP-K30 solution. The granules so obtained were dried at 40 °C for 2 hr in the oven. Dried granules were passed through 20-mesh sieve and were lubricated with mixture of talc and magnesium stearate (2:1). Curcumin core tablets were compression coated with a different coating mixture. Initially, 40% of coat weight was placed in a 12.4 mm die cavity of a multipunch tablet compression machine followed by carefully centering the core tablet and addition of reminder of coat weight. The coating material was compressed around the core tablet with high compression force.

Evaluation parameters[20-23]:

Determination of swelling index of sesbania gum powder:
Swelling characteristics of the treated SG was studied in different medium (0.1 M HCl, pH-7.4 phosphate buffer and distilled water). 100 mg of the powder sample was transferred to a dry 10 ml graduated cylinder and the volume occupied by the sample was noted. The sample was wetted with 1 ml of rectified spirit (95 %) and the powder sample was thoroughly dispersed by shaking the cylinder for one minute. Sufficient quantity of medium (0.1 M HCl, pH-7.4 phosphate buffer and distilled water) was added to the cylinders to make the total volume to 10 ml. The cylinder was shake vigorously every 10 minutes for 1 hr and allowed to stand for 24 hr. The volume occupied by the swollen settled powder samples were noted. Taking the dry volume as 100 %, volume occupied by the swollen particles was converted into percentage by using following formula. ***Swelling Index = Swollen height /Initial height***

Thickness:
The thickness of the tables was determined by using vernier caliperse. Five tablets from each formulation were used, and average values were calculated.

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

Hardness:
For each formulation, the hardness of 6 tablets were determined using the validated dial type hardness tester

Friability:
For each formulation, the friability of 6 tablets was determined using Roche friabilator (Camp-bell Electronics, Mumbai, India).

Determination of curcumin content in tablets:
The curcumin tablets were tested for their drug content. Ten tablets were finely powdered; quantities of the powder equivalent to 50 mg of curcumin were accurately weighed and transferred to a 100-ml of volumetric flask. The flask was filled with methanol and mixed thoroughly. The solution was made up to volume and filtered. Dilute 10 ml of the resulting solution to 100 ml with methanol and measure the absorbance of the resulting solution at the maximum at 425 nm using a Systronic-2201 UV/Vis double beam spectrophotometer. The linearity equation obtained from calibration curve as described previously was use for estimation of curcumin in the tablet formulations. The results are shown in Table 5.

In-vitro drug release studies:
The ability of matrix, enteric coated and compression coated tablets of curcumin to remain intact in the physiological environment of stomach and small intestine was assessed by conducting in vitro drug release studies. Drug release studies were carried out using a USP XXIII dissolution rate test apparatus (Apparatus 1, 100 rpm, 37 °C) in pH 1.2 for first 2 hrs then by pH 4.6 for 2 hrs followed by pH 6.8 for 1 hr and then next by pH 7.4. At the end of the time period 10 ml of the samples were taken and analyzed for cucumin content as described previously as chapter 6.3. A 10 ml volume of fresh and filtered dissolution medium was added to make the volume after each sample withdrawal. The results are shown in Table 6 to 8 and Figure 1 to 3.

Erosion study for compression-coated tablets:
The compression-coated tablets were subjected to erosion studies. The USP dissolution apparatus-1 was used at 100 rpm at 37 ± 0.5 °C. First, medium used was 900 ml of pH 1.2 for first 2 hrs then by pH 4.6 for 2 hrs followed by pH 6.8 for 1 hr and then next by pH 7.4 for 24 hr. After each sampling time one tablet was removed and dried overnight at 45 °C in an oven and the remaining tablet mass was determined gravimetrically as described by. The extend of erosion (E) was determined from: $E\ \% = 100(W_i - W_f)/W_i$ Where W_i is the initial starting dry weight and W_f is the final dry weights of the same dried and partially eroded tablet respectively. The results are shown in Table 9 and Figure 4.

