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Research Article

Formulation and Evaluation of Colon Targeted Drug Delivery of Mesalamine

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ABSTRACT

In this study, we report pectin–Chitosan compression coated core tablets of Mesalamine for colonic delivery. Each 150 mg core tablet contained Mesalamine and was compression coated using 100% pectin 1:1, 10 pectin:1 Chitosan, or 10 pectin :2 Chitosan, at coat weights as 400mg. Drug dissolution or system erosion or degradation studies were carried out in pH 1.2, 6.8,7.4 phosphate buffers using a pectinolytic enzyme. The system was designed based on the gastrointestinal transit time concept, under the assumption of colon arrival times of 6 h. It was found that pectin alone was not sufficient to protect the core tablets and Chitosan addition was required to control the solubility of pectin. The optimum Chitosan concentration was 1 and such system would protect the cores up to 6 h and after that under the influence of pectinase the system would degrade faster and delivering 5-ASA to the colon. The pectin– Chitosan (10:1) envelope was found to be a promising drug delivery system for those drugs to be delivered to the colon.

Keywords: Colonic delivery, 5-Aminosalicylic acid, Pectin, Chitosan, Compression coating, Pectinase.

INTRODUCTION

Delivery of a drug to a specific organ or tissue i.e. spatial placement and controlling the rate of drug delivery to the specific sites i.e. temporal delivery are the two main aspects of the drug delivery systems[1]. Now a day the colon has recently become accepted as an increasingly important site for drug delivery. Colon specific diseases are often inefficiently managed by oral therapy, colon specific drug delivery systems, which can deliver drugs to the lower gastrointestinal tract without releasing them in the upper GI-tract, can be expected to increase the quality of life for patients suffering from colon specific diseases. Treatment might be more effective if the drug substances were targeted directly on the site of action in the colon. The concentration of drug reaching the colon depends on formulation factors, the extent of retrograde spreading and the retention time[2]. Number of serious diseases of the colon might be capable of being treated more effectively if drugs were targeted on the colon. Therefore, it appears that targeted drug delivery with an appropriate release pattern could be crucial in providing effective therapy for these chronic diseases. In addition to providing more effective therapy of colon related diseases, colon specific delivery has the potential to address important unmet therapeutic needs including oral delivery of macromolecular drugs[3]. In the past two decades, the pharmaceutical scientists are extensively investigated in the area of colonic region for targeted drug delivery system Local action in the treatment of ulcerative colitis and Systemic absorption of protein and peptide drugs.

MATERIAL AND METHODS

Equipments used

Method

Micronization of Mesalamine

Micronization Parameters (Spiral Air jet mill)

Air pressure – 8 bar

Grinding Pressure – 4 kg/cm2

Ventury pressure – 1 kg/cm2

Preparation of 5-ASA core tablets

Weigh mesalamine, Sodium starch glycolate, MCC (Avicel PH 101) & pass through sieve no. 40. PVP (K 30) solution in water was prepared for granulation purpose. Wet granules were prepared & sieved through 18 no sieve and dried overnight at 40^0C to obtain LOD up to 2% moisture content then granules pass through sieve no 20. After adding 4% magnesium stearate as a lubricant & talc as glidant lubricated granules compressed using a laboratory size multi station tablet press (Emtech) with 8 mm flat faced punches. Tablet quality control tests such as weight variation, crushing strength, friability, thickness, and dissolution were performed on the core tablets.

Compression Coating of Core Tablets[4-7]

Core tablets were first dedusted then placed in 12 mm die cavity of a laboratory multi press. Depending on the design 100%pectin, pectin: Chitosan (5:1), pectin: Chitosan (10:1) combinations were used for the outer shell compression the coat weights were 400 mg. Tablet quality control tests such as weight variation, crushin strength, friability, thickness, dissolution & erosion rates in different media were carried out.

Evaluation of Pre-compressed granules of Mesalamine

Angle of repose

In this method weighed 20 gm of granule, allowed to flow

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List of Ingredients.

