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RESEARCH ARTICLE
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FORMULATION AND EVALUATION OF COLON TARGETED DRUG DELIVERY SYSTEM OF MESALAMINE

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ABSTRACT:
Conventional drug delivery systems for treating colon disorders, such as inflammatory bowel diseases, infections, and colon cancer, often fail due to insufficient drug concentrations reaching the targeted site. Therefore, the development of effective, site-specific drug delivery systems presents a significant challenge in pharmaceutical technology. A major obstacle is the premature absorption or degradation of active ingredients in the upper gastrointestinal (GI) tract, which must be addressed for successful colonic drug delivery. Mesalamine, a drug commonly used to treat ulcerative colitis, has a half-life of 5-7 hours, is water-insoluble, and exhibits low oral bioavailability (20-30%). This study aimed to develop colon-targeted matrix tablets of Mesalamine using xanthan gum and guar gum to improve drug release in the colon. The tablets were evaluated for hardness, friability, weight variation, drug content uniformity, swelling index, and in-vitro drug dissolution. FT-IR analysis confirmed no interactions among the drug, polymers, and excipients. A 3^2 factorial design was employed to assess the effects of varying amounts of xanthan and guar gum on formulation characteristics. Rheological properties, including bulk and tapped densities, compressibility index, Hausner's ratio, and angle of repose, were also measured. Tablets were compressed using a 10-station R&D tablet press with 13 mm flat-faced punches and further evaluated for physicochemical properties and drug release profile using USP Type I dissolution apparatus at 50 rpm. Simulated colonic conditions were maintained during in-vitro release studies, and stability testing was conducted at 40°C/75% RH for 180 days. Statistical analysis indicated that formulation variables significantly influenced matrix integrity and drug release ($P < 0.05$). Formulation F3, which demonstrated optimal release characteristics, was selected for long-term stability studies. Results

showed no significant changes in drug content or dissolution profiles, confirming the stability of the formulation.

KEYWORDS: Colon-targeted tablet, Mesalamine, Xanthan gum, Guar gum, in-vitro release

INTRODUCTION:

Colonic drug delivery has emerged as a promising approach for the treatment of various localized disorders in the colon, including inflammatory bowel disease (IBD), such as ulcerative colitis and Crohn's disease, as well as infectious colitis and colorectal cancer.[1-3] The conventional oral drug delivery systems typically fail to deliver therapeutic drug concentrations specifically to the colon, as drugs are often absorbed or degraded in the upper gastrointestinal (GI) tract before reaching the target site. Consequently, achieving effective drug concentrations at the colon requires an innovative formulation that ensures minimal drug release in the stomach and small intestine while enabling a controlled release in the colon.[4-6] This challenge has led researchers to explore and develop advanced drug delivery systems that can respond to physiological conditions specific to the colonic region, thereby enhancing therapeutic outcomes and reducing systemic side effects.[6-8]

Mesalamine, also known as 5-aminosalicylic acid (5-ASA), is widely used as an anti-inflammatory agent for the management of IBD, particularly ulcerative colitis. It works by inhibiting the production of pro-inflammatory cytokines and blocking inflammatory pathways in the colonic mucosa. However, its therapeutic efficacy is limited by several pharmacokinetic challenges: Mesalamine has a short half-life of 5-7 hours, is poorly soluble in water, and possesses a low oral bioavailability of only 20-30%. These factors necessitate frequent dosing to maintain effective therapeutic levels, which can lead to decreased patient adherence, inconsistent drug levels, and increased risk of adverse effects. Therefore, a colon-targeted delivery system for Mesalamine would be beneficial, as it could allow for lower and less frequent dosing while achieving higher local drug concentrations specifically in the colon, improving both efficacy and patient compliance.[9-12]

Polysaccharides such as xanthan gum and guar gum have been studied extensively as potential carriers for colonic drug delivery systems. These natural polysaccharides offer several advantages: they are biocompatible, biodegradable, and resistant to enzymatic degradation in the stomach and small intestine but are selectively degraded by the colonic microbiota. When used as matrix-forming agents in the tablet formulation, xanthan gum and guar gum can act as effective release modifiers, delaying drug release until the formulation reaches the colon. This natural polysaccharide-based approach is particularly advantageous for drugs like Mesalamine, which benefit from delayed release and targeted delivery. By utilizing xanthan gum and guar gum, this study aims to achieve a sustained and targeted release of Mesalamine in the colon, where the drug's anti-inflammatory effects are most needed.[12-15]