Stability study:
Stability studies were conducted on the optimized/most satisfactory formulation for 3 months (CS2). The tablet formulations were packed in aluminum foil and were exposed to 40°C ± 2°C / 75% ± 5% RH and 30°C±2°C/65%±5% RH in humidity control oven as per ICH guidelines118 Q1C: "Stability testing of new dosage

ISSN: 0976-7126

forms." Sampling was done at predetermined time intervals of 30, 60 and 90 days. The tablets were evaluated for various physico-chemical parameters viz., appearance, drug content, hardness, and in vitro drug release. The results are shown in Table 10.

Result and Conclusion

Swelling study of sesbania gum powder:

Swelling characteristics of the treated SG was studied in different medium (0.1 M HCl, pH-7.4 phosphate buffer and distilled water). The swelling index of SG powder was 8.0, 27.5, and 30 in 0.1 M HCl, pH 7.4-phosphate buffer and distilled water respectively.

Treated SG shows pH dependent swelling characteristics and has better swelling in pH 7.6 phosphate buffer and distilled water as compared to 0.1 M HCL. These differences in swelling can be effectively explored in the formulation of intestinal/colonic drug delivery systems.

Characteristics of tablets:

Matrix tablets of curcumin were prepared by wet granulation method using PVP-K30 solution (5 %w/v in IPA) as the binder. The tablets of different formulations were subjected to various evaluation tests, such as thickness, uniformity of weight, hardness, friability, and drug content.All the formulations showed uniform thickness. The thickness of the tablets was in the range of 3.8 - 4.0 mm. The hardness of the tablets was found to be in the range of 6.3-6.6 kg. Tablet hardness is not the absolute indicator of the strength, another measure of tablet's strength is friability. Conventional compressed tablets that loose less than 1% of their weight are generally considered acceptable. In the present study, the percentage friability of all the formulations was below 1% indicating that the friability is within the prescribed limits. In a weight variation test, the pharmacopoeial limit for the percentage deviation of all the tablet of more than 250 mg is ± 5%. The average percentage deviation of all tablet formulations was found to be within the limit, and hence all the formulation passed the test for uniformity of weight as per official requirements. The matrix tablets were found to contain 98.6-101.4% of the labeled amount of curcumin indicating uniformity of drug content. All the tablet formulations showed acceptable pharmaco technical properties (Table 5).

Matrix tablets of curcumin using sesbania gum:

For the formulation of a delivery system for colon targeting, it is a prerequisite that the drug release should be minimal until the dosage form reaches the colon. The matrix tablets were subjected to in vitro drug release studies in pH 1.2 for first 2 hrs then by pH 4.6 for 2 hrs followed by pH 6.8 for 1 hr and then next by pH 7.4 for 24 hr. The results of dissolution study were shown in Table 6 and Figure 1. In drug release studies, the percent of curcumin release from matrix tablets of SG at the end of 5 hr and was found to be around 49 ± 10/%. All the matrix tablets were failed to retard the drug release in physiological environment of stomach and small intestine. It can be attributed to formulation of a very loose gel upon introduction of the tablets in the dissolution media, leading to drug release from the outer layer of the tablets. At the end of dissolution studies, 80 ± 15% drug release from the matrix tablets. From the swelling study, it was showed that sesbania gum powder has swelling index 8.0 in 0.1 M HCl while 27.5 in pH-7.4 phosphate buffer.So, SG has better swelling in pH-7.4 phosphate buffer as compared to 0.1M HCL. But it may observe from the results that about 30 ± 10 % of the drug was released from the formulations (SG1-SG4) in 0.1 M HCl. This may be because of the release of highly soluble (in 0.1 M HCl) Cucumin present on the surface of the matrix tablets. Hence, further studies were not carried out on formulations SG1-SG4 as they also released almost 50% of its drug in physiological environment of stomach and small intestine. It was found that only formulation SG3 (Cucumin:SG - 1:1) give fewer drug release compare to other formulation at the end of 5hr, it was 47.70%. So formulation SG3 (Cucumin:SG - 1:1) was selected for further studies. The results, thus, show that the matrix formulations containing different ratio of Cucumin and SG failed to control the drug release in the physiological environment of stomach and small intestine. Hence, it was planned to control the release of curcumin by applying enteric-coating on the formulation SG3.