Sr. No.	Ingredients	Specifications	Supplied by
1.	Mesalamine	USP	Pharmazell Ltd. A.P.
2.	Povidone K-30	USP NF	Chempure ltd. Bombay.
3.	SSG (primogel)	IP	Chempure ltd. Bombay.
4.	Crosscarmellose sodium	USP NF	Chempure ltd. Bombay.
6.	MCC (Avicel PH 101)	USP NF	Chempure ltd. Bombay.
7.	Magnesium Stearate	USP NF	Chempure ltd. Bombay.
8.	Talc	USP NF	Chempure ltd. Bombay.
9	Pectin	USP NF	Chempure ltd. Bombay.
10.	Chitosan	USP NF	Chempure ltd. Bombay.
11.	Pectinase enzyme		Chempure ltd. Bombay.

List of Equipments.

Sr. No	Equipment	Model no.	Mfg. By
1.	Electronic weighing bal	2002	Schimadzu, Japan
2.	Tablet Compression Ma	2004	Emtech
3.	Hot air oven	2005	Bio Techno Lab.
4.	Dissolution apparatus	TDT-08L	Elecrolab
5.	U.V. Spectrophotometer	2005	Shimadzu 1800
6.	I.R. Spectrophotometer	2004	Perkin Elmer
7.	Hardness tester	2003	Monsento
8.	Disintegration Apparatu	2012	Electrolab
9.	Friabilator	Veego VFT 1	Roche
10.	Tap density Apparatus	ETD2	Electrolab
11.	Stability chamber	2010	Biotechno

Table 1: formula for preparation of immediate release tablet of mesalamine.

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Intra-granular part									
Mesalamine	100	100	100	100	100	100	100	100	100
MCC(AvicelPH101)	31.5	28	25.5	38	33	28	28	27.5	13
Sodium starch glycolate	10	12.5	15	-	-	-	10	12.5	15
Crosscarmellose Na	-	-	-	2.5	7.5	12.5	2.5	7.5	12.5
Povidone K-30	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Extra-granular part									
Magnesium stearate	3	3	3	3	3	3	3	3	3
Talc	4	4	4	4	4	4	4	4	4
Total weight(core)	150	150	150	150	150	150	150	150	150

Table 2: formula for preparation of compression coated tablet.

Batch code		Fp1	Fp2	Fp3
Core tablet(mg)		150	150	150
Coating(mg)	(Pectin:chitosan)	400:0	1:5	10:1
			66:333	364:36
	Magnesium stearate + Talc	2% + 3%	2% + 3%	2% + 3%
Total weight(Coated tablet)		550	550	550

under gravity though funnel and angle of incline of the formed. That is produced is assayed by measuring the height and having a fixed base i.e. diameter.

Determination of Density

Bulk Density

Determined by pouring granules in to a graduated, cylinder via large funnel in and measuring the volume and weighed. As tapped density is determined by placing a graduated cylinder containing a known mass of drug or formulation an a mechanical tapper apparatus. This is operated for a fixed no. of taps i.e. 100 taps. The granules bed volume has reached minimum.

Then quantities putted in formula:

Bulk density: Mass / Bulk volume

True density: Mass / tapped volume

Compressibility index

It is determined by taking tapped density and bulk density. Which has been putted in the formula given below and determined compressibility index using following formula.

Tapped density – bulk density / tapped density x 100

Hausner's Ratio

Table 3: Stability Test.

Stability study	Storage condition	Duration
Long term	25^0 C ± 2 ^{0}C, RH 60% ± 5%	12 months
Intermediate	30°C ± 2 ^{0}C, RH 75% ± 5%	6 months
Accelerated temperature	40°C ± 2 ^{0}C, RH 75% ± 5%	6 months
Short Term	45°C ± 2 ^{0}C, RH 75% ± 5%	1 Month

Table 4: Organoleptic Characters.

Test	Specification	Observation
Color	Whitwhite or light grey or light pink powder or crystals.	Light pink powder
Odor	Odorless or with a slight characteristic odor.	Characteristics

Table 5: Loss on drying.

Test	Specification	Observation
Loss on drying	Not more than 0.5%	0.47%

Table 6: Melting point.

Material	Specification	Observation
Mesalamine	283-285^{0}C	283^{0}C

It is the ratio of tapped density to the bulk density. It is given by- D_b=Tapped Density/Bulk Density

Evaluation of the core tablets

The tablets were subjected to evaluation for the following parameters.