This research investigates the formulation and evaluation of a colon-targeted Mesalamine matrix tablet using xanthan gum and guar gum as matrix polymers. Key formulation parameters, including drug-excipient compatibility, drug release profile, and tablet stability, were assessed to develop an optimized delivery system. A 3^2 factorial design was employed to systematically examine the impact of varying the concentrations of xanthan gum and guar gum on the tablet's release characteristics, aiming to identify the optimal polymer matrix composition. The tablets were evaluated for critical physical properties such as hardness, friability, weight variation, drug content uniformity, and swelling index. Additionally, in-vitro drug release studies were conducted using a dissolution apparatus under conditions simulating the colonic environment, to determine the rate and extent of Mesalamine release.[16-18]

Finally, stability testing was performed to ensure the formulation's resilience under accelerated conditions (40°C and 75% relative humidity) over a period of 180 days. This investigation aims to establish a novel colon-targeted delivery system for Mesalamine that improves the therapeutic management of ulcerative colitis and potentially other colonic diseases, providing a viable and stable formulation for enhanced colonic drug delivery.[19-20]

MATERIALS AND METHODS:

MATERIALS:

The materials used in this research included Mesalamine, which was sourced from Wockhardt Pharmaceutical Ltd., Aurangabad. The polymers used for matrix formulation, xanthan gum and guar gum, were obtained from Genuine Chemical Company, Mumbai, and Research Lab Fine Chemical Industries, Mumbai, respectively. Additional excipients were also utilized: lactose and magnesium stearate, both supplied by Ozone International, Mumbai; talc, starch, and sodium starch glycolate, which were all acquired from Research Lab Fine Chemical Industries, Mumbai. These materials were selected for their compatibility with the active drug and their roles in the formulation of a colon-targeted drug delivery system.

METHODS:

Preformulation Studies:

Preformulation studies investigate the physical and chemical properties of a drug substance alone and in combination with excipients, serving as a foundation for rational dosage form development. Drug selection relies on evaluating physicochemical properties and compatibility with formulation excipients. This research focuses on preformulation studies for Mesalamine, including compatibility profiling, to support the development of a colon-targeted drug delivery system for ulcerative colitis. Key parameters assessed include melting point, solubility, λ max, UV quantitation, and powder characteristics such as particle size, density, flowability, loss on drying, and drug-excipient compatibility.[21-22]

Physical Characterization of Drug Sample:

Nature: The drug sample's physical nature was assessed visually and with a compound microscope.
Color: The color of the drug sample was observed visually against contrasting backgrounds.
Solubility: Solubility, crucial for drug dissolution and bioavailability, was studied in 0.1 N hydrochloric acid, water, and pH 6.8 buffers at 20°C. After shaking on an orbital shaker for 24 hours, the solution was filtered, and solubility was measured using a UV spectrophotometer. Triplicate readings were taken and averaged.

Melting Point: Determined via the capillary method, the drug's melting point was noted as the temperature at which the sample just melted in a liquid paraffin bath. The average was calculated from three readings.

Partition Coefficient: Equal volumes of n-octanol and aqueous phases were used with a 1 mg/mL drug solution in a separating funnel. After shaking and centrifugation, the partition coefficient was obtained by UV spectrophotometric analysis of the aqueous phase before and after partitioning, with triplicate measurements averaged.[23-25]

Drug excipients compatibility studies:

FTIR studies:

The integrity and compatibility of mesalamine and polymers used in the tablets was studied by using Fourier transform-infrared spectroscopy (Bruker). The pellatization was done by the KBr press. The FTIR spectra were recorded in the wavelength region between 4000 and 400 cm^{-1}. The spectra obtained for pure mesalamine and formulation were compared for compatibility.[26-28]

Statistical design of formulation using 3^2 factorial designs:

A factorial design is used to evaluate two or more factors simultaneously. The treatments are combinations of levels of the factors. The advantages of factorial design over one factor at a time experiments are that, they are more efficient and allow interaction to be detected. Intervention studies with two or more categorical explanatory variables leading to a numerical outcome variable are called factorial design. A factor is simply a categorical variable with two or more values,

referred to as levels. A study, in which there are 2 factors with 3 levels, is called a 3^2 factorial design.[29-30]

