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PREPARATION, CHARACTERIZATION AND EVALUATION OF TABLET FOR COLONIC DELIVERY

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ABSTRACT: The aim of the present work is to develop and evaluate colon targeted drug delivery of satranidazole for an effective and safe therapy of amoebiasis. Amoebiasis is a parasitic disease caused by *E. histolytica* and it causes about 34 - 50 million symptomatic infections each year. The treatment of amoebiasis is effective with satranidazole. Therefore it was planned to develop a suitable dosage form, which can deliver maximum amount of the drug in the colonic environment such that there would be effective action on amoebiasis. This investigation was planned to characterize the satranidazole for their physico-chemical properties and to evaluate rheological and compressional characteristics of the tablets. It was planned to optimize the amount of PH dependent polymer eudragit L100 and eudragit S100 carriers for colonic delivery. The coating formulation consisted of Eudragit L100: Eudragit S100 in ratio of 6:4 at 10% coating level has potential for the required lag time of 5 hours. In-vitro release study was shown after effective lag time.

INTRODUCTION: Colon drug delivery system improves the localized action of drug. Present study will take up with following objectives drug directly available at the target site, decreased dose to be administered by controlling release rate, decreased side effect by direct treating disease site and improved drug utilization by prolonging effect of drug colon is attracting interest as a site where poorly absorbed drug molecule may have an improved bioavailability [1]. This region of the colon is recognized as having a somewhat less hostile environment with less diversity and intensity of activity than the stomach and small intestine [2].

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Oral delivery of drugs to the colon is valuable in the treatment of diseases of colon (ulcerative colitis, Crohn' disease, carcinomas and infections) whereby high local concentration can be achieved while minimizing side effects that occur because of release of drugs in the upper GIT or unnecessary systemic absorption.

The colon is rich in lymphoid tissue, uptake of antigens into the mast cells of the colonic mucosa produces rapid local production of antibodies and this helps in efficient vaccine delivery. The colon has a longer retention time and appears highly responsive to agents that enhance the absorption of poorly absorbed drugs. The simplest method for targeting of drugs to the colon is to obtain slower release rates or longer release [3, 4].

Approaches to Colon Specific Drug Delivery: The most direct route for delivery of drugs into the colon is by rectal administration. Since there are

problems in both patient acceptability and accessing the proximal colon using rectally administered dosage forms, orally administered colon specific delivery systems have been developed. There are three practical mechanisms by which a delivery system can be targeted into the colon following oral administration [5].

The targeting of orally administered drugs to the colon is accomplished by:

- Coating with pH dependent polymers,
- Time release dosage forms,
- Delivery systems based on the metabolic activity of colonic bacteria.

Coating with pH Dependent Polymers: In these systems, drugs are formulated into solid dosage forms such as tablets, capsules and pellets and coated with pH sensitive polymers as in enteric coating. Widely used polymers are methacrylic resins (Eudragits) which are available in water-soluble and water-insoluble forms. It is well known that the pH value increases as it goes from stomach to the rectum [6]. The slight differences in pH between the small intestine (pH 6.5 - 7) and large intestine (pH 7 - 8) gives many fold difference in their hydrogen ion concentration which can be utilized to deliver the drug to the large intestine with the help of a pH dependent polymer. The carboxyl group present in these polymers are soluble at higher pH values. The pH at which these dissolve is known as threshold pH and depends on the number of the carboxyl groups in the molecules [7].

TABLE 1: POLYMERS USED IN THE DEVELOPMENT OF MODIFIED-RELEASE FORMULATIONS FOR COLONIC DRUG DELIVERY SYSTEMS [8]

Polymers	Optimum pH for dissolution of drug
Polyvinyl acetate phthalate (PVAP)	5.0
Cellulose acetate trimelitate (CAT)	5.5
Hydroxypropyl methylcellulose phthalate (HPMCP)	≥ 5.5
Hydroxypropylmethylcellulose acetate succinate (HPMCAS)	≥ 6.0
Methacrylie acid copolymer, Type C (Eudragit L100-55)	≥ 6.0
Methacrylic acid copolymer dispersion (Eudragit L30D-55)	≥ 5
Methacrylic acid copolymer, Tyep A	≥ 6.0
(Eudragit®L-100 and Eudragi st L12,5)	-
Cellulose acetate phthalate (CAP) (Aquateric)	6.0
Methacrylic acid copolymer, Type B	≥ 7.0
(Eudragist S-100 and Eudragit S12,5)	-
Eudragit FS30D	> 7.0
Shellac (MarCoat 125 &125N)	7.0

Satranidazole: Satranidazole is a 5- nitroimida zoles with a potent antiprotozoal activity, effective in treating intestinal amoebiasis, giardiasis trichomoniasis or bacterial vaginosis. It is of synthetic origin and belongs to Nitroimidazole. It belongs to Amebicides pharmacological group.