Tablet Shape

It may be have a significant effect on the performance of applied functional films including enteric coatings. Shall oval shapes are more prone to edge attrition and may result in non uniform film coverage on the edges of the tablet.

Weight variation

20 tablets of each of formulation were weighed individually using an electronic balance. The average weight was calculated and individual tablet weight was compared with average value and the deviation was recorded.

Tablet hardness

Tablet hardness is also known as tablet crushing strength. Monsanto Hardness tester was used. It applies force to the tablet diametrically with the help of an in built spring. Triplicate determinations were done.

Friability test

Friability test is performed to assess the effect of abrasions and shock that may often cause tablet to chip, cap or break. Roche Friabilator was used for the purpose. Compressed tablets should not lose more than 1% of their weight (as per IP 96) It is a difficult job to maintain the percentage of friability within the limit, since all the methods of preparation of oral dispersible tablets have a tendency to increase the percentage of friability. In all aspect, the range is within limit of 0.1%-0.9%. Roche friabilator is used in conventional form in order to measure friability of the tablets[49].

Thickness

The thickness of tablets was determined using Digital Vernier Caliper, (Mitutoyo, Japan). It is expressed in mm.

In vitro Disintegration time

The disintegration time of the tablet was measured in water (37±2°C) according to IP 96 disintegration test with disc.

a. Speed of paddle :50 rpm
b. Temperature : 37±2°C
c. Sampling time : 10 min.
d. Volume drawn : 5ml
e. Dilution factor : 10
f. Volume of dissolution medium : 900 ml
g. Dissolution medium : 0.1 N HCl

Three tablets from every batch (formulation) were tested for the disintegration time. The in-vitro disintegration time was determined using disintegration test apparatus. A tablet was placed in each of the six tubes of the apparatus and one disc was added to each tube. The time in seconds taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured in seconds[49,60].

Uniformity of content

The mesalamine content in tablets was determined by powdering 20 tablets in each batch. Powder equivalent to 100 mg of mesalamine was dissolved in 0.1 N HCl. 1 ml of filtrate was further diluted to 100 ml with 0.1 N HCl and it was determined by spectroscopy at 302 nm.

In vitro release profile of formulated Mesalamine tablet

All the tablet dissolution studies were carried out for three tablets (triplicate) per formulation. USP Type II dissolution apparatus was used for drug release studies. Following parameters were used in release study.

Characterization of Mesalamine compression coated tablets

Hardness test

The prepared tablets were subjected to hardness test. It was carried out by using hardness tester and expressed in Kg/cm^2.

Friability test

The friability was determined using Roche friabilator and expressed in percentage (%). 20 tablets from each batch were weighed separately ($W_{initial}$) and placed in the friabilator, which was then operated for 100 revolutions at 25 rpm. The tablets were reweighed (W_{final}) and the percentage friability was calculated for each batch by using the following formula. $F(\%)=(W_{initial}-W_{final}) / W_{initial} * 100$

Weight variation test

20 tablets were selected at random from the lot, weighed individually and the average weight was determined. The

Table 7a: Saturation Solubility.

Solvent	Solubility(mg/ml)	Inference
Distilled water	1.21	Slightly soluble
Acetone	0.74	Practically insoluble
Methanol	0.65	Practically insoluble
Phosphate buffer 6.8	7.28	Soluble
Phosphate buffer 7.4	8.13	Soluble
0.1 N HCL	10.23	Soluble

Table 7b: Interpretation of IR spectrum of Mesalamine.

Sr. No.	IR frequency (cm^{-1})	Functional Group
1.	1621.24	C=C stretch of the aromatic group; N-H bond scissoring
2.	2976.52	C-H stretch of the aromatic group
3.	1487.79	C-C stretching mode
4.	1582,1487,1450	O-H deformation of the hydroxyl groups
5.	1194.90	C-O stretching mode
6.	1192.24-1265.96	In plane bending mode
7.	685.01	C-H bond out of plane bending mode; Ring deformation of the aromatic group