Enteric-coated Curcumin matrix tablets:

The formulation SG3 containing curcumin and SG in the ratio of 1:1 respectively was used for the enteric coating using different ratio of Eudragit L100 and Eudragit S100 (1:0, 1:1, 0:1). The enteric-coated tablets were subjected to in vitro drug release studies in pH 1.2 for first 2 hrs then by pH 4.6 for 2 hrs followed by pH 6.8 for 1 hr and then next by pH 7.4 for 24 hr. The cumulative percent drug release of formulations ES1, ES2 and ES3 was shown in Table 6.7 and Figure 6.2. The formulations ES1, ES2 and ES3 give only 3 ± 1.5% of curcumin released in the physiological environment of stomach (0.1 M HCl for 2 hr). The enteric polymers are insoluble at lower pH so the penetration of the dissolution medium in the matrix was not possible at lower pH and therefore very less amount of drug was released in 0.1 M HCl. After 2 hr, the dissolution study was conducted in higher pH up to 5 hr. At this pH, the formulations give faster drug release that was 27 ± 2%. It can be attributed that the enteric polymers get dissolved slowly and the leakage of the dissolution fluid was shown in the matrix and that's why higher amount of curcumin release at this condition. The formulation ES3 (47.70%) released fewer drug as compare to formulation ES1 (56.28%) and ES2 (53.35%) at the end of 12 hr dissolution study. It was suggested that Eudragit S100 alone at higher concentration is able to retard the drug release in the physiological environment of stomach and small intestine. Thus, the results were showed that the enteric-coated formulations of SG3 failed to control the drug release in the physiological environment of stomach and small intestine. Hence, it was planned to control the release of curcumin by applying different amounts of sesbania gum as a release controlling layer by compression-coated tablets.

Compression coated curcumin tablets:

The matrix and enteric-coated tablets of curcumin were failed to retard drug release in upper GIT, it was essential to minimize the release of curcumin in the physiological environment of stomach and small intestine. So, curcumin core tablet compression–coated using different amount of sesbania gum. Fast-disintegrating curcumin core tablets were characterized for different parameters. The core tablets of curcumin were compression coated with a coat formulation containing different amount of sesbania gum. The cumulative amount of curcumin release from tablets coated with coat formulations containing 265 mg SG (CS1), 345 mg SG (CS2) and 370 mg SG (CS3) was found to be 21.13 %, 8.37 % and 0.0 % respectively after 5 h of the dissolution study in simulated gastric and intestinal fluids. From the dissolution studies, it was reveled that formulation CS1 give faster drug release in simulated gastric and intestinal fluids. This might be due to lower sesbania gum content and higher quantity of DCP in the coat formulation. So, SG as compression coat in fewer amounts (265 mg) was not able to retard the drug release in simulated gastric and intestinal fluids. But, the formulation CS2 and CS3 was capable of protecting the drug from being released in the physiological environment of stomach and small intestine. At the end of the 12 hr of the dissolution studies, the percent drug release from Curcumin tablets coated with coat formulation CS1, CS2 and CS3 was found to be 92.26 %, 98.33 % and 62.55 % respectively (Table 6.8 and Figure 6.3). The presence of higher amount of sesbania gum (370 mg, CS3) might not have allowed complete degradation of the coat during the time period of testing. The gel strength of the swollen coat of SG might be too high and prevented the drug release from the formulation. The percent drug release from curcumin core tablets coated with coat formulation CS2 was found to increase from 8 hr onwards indicating the commencement of disruption of the hydrated SG coats. The results show that tight control of drug release from compression coated formulation CS2 might have facilitated the colonic bacterial action on SG and resulted in the degradation of the formulation thereby releasing the drug in the physiological environment of colon. The results of the study indicate that curcumin tablets compression coated with SG (345 mg) would be potential formulations in delivering the drug to the colon.