A 3^2 full factorial design (FFD) was constructed where the amounts of Xanthan gum i.e. XG (X_1) and Guar gum i.e. GG (X_2) were selected as the factors. The levels of two factors were selected on the basis of the preliminary studies carried out before implementing the experimental design. All other formulation and processing variables were kept invariant thoughout the study. Table 1 and 2 summarizes the translation of the coded levels to the experimental units and the experimental runs, their factor combinations used in the study.[31]

Table 1: Amount of variables in 3^2 full factorial designs

Coded Values	Actual Values (mg)	
	X_1	X_2
-1	105	105
0	140	140
+1	175	175

Table 2: A 3^2 full factorial experimental design layout

Formulation Code	Coded Values	
	X1	X2
F1	-1	-1
F2	0	-1
F3	+1	-1
F4	-1	0
F5	0	0
F6	+1	0
F7	-1	+1
F8	0	+1
F9	+1	+1

Preparation of Mesalamine matrix tablets:

The colon targeted matrix tablets of Mesalamine were prepared by wet granulation technique using 10 % (w/v) starch paste as binder. Lactose was used as diluents and a mixture of talc with magnesium stearate at 2:1 (w/w) ratio was used as lubricant. Mesalamine and all the excipients were previously passed though sieve no. #150 individually. Then, Mesalamine was mixed with the excipients like Xanthan gum and guar gum except the binding agent and lubricant. The blend was mixed for 10 mins in a polybag and later the mixture was granulated with starch paste. The resulting wet mass was passed through a sieve no. #12 and the granules were dried at 50 ^{0}C for 15 min to get a loss on drying (LOD) value between 1 % and 1.2 %, after which they were passed though sieve no #22. Dried granules were blended with magnesium stearate and talc (1:2 w/w). The lubricated granules were then compressed using 13 mm punch at pressure of 5.3 Kg/cm^2. Totally 9 formulation were developed using 3^2 factorial design each of 700 mg but, formulation 9 was adjusted for a weight of 750 mg. The weight and proportions of the entire ingredient were the same order.[32]

Table 3: Formulation of Mesalamine matrix tablet in 3^2 factorial designs

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Mesalamine	300	300	300	300	300	300	300	300	300
Xanthun gum	105	140	175	105	140	175	105	140	175

Guar gum	105	105	105	140	140	140	175	175	175
Sodium Starch Glycolate (4 %)	28	28	28	28	28	28	28	28	28
Starch (10 %)	35	35	35	35	35	35	35	35	35
Mg. Stearate & Talc 1:2 (2%w/w)	14	14	14	14	14	14	14	14	14
Lactose	113	78	43	78	43	8	43	8	23
Total (mg)	700	700	700	700	700	700	700	700	750

Evaluation of Tablets:

Pre-compression Parameters

Bulk Density: Bulk density was calculated by measuring the volume and weight of pre-sieved granules placed in a 100 mL graduated cylinder. It is expressed as the ratio of mass to bulk volume.

Tapped Density: A weighed sample of granules was transferred to a graduated cylinder and subjected to 100 taps on a tapped density apparatus. The tapped density was then calculated as the weight divided by the tapped volume.

Compressibility Index (Carr's Index): This index was calculated to assess the rate at which granules compact. It is derived from the difference between tapped density and bulk density, divided by tapped density, and expressed as a percentage. Lower values indicate better flow properties.

Hausner's Ratio: Used to assess powder flowability, Hausner's Ratio is the ratio of tapped density to bulk density. A lower ratio (<1.25) suggests better flow properties, while higher values (>1.25) indicate poorer flow.

Angle of Repose: The angle of repose was determined using the fixed funnel method, where granules are poured to form a conical pile. The angle between the pile's surface and the horizontal platform is calculated as $\tan^{-1}(h/r)$, with a lower angle indicating better flowability.

Post-compression parameters:

Post-compression parameters of the tablets included shape, appearance, thickness, diameter, hardness, friability, weight variation, and drug content uniformity. Tablets were examined under a lens for shape and color, while thickness and diameter of twenty tablets were measured with Vernier calipers, and the average was calculated. Hardness, assessed using a Monsanto hardness tester, indicated resistance to mechanical shocks. Friability was tested using a Roche friabilator, with acceptable weight loss below 0.8%. Weight variation was evaluated by weighing twenty tablets individually and comparing them to the average weight, ensuring compliance with IP standards. For drug content uniformity, tablets were powdered, and the equivalent weight to 300 mg of the active ingredient was extracted and analyzed spectrophotometrically to ensure consistency across the batch.[33]