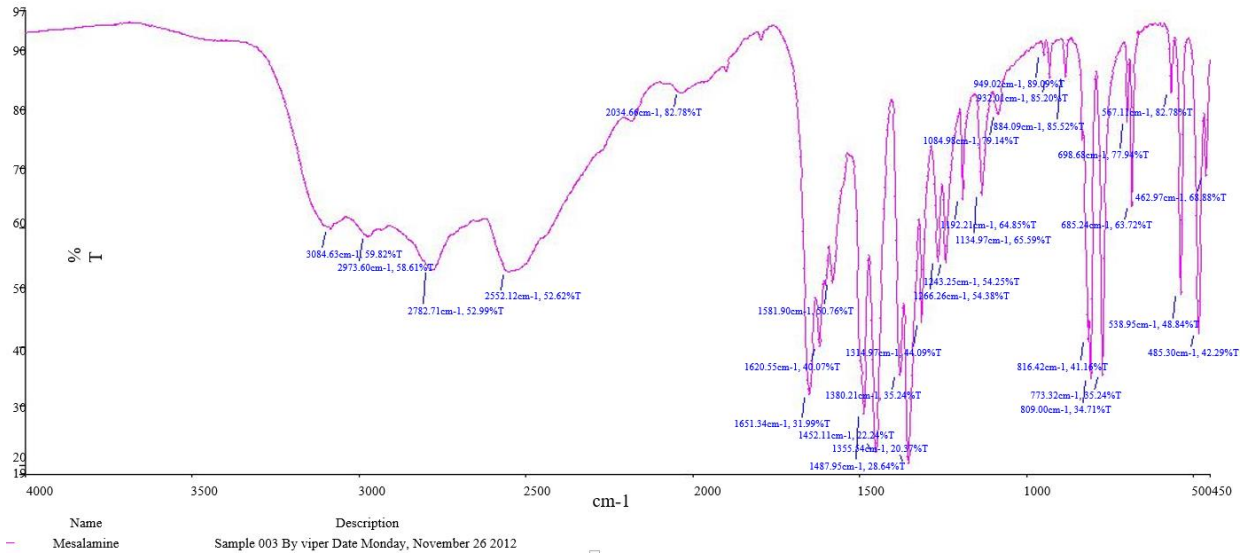

Figure 1: Interpretation of IR spectrum of Mesalamine.

Table 8: Pre Compression Parameter For API.

Parameters	API
Bulk density(g/ml)	0.137
Tapped density(g/ml)	0.155
Compressibility Index (%)	11.61
Hansner's ratio	1.13
Angle of repose	28.96

percent deviation of each tablets weight against the average weight was calculated. The test requirements are met, if not more than two of the individual weights deviate from the average weight by more than 5% and none deviates more than 5%.

Test method for pectin–HPMC coat erosion

After compressing the tablets a erosion study was performed. First medium was 500 ml 0.1 N HCl solution. The USP XXIII dissolution apparatus 2 was used at 50 rpm at 37^0C. The test was continued for 2 h, at the end of the time period the medium was discarded and refilled with USP pH 6.8 buffer solution and the test was continued for additional 6 h. After 6 h, depending on the design 1mg/ml Pectinase was added to the dissolution vessels containing 7.4 phosphate buffer and the test was continued until for a pre-determined time depending on the study design. Tablets were dried overnight at 45^0C in an oven. In the case of drug dissolution 5-ASA concentration was determined spectrophotometrically at 303 nm (Shimadzu UV 1800, Japan).

In vitro drug release studies

Drug release studies were conducted under conditions mimicking mouth-to-colon transit. The dissolution medium consisted of 900 ml 0.1 mol/l HCl for 2 h, re-placed by 900 ml phosphate buffer, pH 6.8 for 4 h, kept at 37 ± 0.5°C and stirred at 100 rpm, using USP dissolu-tion apparatus 2. Samples were withdrawn at the end of the specified periods (2 h and 4 h), filtered and assayed spectrophotometrically (UV-1800 UV-VIS-NIR,

Table 9: Evaluation of precompressed granules of mesalamine.