Results of erosion study of compression coated tablets:

Erosion study of compression-coated tablets was carried out in different dissolution medium to mimic the physiological condition of gastrointestinal tract. Three levels of formulations containing 265 mg SG (CS1), 345 mg SG (CS2) and 370 mg SG (CS3) were studied. The results of erosion study were shown in Figure 4 and Table 9. The fastest erosion was seen in formulation containing 265 mg SG. Among all the batches, the slowest erosion pattern was observed with formulation containing 370 mg SG (Figure 4). Thus we can conclude that formulation containing 345 mg SG assist in slow erosion pattern of the tablets. At the end of 24 hr, the tablet of formulation CS1 had already lost 98.66% of coat weight but for formulation CS3, 65.43% of coat weight was lost.

Stability studies:

Further the selected formulation of compressed coated tablet of curcumin was subjected for accelerated stability studies for three months at 40^0 in hot air oven, the formulation was found to be stable as per the drug content and physical appearance which showed satisfied pharmacopeial limits (Table 10).

ISSN: 0976-7126

Successful delivery of drugs specifically to the colon requires the protection of drug from being released in stomach and small intestine. In the present investigation, sesbania gum was applied in the form of matrix, enteric-coated and compression-coated tablets and drug release studies were carried out under the conditions mimic mouth to colon transit.

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Table 1: Physicochemical properties of treated sesbania gum powder

Sr.No.	Properties	Characteristics
1	Average particle size (µm)	17.12 µm
2	Loss on drying (%)	11.00%
3	Ash value (%)	1.5%
4	Solubility in water	Quickly soluble in hot water, 1 gm in 100 ml water produces viscous, pourable and opaque solution
5	pH	7.16
6	Density (gm/ml) 0.5%w/v solution	1.059
7	Specific gravity	0.9442
8	Microbial load	Bacteria-2700 CFU/gm Fungi - 200 CFU/gm
9	Volatile acidity	9%

Table 2: Composition of curcumin matrix tablets containing SG

Ingredients	Quantity (mg) per each tablet			
	SG1	SG2	SG3	SG4
Curcumin	450	450	450	450
Sesbania gum	400	425	450	475
DCP	75.5	50.5	25.5	0.5
Tartaric acid	4.5	4.5	4.5	4.5
PVP-K30 (added as binder)	40	40	40	40
Talc	20	20	20	20
Magnesium Stearate	10	10	10	10
Total (mg)	1000	1000	1000	1000

Table 3: Composition of fast-disintegrating core tablets of curcumin

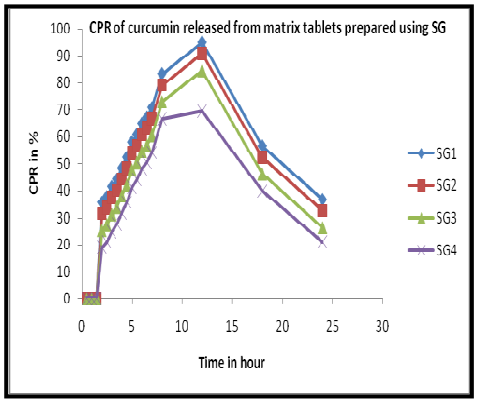
Ingredients	Quantity (mg)
Curcumin	450
DCP	5.5
Tartaric acid	4.5
Sodium starch glycolate	20
PVP-K30 (as binder)	20
Talc	10
Magnesium stearate	05