Amebiasis and giardiasis Satranidazole is extremely effective against anaerobic bacterial infections and is also used to treat Crohn's disease, antibiotic-associated diarrhea, and rosacea.

Nitro group covalently binds to DNA, disrupt its helical structure, inhibiting bacterial nucleic acid synthesis and resulting in bacterial cell death [9].

Dosage: [10] For amoebiasis 300 mg two times a day for 3 - 5 day. For trichomoniasis and giardiasis 600 mg as a: single dose.

Materials: Satranidazole gifted from Alkem laboratory, Mumbai**,** Gaur gum, Microcrystalline cellulose, Mg. stearate, Talc, Eudragit L100, Eudragit S 100 gifted by Evonik India Pvt. Ltd., Mumbai, Methanol, Dibutyl phthalate, Lactose.

Formula for Core Tablets:

TABLE 2: FORMULA FOR CORE TABLETS (500mg)

S. no.	Name of Ingredient	Quantity (mg)
1	Satranidazole	300
2	Gaur gum	50
3	Microcrystalline cellulose	135
4	Magnesium stearate	5
5	Talc	10

Procedure: All the ingredients were weighed properly and mixed thoroughly. The tablets were prepared from the mixed powder by direct compression method.

Formula for Coating Solution: The core tablet was coated with polymer Eudragit L100 and Eudragit S100 in combination in different concentration, formulation developed from batch F1 to F9 give in **Table 3**.

TABLE 3: COMBINATION OF EUDRAGIT L100: EUDRAGIT S100

Batch No.	Polymer Ratio
	Eudragot L100:Eudragit S 100
F1	1:9
F2	2:8
F3	3:7
F4	4:6
F5	5:5
F6	6:4
F7	7:3
F8	8:2
F9	9:1

TABLE 4: FOMULA FOR COATING CORE TABLET OF DRUG

Polymer	F1	F2	F3	F4	F5	F6	F7	F8	F9
Eudragit L100: Eudragit S100	1:9	2:8	3:7	4:6	5:5	6:4	7:3	8:2	9:1
Methanol	100	100	100	100	100	100	100	100	100
Dibutyl pathlate	0.6	0.6	0. 6	0.6	0.6	0.6	0.6	0.6	0.6

TABLE 5: COATING PARAMETER

Inlet temperature (°C)	60-75
Outlet temperature (°C)	40-45
Nozzle diameter (mm)	1 mm
Atomization pressure	0.5 bar
Spray rate (ml/min)	1 ml/min
Pan speed	12.5-14 rpm
Preheating of core tablet	10-20 min

Preparation of Coating Solution: Coating solution was made using different ratios of material like Eudragit L100 and Eudragit S100. Required quantity of polymers were dissolved in solvents and stirred on magnetic stirrer to get homogeneous coating solution. Dibutyl pthalate was added in above solution as plasticizer (0.6% w/v). After getting homogeneous coating solution; coating was done on tablets.

Pre-Compression Characteristics of Powder Bed: [11] Powder used for direct compression of core tablet were evaluated for various rheological properties like bulk density, tapped density, compressibility index, flow properties (angle of repose) by using standard procedures. All studies were carried out in triplicate (n = 3) and average values were reported.

Bulk Density: Bulk density was determined (bulk density apparatus, Konark instruments, India) by taking the Powder in a measuring cylinder and measures the volume and weight of the total Powder.

Bulk density = Total weight / Total bulk volume

The results are shown in **Table 20**.

Tapped Density: Tapped density was determined (Tapped density apparatus, Konark instruments, India) by taking the powder in a measuring cylinder and the volume of powder after 100 tapping and weight of the total Powder.

Tapped density = Total weight / Total volume after Tapping

The results are shown in **Table 20**.

Compressibility Index: Compressibility index was determined by placing the powder in a measuring cylinder and the volume (V_0) was noticed before tapping, after 100 tappings again volume (V) was noticed.

Compressibility index = $(1- V/ V_0) X 100$

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

Angle of Repose (Ø): Angle of repose was determined by measuring the height, radius of the heap of the powder. A cut system funnel was fixed to a stand and bottom of the funnel was fixed at a height of 5 cm from the plane. Powder were placed in funnel and allowed to flow freely and measured the height and radius of the heap of powder. These studies were carried out before and after incorporating lubricants / glidants.

$$\text{Tan } ø = h / r$$

h = height of heap of powder.
r = radius of heap of powder.

Compression of Tablets: The core tablet were prepared by mixing 300 mg of satranidazole, 50 mg of guar gum, 135 mg of microcrystalline cellulose. After adding lubricant (talc) and anti-adherent (Magnesium stearate) to the powder bed and subsequent blending of the powder, were compressed into tablets on a pilot plant (Vidyabharti College of Pharmacy, Amravati) press machine using 10 mm diameter, convex punches at a pressure of approximately 5 kgs /cm^2.