Swelling studies:

Swelling studies were conducted to measure the percentage weight gain of tablets as an indicator of swelling. One tablet from each formulation was placed in a petri dish containing pH 6.8 phosphate buffer solution at 37±0.5°C. At set intervals (1, 2, 3, 4, 5, and 6 hours), each tablet was removed, gently blotted to remove excess water, and weighed to calculate its swelling behavior.[34]

Stability studies:

Stability studies were conducted to examine the impact of temperature and humidity on the drug content of Mesalamine formulations. A short-term stability study was performed under conditions of 40°C ± 2°C and 75% RH ± 5% RH for six months (180 days) on the selected colon-targeted matrix tablets. Tablets were wrapped in aluminum foil, packed in screw-cap bottles, and stored in a stability chamber. Samples were taken every ten days to assess in vitro drug release.[35]

RESULT AND DISCUSSION:

Preformulation Studies:

The Preformulation study, it's like qualitative analysis of raw materials and pure drug which includes physical characterization and analytical methods and evaluation of tablet blends including determination of bulk density, tapped density, compressibility index, Hausner's ratio and angle of repose were performed.

Physical characterization of drug sample:

Description:

The received sample of Mesalamine was found to be white crystalline and odorless powder.

Melting Point:

The average melting point of Mesalamine was determined by capillary method in triplicate and was found to be 281^0C, which is in good agreement with reported melting point range 281-283^0C.

Solubility:

The solubility of Mesalamine was assessed in various solvents, yielding the following results: 9.97 mg/mL in 0.1 N hydrochloric acid, 7.63 mg/mL in phosphate buffer pH 6.8, 5.84 mg/mL in phosphate buffer pH 7.4, and 0.78 mg/mL in distilled water. The solubility trend observed was 0.1 N hydrochloric acid > phosphate buffer pH 6.8 > phosphate buffer pH 7.4 > distilled water.

Partition Coefficient studies:

Partition coefficient studies were conducted to determine the octanol-water partition coefficient (Ko/w) of Mesalamine. Absorbance measurements were recorded in both water and octanol, yielding values of 0.3850 nm in water and 0.6115 nm in octanol. Based on these values, the partition coefficient (Ko/w_\text{o/w}o/w) was calculated to be 1.6087, indicating a moderate preference of Mesalamine for the octanol phase, which suggests limited but significant lipophilicity.

Drug polymer compatibility studies:

FTIR spectra were recorded for Mesalamine, the polymer blend (xanthan gum with guar gum), and formulations containing various excipients. The characteristic absorption peaks for pure Mesalamine were observed at 3400 cm^{-1} (NH stretching), 3010 cm^{-1} (CH stretching), 1642.37 cm^{-1} (C=O stretching), and 1442.88 cm^{-1} (C=C stretching). These peaks were consistently present in the Mesalamine formulation, as shown in Figure 1, indicating that no chemical interactions occurred between Mesalamine and the polymers.