Formulation code	Angle of repose(θ)	Bulk density(gm/cc)	Tapped density (gm/cc)	Compressibility Index	Hausner's ratio
F1	25.58	0.71	0.99	28.64	1.4
F2	25.08	0.74	0.98	24.21	1.32
F3	23.4	0.86	0.99	12.5	1.14
F4	23.72	0.85	0.98	13.31	1.15
F5	24.47	0.8	0.96	16.66	1.2
F6	23.29	0.86	0.97	11.38	1.13
F7	22.68	0.88	0.98	10.84	1.12
F8	22.77	0.87	0.99	11.49	1.13
F9	22.49	0.88	0.98	10.54	1.12

As per IP specification all the parameters are within limit.

Table 10: Evaluation of formulations of mesalamine core tablets.

Formulation Code	Thickness (mm)	Hardness Kg/cm2	Friability (%)	Disintegration time	Weight Variation	Content uniformity	% drug release
	Mean±S.D	Mean±S.D	Mean±S.D	(sec.)	(mg)	(%)	
				Mean±S.D	Mean±S.D	Mean±S.D	
F1	2.717 ±00.071	3.6±0.67	0.14±0.01	49±0.01	149.23±0.12	98.32±0.15	93.89
F2	2.644 ±00.064	3.7±0.35	0.12±0.00	51±0.05	151.04±0.32	98.67±0.19	90.94
F3	2.687 ±00.053	3.0±0.61	0.11±0.00	45±0.13	150.1±0.21	99.49±0.12	97.41
F4	2.777 ±00.051	3.8±0.5	0.12±0.02	53±0.07	149.12±0.36	99.03±0.35	84
F5	2.606 ±00.041	4.0±0.5	0.13±0.01	56±0.04	151.09±0.43	97.45±0.23	80.01
F6	2.767 ±00.013	4.3±0.12	0.42±0.01	55±0.26	151.12±0.26	98.54±0.17	86.95
F7	2.727 ±00.024	3.8±0.08	0.34±0.01	54±056	149.72±0.56	98.56±0.14	82.74
F8	2.613 ±00.068	3.5±0.04	0.25±0.05	50±0.35	150.17±0.35	96.36±0.54	90.52
F9	2.604 ±00.076	3.6±0.05	1.14±0.01	58±0.15	151.02±0.15	98.09±0.12	87.58

Table 11: In vitro dissolution of core tablet of mesalamine.

Time(min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
5	20.92	19.03	26.64	20.5	17.76	18.18	18.82	20.08	19.87
10	28.07	31.64	30.46	37.32	36.69	41.74	33.96	35.01	41.74
15	36.9	41.53	37.79	54.56	54.35	57.93	50.36	49.94	57.51
30	59.82	65.29	61.91	62.76	65.92	70.12	65.92	59.07	68.86
45	93.25	90.73	97.41	84	80.01	86.95	82.74	90.52	87.58

Shimadzu, Japan) for Mesalamine, at 301.5 nm in 0.1 mol/l HCl and 333.5nm in pH 6.8 buffer. After 6hr dissolution medium replaced with 7.4 phosphate buffer. To assess the susceptibility of the prepared Mesalamine delivery systems to the enzymatic action of colonic bacteria, drug release studies were continued in Phosphate buffer pH 7.4 in the absence (control) and presence of pectinase enzyme since these are known to have similar contents to those of human intestinal microflora. The studies were carried out using USP dissolution apparatus 2 (100 rpm, 37°C)

Stability Study[8]

FDA and ICH specifies, the guidelines for stability testing of new drug products, as a technical requirement for the registration of pharmaceuticals for human use. The ICH Tripartite Guidelines have established that long term stability testing should be done at 25°C/60% RH for 12 months. Accelerated stability testing should be done at 40°C/75% RH for 6 months. Stability testing at intermediate storage condition should done at 30°C/75% RH. In the present work, stability study was carried out for formulation containing pectin:chitosan(10:1), at 40°C ± 2 ^{0}C, RH 75% ± 5% conditions for 2 months. Formulation Fp3 was selected for stability study because it protect drug release up to colon & gives faster drug release (100% within 9hrs) from the tablet and Fp3 have well dissolution time as compared to other formulations. The formulations

Table 12: Drug release kinetics of 9 batches of core tablets.