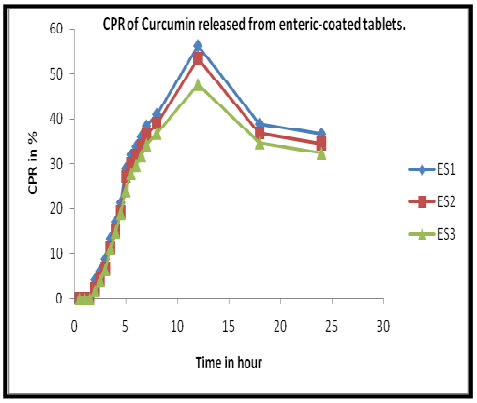
ISSN: 0976-7126

Table 4: Composition of sesbania gum coat formulation			
Ingredients	**Quantity (mg) present in the coat formulation**		
	CS1	**CS2**	**CS3**
Sesbania gum	265	345	370
DCP	185	105	80
PVP-K30 (as binder)	20	20	20
Talc	10	10	10
Magnesium stearate	5	5	5

Table 5: Characteristics of curcumin matrix tablets containing sesbania gum in various proportion					
Tablets	Thickness (mm)	Hardness (kg/cm^2)	Friability (%)	Weight variation (mg)	Drug content (%)
SG1	3.9 ± 0.1	6.5. ± 0.3	0.32 ± 0.03	448 ± 4.56	98.64 ± 0.43
SG2	3.9 ± 0.1	6.3 ± 0.2	0.49 ± 0.02	447 ± 3.94	101.31 ± 0.29
SG3	3.9 ± 0.1	6.6 ± 0.1	0.54 ± 0.03	551 ± 5.31	99.94 ± 0.46
SG4	3.9 ± 0.1	6.5 ± 0.2	0.39 ± 0.04	449 ± 6.84	99.83 ± 0.68

Table 6: Cumulative percent of curcumin released from matrix tablets prepared using SG					
pH	**Time in Hr**	**SG1 (%)**	**SG2 (%)**	**SG3 (%)**	**SG4 (%)**
1.2	0.5	0	0	0	0
1.2	1	0	0	0	0
1.2	1.5	0	0	0	0
1.2	2	35.77	31.59	25.31	19.04
4.6	2.5	37.87	33.68	27.41	21.13
4.6	3	41.63	37.45	31.17	24.90
4.6	3.5	44.35	40.17	33.89	27.62
4.6	4	48.54	44.35	38.08	31.80
6.8	4.5	52.51	48.33	42.05	35.77
6.8	5	58.16	53.97	47.70	41.42
7.4	5.5	60.88	56.69	50.42	44.14
7.4	6	65.06	60.88	54.60	48.33
7.4	6.5	67.36	63.18	56.90	50.63
7.4	7	70.92	66.74	60.46	54.18
7.4	8	83.47	79.29	73.01	66.74
7.4	12	95.08	90.90	84.52	69.67
7.4	18	56.69	52.51	46.23	39.96
7.4	24	36.82	32.64	26.36	21.13





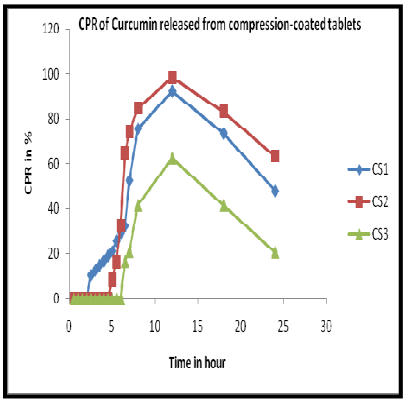


Figure 1: CPR of curcumin released from matrix tablets prepared using SG
Figure 2: CPR of curcumin released from enteric-coated tablets
Figure 3: CPR of curcumin released from compression-coated tablets

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Table 7: Cumulative percent of curcumin released from enteric-coated tablets				
pH	**Time in Hr**	**ES1 (%)**	**ES2 (%)**	**ES3 (%)**
1.2	0.5	0	0	0
1.2	1	0	0	0
1.2	1.5	0	0	0
1.2	2	4.18	2.09	1.67
4.6	2.5	6.28	4.18	3.97
4.6	3	8.79	6.69	6.49
4.6	3.5	13.39	11.30	11.09
4.6	4	17.15	15.06	14.85
6.8	4.5	21.34	19.25	19.04
6.8	5	28.97	27.15	24.06
7.4	5.5	32.01	29.92	27.82
7.4	6	33.89	31.80	29.71
7.4	6.5	35.98	33.89	31.80
7.4	7	38.49	36.40	34.31
7.4	8	41.00	38.91	36.82
7.4	12	56.28	53.35	47.70
7.4	18	38.91	36.82	34.73
7.4	24	36.61	34.52	32.43