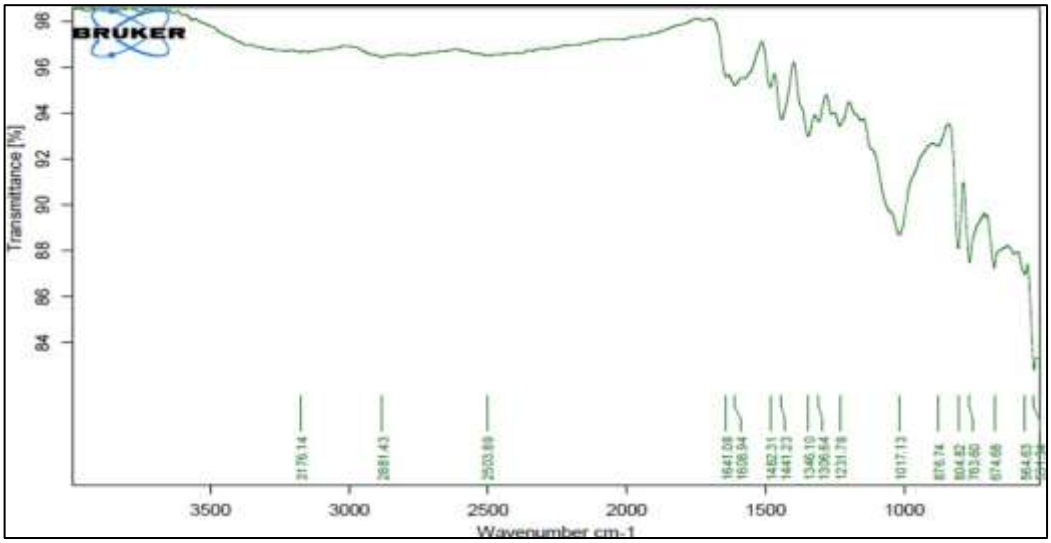

Figure 1: FTIR Spectra of Mesalamine, Xanthan gum with Guar gum

Formulation development by using 3^2 factorial designs:
A total of 9 formulations was developed using 3^2 factorial designs. 8 (F1-F8) formulations were of 700 mg weight each and F9 was adjusted for a weight of 750 mg.

Evaluation of Pre-compression parameters:
The powder blends for all formulations were assessed for pre-compression parameters, including angle of repose, bulk density, tapped density, compressibility index, and Hausner's ratio. These values are presented in Table 4. The angle of repose for all batches ranged from 17.29°±1.555 to 23.84°±1.985, indicating good flow properties of the powder blends. Bulk densities ranged between 0.57±0.015 g/mL and 0.64±0.030 g/mL, while tapped densities fell between 0.66±0.012 g/mL and 0.75±0.01 g/mL. These densities suggest minimal porosity, facilitating effective compaction during compression. The compressibility index values were within 13.51±1.179% to 15.88±1.363%, meeting acceptable standards, and Hausner's ratios ranged from 1.15±0.015 to 1.22±0.049, further confirming the good flow properties and compressibility of the powder blends across all formulations from F1 to F9.

Table 4: Rheological properties of powder blend of F1 to F9 (n=3)

Batch	Angle of Repose (º)±S.D.	Bulk Density (gm/mL)±S.D.	Tapped Density (gm/mL)±S.D.	Compressibility Index (%)±S.D.	Hausner's Ratio±S.D.
F1	23.84±1.985	0.61±0.010	0.71±0.005	14.49±0.874	1.17±0.011
F2	21.97±1.770	0.64±0.017	0.75±0.01	14.67±1.455	1.17±0.020
F3	22.96±0.875	0.62±0.010	0.72±0.015	14.27±1.392	1.16±0.015
F4	19.47±0.352	0.58±0.020	0.68±0.011	14.29±1.849	1.16±0.023
F5	20.78±2.283	0.62±0.035	0.74±0.03	15.79±1.358	1.22±0.049
F6	17.29±1.555	0.60±0.020	0.71±0.025	15.88±1.363	1.18±0.005
F7	19.60±2.797	0.63±0.032	0.74±0.03	14.43±1.647	1.16±0.025
F8	19.46±2.085	0.64±0.030	0.74±0.03	13.51±1.179	1.15±0.015
F9	18.56±2.018	0.57±0.015	0.66±0.012	13.57±1.514	1.15±0.020

Evaluation Post compression parameters:
The post-compression parameters of all tablet formulations, including thickness, hardness, friability, weight variation and drug content uniformity, were evaluated and summarized in Table 5. Thickness and diameter were measured for 20 tablets per batch, showing uniform thickness (4.00±0.031 mm to 4.21±0.020 mm) and diameter (13.05±0.020 mm to 13.15±0.057 mm), indicating consistency in tablet production. Hardness values ranged from 5.23±0.0577 Kg/cm² to 6.20±0.1001 Kg/cm², confirming adequate mechanical strength to endure handling and shipping. Friability values between 0.31% and 0.47% met the standard (≤1.0%), reflecting strong structural integrity. Weight variation tests showed all formulations within acceptable limits (699.60±4.453 mg to 750.40±3.978 mg). Drug content uniformity for all batches ranged from 96.10±0.004% to 99.75±0.007%, ensuring reliable drug distribution across tablets.