Batch No.	Zero order		First order		Matrix		Peppas		Best Fit Model
	R	K	R	K	R	k	R	k	
F1	0.910	2.389	0.964	-0.059	0.988	13.65	0.983	9.127	Matrix
F2	0.904	2.432	0.960	-0.064	0.988	13.92	0.980	9.130	Matrix
F3	0.967	2.212	0.895	-0.062	0.961	12.33	0.961	8.734	Zero
F4	0.879	2.164	0.979	-0.041	0.987	12.45	0.974	9.282	Matrix
F5	0.875	2.130	0.983	-0.038	0.985	12.27	0.964	7.784	Matrix
F6	0.876	2.297	0.988	-0.047	0.984	13.23	0.957	8.077	$_1$st order
F7	0.937	2.108	0.991	-0.039	0.972	11.91	0.965	6.112	$_1$st order
F8	0.938	2.281	0.981	-0.050	0.989	12.94	0.993	7.700	Peppas
F9	0.878	2.345	0.995	-0.049	0.988	13.51	0.969	8.717	$_1$st order

F3 batch shows zero order release.

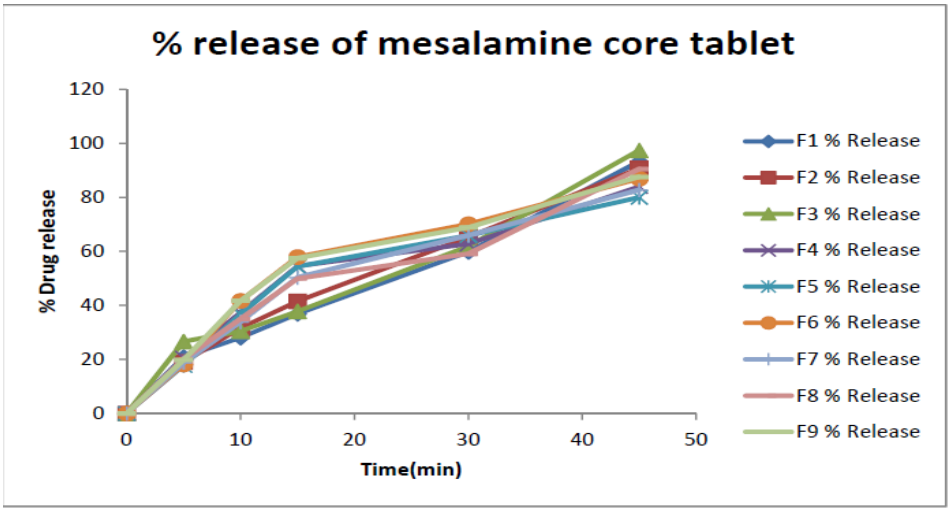

Figure 2: Comparative dissolution Study for 9 Batches of Mesalamine.

Table 13: Evaluation of compression coated tablets of mesalamine.

Batch Code	Parameter			
	Hardness (kg/cm2)	Friability (%)	Weight variation (mg)	Thickness(mm)
Fp1	5.5 ± 0.21	0.06 ± 0.021	550 ± 0.034	4.60±0.06
Fp2	5.8 ± 0.24	0.07 ± 0.016	549 ± 0.052	4.50±0.05
Fp3	5.9 ± 0.52	0.08 ± 0.015	550 ± 0.074	4.60±0.08

All compression coated tablet passes friability test & has hardness of 7.8 kg/cm2.

Table 14: Comparative dissolution study for 3 batches of compression coated tablet of mesalamine.

Time	Fp1	Fp2	Fp3
0	0	0	0
2	0	0	0
4	23.5	0	0
6	28.5	0.25	1.75
6.5	35.67	14.7	16.81
7	47.46	22.56	24.15
7.5	55.33	26.49	31.26
8	56.64	33.48	36
8.5	59.7	36.76	42.15
9	62.54	40.91	49.5

were evaluated for hardness, friability, erosion study and In-Vitro drug release.

RESULT AND DISCUSSION

Preformulation Study of Mesalamine[9-11]

Organoleptic Properties

These test performed as per procedure given in method and material section. The results are illustrated in following table.

Loss on drying

These test performed as per procedure given in method and material section. The results are illustrated in following table.

Melting point

These test performed as per procedure given in method and material section. The results are illustrated in following table.

Assay

Assay 96.6% on dried basis.