Table 8: Cumulative percent of Curcumin released from compression-coated tablets				
pH	**Time in Hr**	**CS1 (%)**	**CS2 (%)**	**CS3 (%)**
1.2	0.5	0	0	0
1.2	1	0	0	0
1.2	1.5	0	0	0
1.2	2	0	0	0
4.6	2.5	10.46	0	0
4.6	3	12.55	0	0
4.6	3.5	14.85	0	0
4.6	4	16.74	0	0
6.8	4.5	19.04	0	0
6.8	5	21.13	8.37	0
7.4	5.5	25.73	16.53	0
7.4	6	29.08	32.43	0
7.4	6.5	32.43	64.85	16.74
7.4	7	52.51	74.27	20.92
7.4	8	75.52	84.73	41.63
7.4	12	92.26	98.33	62.55
7.4	18	73.43	83.26	41.63
7.4	24	47.91	63.39	20.71

Table 9: Results of erosion studies of compression coated tablets			
Time in Hr	**CS1**	**CS2**	**CS3**
4	7.12	4.22	2.88
10	38.21	26.11	13.31
14	62.13	48.09	31.22
20	85.32	71.17	56.34
24	98.66	87.99	65.43

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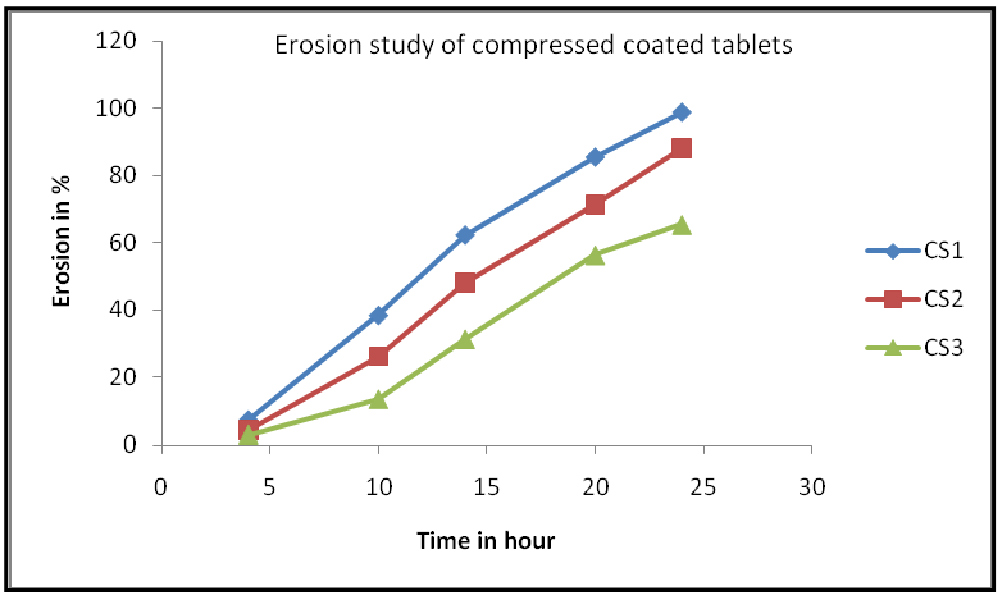

Figure 4: Erosion studies of compression coated tablets

Table 10: Stability studies compressed coated CS2 formulations for three months.

Month	Sample	Drug content	Appearance
1 st Month	1	98.4 %	+++
	2	98.5%	+++
	3	97.8%	+++
2 st Month	1	97.3%	+++
	2	96.3%	+++
	3	96.7%	++
3 st Month	1	95.1%	++
	2	88.4%	++
	3	86.6%	++