Table 5: Evaluation parameters of formulations F1 to F9 (n=3)

Batch	Thickness (mm)±S.D.	Diameter (mm)±S.D.	Hardness (Kg/cm^2) ±S.D.	Friability (%)	Average weight variation (mg)±S.D.	Drug content (%)±S.D.
F1	4.04±0.010	13.09±0.010	5.33±0.152	0.31	700.50±3.120	98.25±0.042
F2	4.05±0.030	13.12±0.030	5.63±0.152	0.41	700.15±2.889	96.49±0.056
F3	4.00±0.031	13.13±0.015	5.27±0.152	0.34	700.80±4.124	96.10±0.043

F4	4.08±0.015	13.07±0.025	5.76±0.152	0.37	701.15±4.442	97.86±0.082
F5	4.07±0.025	13.05±0.020	5.57±0.152	0.46	701.05±4.453	97.34±0.071
F6	4.06±0.015	13.10±0.021	5.23±0.057	0.35	699.60±4.453	98.51±0.057
F7	4.05±0.015	13.14±0.025	6.20±0.100	0.40	701.10±4.102	99.31±0.084
F8	4.04±0.015	13.11±0.011	5.67±0.152	0.38	700.95±4.628	99.75±0.075
F9	4.21±0.020	13.15±0.057	5.43±0.153	0.47	750.40±3.978	99.25±0.049

Swelling index studies:

The Swelling Index for each matrix tablet formulation was determined in triplicate, with results presented in Table 6. Swelling increased over time as the hydrophilic polymers absorbed water, forming a gel layer on the tablet surface. The extent of swelling depended on the matrix carrier content, with tablets retaining shape and integrity throughout the study. The percent swelling ranged from 23.86±0.0052% to 69.42±0.0060%, showing a clear trend of increased swelling with prolonged polymer contact.

Formulations with Xanthan gum and Guar gum exhibited a progressive increase in the swelling index from 1 to 6 hours, with higher polymer content enhancing swelling capacity. Among the formulations, the swelling order was observed as F9 > F8 > F7 > F6 > F5 > F4 > F3 > F2 > F1.

Table 6: Swelling behavior of Mesalamine colon targeted matrix tablet (n=3)

Batch	**Time (h)**					
0	**1**	**2**	**3**	**4**	**5**	**6**
F1	15.71±0.01	24.28±0.010	35±0.051	41.67±0.002	52.14±0.05	59.28±0.01
F2	17.04±0.04	27.62±0.028	36.76±0.02	42.38±0.051	53.09±0.02	60.47±0.02
F3	17.62±0.02	28.33±0.029	38.48±0.04	43.00±0.052	54.19±0.04	61.67±0.02
F4	18.80±0.07	28.80±0.076	40.09±0.06	45.09±0.06	54.76±0.02	63.57±0.05
F5	19.71±0.05	29.52±0.028	41.19±0.02	45.95±0.02	56.42±0.05	65.76±0.04
F6	20.80±0.03	30.48±0.07	43.80±0.01	48.09±0.07	59.05±0.02	67.24±0.04
F7	22.28±0.06	30.86±0.060	44.76±0.07	49.05±0.02	61.80±0.09	68.48±0.09
F8	23.05±0.05	31±0.095	45.48±0.09	49.33±0.09	62.52±0.09	68.95±0.08
F9	23.86±0.07	32.80±0.086	45.78±0.02	52.09±0.01	64.31±0.06	69.42±0.06

Stability studies:

Stability studies on the colon-targeted matrix tablets were conducted by storing them in high-density polyethylene sealed covers under refrigeration and at 40 ºC/75% RH. Samples were withdrawn monthly over six months and tested for dissolution. Results confirmed no significant change in dissolution profiles over this period.

These studies indicate that formulation F3 showed no significant difference ($p > 0.05$) in drug release after storage for 180 days (6 months) at 40 ºC/75% RH. This suggests that formulation F3 could remain stable and effective for at least two years at room temperature.

Table 7: Summary of F3 formulation before and after accelerated stability studies

Para meter	**Initial**	**30 Days (40 ºC/75 % RH) Accelerated Condition**	**60 Days (40 ºC/75 % RH) Accelerated Condition**	**90 Days (40 ºC/75 % RH) Accelerated Condition**	**120 Days (40 ºC/75 % RH) Accelerated Condition**	**180 Days (40 ºC/75 % RH) Accelerated Condition**
Time (min)	**%CDR±SD**	**%CDR±SD**	**%CDR±SD**	**%CDR±SD**	**%CDR±SD**	**%CDR±SD**
0	**0**	**0**	**0**	**0**	**0**	**0**
1	0.02±0.0014	0.04±0.0021	0.05±0.0013	0.03±0.0019	0.04±0.0022	0.06±0.0017
3	0.06±0.0021	0.09±0.0022	0.11±0.0017	0.13±0.0032	0.15±0.0027	0.16±0.0037