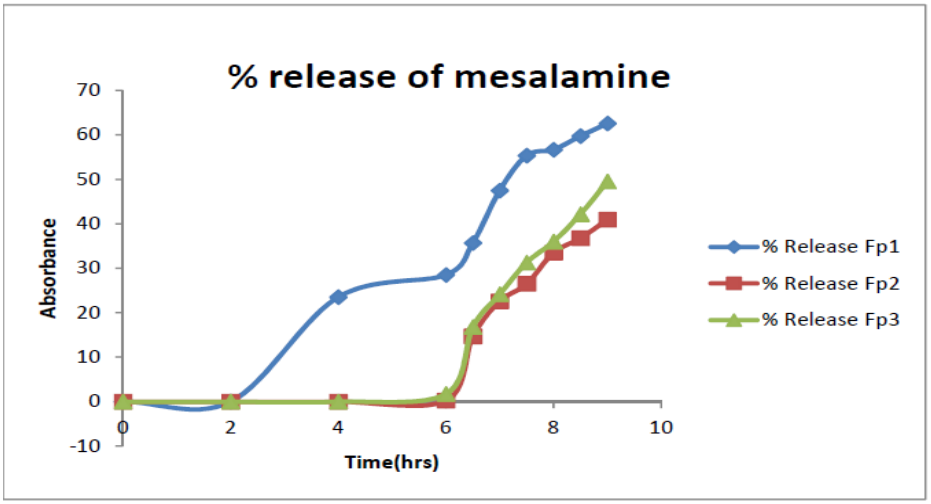

Figure 3: Comparative dissolution Study for 3 Batches of compression coated.

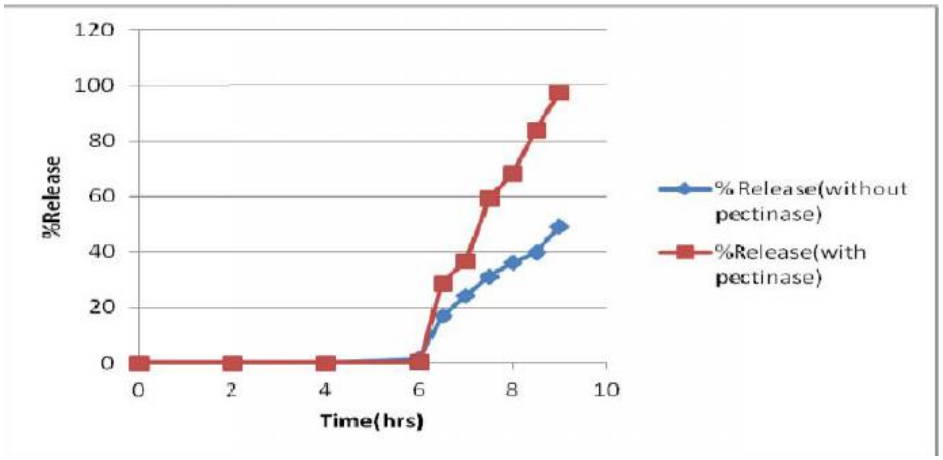

Figure 4: Comparative Release of FP3 batch in presence and absence of pectinase enzyme.

Table 15: Comprative release of fp3 batch in presence and absence of pectinaze enzyme.

Time(Hrs)	% Release (without pectinase)	%Release (with pectinase)
0	0	0
2	0	0
4	0	0
6	1.75	0.25
6.5	16.81	28.68
7	20.84	36.54
7.5	31.26	59.26
8	36	68.22
8.5	39.78	83.91
9	49.15	97.49

Solubility

These test performed as per procedure given in method and material section. The results are illustrated in following table.

Infra – red Spectrum

Evaluation of the formulations

Precompression parameters

For API

API was characterized for their physical properties such as density, compressibility and Hausner's ratio. Results are shown below,

Table 16: pectin-hpmc coat erosion study.

Time(hrs)	% Errosion (without pectinase)	% Errosion (with pectinase)
1	100	100
2	84.61	76 .92
3	76.92	23 .07
4	61.53	7 .09

Evaluation of Precompressed granules of Mesalamine

Table 9 shows the results of Angle of Repose, Bulk Density, Tapped Density, Compressibility index, Hausner's ratio for various tablet formulations.