5	0.12±0.0020	0.16±0.0025	0.17±0.0028	0.18±0.0037	0.21±0.0032	0.23±0.0042
15	0.23±0.0017	0.26±0.0014	0.28±0.0039	0.29±0.0024	0.28±0.0045	0.31±0.0057
30	0.39±0.0011	0.42±0.0017	0.44±0.0020	0.46±0.0026	0.48±0.0052	0.53±0.0065
45	0.6±0.0016	0.65±0.0019	0.7±0.0024	0.69±0.0032	0.71±0.0056	0.77±0.0044
60	1.07±0.0025	1.15±0.0027	1.44±0.0044	1.68±0.0049	1.70±0.0066	1.93±0.0041
75	1.67±0.0035	1.89±0.0042	2.05±0.0059	2.53±0.0066	2.60±0.0047	2.76±0.0056
90	2.53±0.0045	2.61±0.0056	2.78±0.0064	2.87±0.0067	2.90±0.0059	3.11±0.0087
120	3.67±0.0078	4.33±0.0055	4.83±0.0060	5.18±0.0063	4.83±0.0052	5.33±0.0054
125	4.9±0.0056	5.09±0.0067	5.53±0.0073	5.98±0.0075	5.77±0.0062	6.07±0.0041
135	7.11±0.0089	7.85±0.0077	8.12±0.0066	8.44±0.0072	8.85±0.0087	9.67±0.0017
150	10.16±0.009	10.92±0.008	11.61±0.008	12.84±0.007	12.92±0.009	14.26±0.012
180	15.58±0.021	16.04±0.036	17.23±0.040	19.35±0.046	20.04±0.039	22.15±0.051
240	22.82±0.032	23.98±0.043	24.72±0.047	25.83±0.057	26.54±0.045	27.95±0.077
300	33.49±0.085	34.09±0.071	33.22±0.077	33.06±0.069	34.19±0.052	34.25±0.043
305	33.95±0.067	36.23±0.058	37.86±0.055	38.26±0.067	38.89±0.032	39.53±0.014
310	34.57±0.047	37.19±0.049	38.92±0.057	40.11±0.039	41.29±0.063	42.17±0.034
315	35.48±0.072	38.72±0.066	39.51±0.062	41.86±0.078	42.72±0.076	43.56±0.065
330	37.82±0.069	40.46±0.070	41.49±0.080	42.98±0.084	43.81±0.057	45.13±0.048
360	41.59±0.096	44.27±0.074	45.60±0.082	46.89±0.077	47.77±0.061	48.85±0.067
420	46.69±0.098	48.67±0.083	49.82±0.076	51.03±0.062	52.67±0.082	54.11±0.073
480	53.72±0.048	56.13±0.052	58.09±0.058	60.65±0.063	61.13±0.062	63.53±0.034
540	62.53±0.073	64.88±0.076	66.59±0.062	68.14±0.066	69.88±0.034	71.14±0.087
600	73.02±0.078	76.33±0.062	78.12±0.066	80.54±0.071	82.33±0.084	83.78±0.061
660	85.05±0.085	88.43±0.077	89.90±0.073	91.05±0.089	92.43±0.056	93.88±0.058
720	99.35±0.088	99.86±0.065	99.94±0.083	99.97±0.057	100.13±0.04	100.23±0.03

CONCLUSION:

In conclusion, this study successfully developed and evaluated a colon-specific drug delivery system for Mesalamine, aimed at providing targeted release for treating colonic disorders. The preformulation studies confirmed the compatibility of Mesalamine with the excipients. Pre-compression evaluations indicated favorable rheological properties of the powder blend, while post-compression tests revealed uniform tablet characteristics in terms of hardness, friability, weight variation, and drug content. The swelling index increased over time and with higher polymer content, demonstrating the role of xanthan gum (XG) and guar gum (GG) in controlling the release profile. A 3^2 factorial design revealed that XG and GG significantly influenced the swelling behavior and drug release. Statistical analysis (ANOVA, $p < 0.05$) confirmed the significance of the results. Among the formulations, F3 exhibited the best drug release profile and was selected for stability studies. Stability tests conducted according to ICH guidelines at 40°C/75% RH for six months showed no significant changes in drug content or release profile, indicating that the formulation remains stable under accelerated storage conditions. This study highlights the potential of colon-targeted drug delivery systems to overcome gastrointestinal barriers and effectively manage colonic disorders.

DISCLOSUREOF INTERESTS:

The author declares that they have no conflict of interest

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