Evaluation of formulations of Mesalamine core Tablets

The hardness values for core tablets of the all formulation were in the range between 3.0-4.0 Kg/cm2. The hardness of all tablets was kept within the above mentioned range to compare the disintegration time between the formulations prepared using different disintegrants and their varying concentrations. The friability of all formulations was determined. The friability values of none of the formulations exceeded 0.87%. The results of friability indicate that the tablets were mechanically stable and can withstand rigors of transportation and handling. Thickness of all tablets was between 2.6 – 2.7 mm showing fairly

Table 17: Evaluation of formulation fp3 kept for stability study at 40±2 ^{0}c and 75±5% rh.

Parameters	Initial	After 1st month	After 2nd month
Shape	Round, oval	No Change	No Change
Colour	yellowish-white	No Change	No Change
Odor	Characteristics	No Change	No Change
Weight Variation(mg)	550± 0.034	549± 0.53	549± 0.53
Hardness (kg/cm2)	5.9 ± 0.21	5.8.0 ± 0.08	5.8 ± 0.08
Friability (%w/w)	0.06 ± 0.021	0.06 ± 0.57	0.06 ± 0.57
% Drug content	98 ± 0.11	98 ± 0.05	98 ± 0.05
%DR	97.49±0.12	97.13±0.07	97±0.07

uniform tableting. *In vitro* disintegration times for different tablets are given in the Table 6. All formulations gave disintegration time between 40-50sec. As the concentration of the superdisintegrants has increased, the disintegration time of tablets increased. All 9 formulations passes the content uniformity, assay, average tablet weight is within the limit as per I.P. Specification.

In-vitro dissolution profile of the formulations in 0.1 N HCL

From all batches F3 batch shows better release so it is selected as optimized batch.

Drug release kinetics

Evaluation of compression coated tablets of Mesalamine

In vitro drug release study

From all three batches in Fp1 drug release occurs before colon & remaining batches (Fp2 & Fp3) shows drug release in colon but Fp3 shows better result than Fp2. So Fp3 is optimized batch.

Tablet of Mesalamine

Comparative Release of FP3 batch in presence and absence of pectinase

Enzyme

From above result it is concluded that drug release in the presence and absence of pectinase enzyme that the maximum amount of drug release occurred by the degradation of the coat material by the enzymes than in absence of pectinase.

Pectin–HPMC coat erosion study

Stability Study

Stability studies of Tablets Fp3 were carried out at 40±2 ^{0}C/75±5% RH for 2 months. The Tablets were evaluated for hardness, friability, weight variation and In-Vitro drug release. The results of stability studies showed the physical and chemical properties of the tested tablets (Fp3) were not altered significantly in that formulation. So these may considered as stable formulation.

CONCLUSION

The present study has been satisfactorily attempted to formulate a colon targeted drug delivery of mesalamine using Pectin: chitosan (10:1) as coating material.From the experimental results it can be concluded that Fp3 batch is best batch. From all results formulations of core tablet f3 batch was selected as optimized batch. Production yield of fp3 was greater than other The production yield of Fp3 is 97.41%. The IR spectra revealed that there was no interaction between polymers and drug, hence they are compatible. From the DSC thermograms of pure mesalamine, mesalamine tablet of Fp3 batch, It was concluded that no interaction between the polymers and drug. The formulation Fp3 showed maximum drug content. Stability study of formulations (Fp3) with sodium starch glycolate showed that the properties of tablets were not altered significantly when kept at different conditions for two month. The optimum concentration of Pectin: chitosan is (10:1) and such system would protect the cores tablet of mesalamine up to 6 hr. and after that under the influence of pectinase the system would degrade faster and delivering 5-ASA to the colon.It was also evident from the results of drug release the presence and absence of pectinase enzyme that the maximum amount of drug release occurred by the degradation of the coat material by the enzymes. Stability studies of Fp3 batch for two month revealed that the formulations were stable up to 40±2 □C and 75± 5% RH. It should be stored in a cool and dry place.The pectin–Chitosan envelope was found to be a promising drug delivery system for those drugs to be delivered to the colon.

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