Evaluation of Post Compression Characteristics of Tablets: [12] Tablets were evaluated for their thickness, weight uniformity, hardness, friability, disintegration time and dissolution profiles by using standard procedures.

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

Weight Uniformity: Ten tablets were taken and weighed individually. Average weight was calculated standard deviation and percent coefficient of variance was computed.

Hardness Test: Prepared tablets were evaluated for their hardness by using Pfizer hardness tester. The hardness was measured in terms of kg/cm^2. Triplicate readings were taken and average was computed.

Friability Test: Roche Friabilator was used for testing the friability of the tablets. Five tablets were weighed accurately and placed in the tumbling chamber and rotated at 25 rpm for a period of 5 min. Tablets were again weighed and the percentage weight loss was determined by using formula given below.

% Friability = Initial wt of tablets – Final wt of tablets × 100 / Initial wt of tablets

Where; W_1 is the initial weight of the tablet,
W_2 is the weight of the tablet after the particular swelling time interval.

Disintegration Time: Disintegration test was performed for core tablets in 0.1N HCl at 37 °C by using USP disintegration apparatus. Triplicate readings were taken and average was computed.

Drug Content Uniformity: From each batch three randomly selected tablets were weighed accurately and powdered in a clean and dry glass mortar with pestle. Powder equivalent to 100 mg of drug was transferred into 100 mL volumetric flask containing distilled water; the remaining volume was made up to 100 mL with distilled water. Shaken intermittently for 24 h and the solution was filtered, make up desired dilutions and analyzed for drug content at λ max 256.5 nm, using a Distilled water as a blank. Triplicate readings were taken and average was computed.

Water Absorption Ratio and Wetting Time: A piece of tissue paper folded twice was placed in a small petridish containing 6 ml of water. A tablet of known weight was put on the paper and the time required for complete wetting of tablet was measured. The wetted tablet was then weighed, water absorption ratio R was determined using the following equation and the result is shown in table

$$R = 100 \times \frac{Wb - Wa}{Wa}$$

Where Wb is weight of tablet before water absorption and Wa is weight of tablet after water absorption.

***In vitro* Dissolution Studies:** The core tablets were evaluated with the aid of USPXXIV type 2 apparatus. The tablet was kept in 900 mL of dissolution medium and the medium was stirred at 100 rpm and the temperature of the medium was maintained at 37 ± 0.5 °C. For the first 2 hours the

jars are filled with phosphate buffer pH 6.8 for a period of 12 h. Samples of 1 mL were collected at predetermined time intervals for 12 h. All the studies were carried out in triplicate and the average was considered (n = 3).

Evaluation of Coating: [13]

% Weight Gain: The tablets were evaluated for their % weight gain. The core tablet of known weight was coated and again weight was taken. The % weight gain was calculated using following formula

$$\% \text{ Weight Gain} = \frac{W_2 - W_1}{W_1} \times 100$$

Coating Thickness: The tablets were evaluated for their coating thickness. The thickness of core tablet measured using a vernier calliper (Mitutoyo, Japan) in terms of micrometer. Again thickness of coated tablet was measured. The difference between two are calculated. Average of three readings were taken and the results were tabulated (n = 3).

***In vitro* Dissolution Studies:** Colon targeted tablets of saitanidazole were evaluated with the aid of USP XXIV type 1 (basket) apparatus. The tablet was kept in basket in the jars containing 900 mL of dissolution medium and the medium was stirred at 100 rpm and the temperature of the medium was maintained at 37 ± 0.5 °C.

For the first 2 hours the jars are filled with buffer of pH 1.2. After 2 h the jar assembly was lifted and the dissolution fluid was replaced with phosphate buffer pH 6.4 for 1hr, 7.4 for a period of 9 h.Samples of 1 mL were collected at predetermined time intervals for 12 h. All the studies were carried out in triplicate and the average was considered (n = 3).

Stability Studies: Stability of a drug has been defined as the ability of a particular formulation, in a specific container, to remain within its physical, chemical, therapeutic and toxicological specifications [14].

RESULT AND DISCUSSION:

TABLE 6: PHYSICAL PROPERTIES OF POWDER FOR FORMULATION BATCH

Formulations	Angle of repose(θ)	Loose Bulk Density (gm/cm)	Tapped Density (gm/cm)	Compressibility (%)	Hausner's ratio
F1	24.560 ±0.02	0.34±0.01	0.38±0.08	11.19 ± 0.12	1.15 ± 0.02
F2	23.320±0.12	0.33±0.02	0.37±0.07	10.82 ± 0.22	1.14 ± 0.07
F3	28.600±0.13	0.33±0.07	0.37±0.01	10.97 ± 0.16	1.17 ± 0.08
F4	25.300±0.12	0.35±0.09	0.39±0.13	10.75 ± 0.21	1.17 ± 0.04
F5	23.240±0.14	0.32±0.04	0.38±0.07	12.76 ± 0.17	1.14 ± 0.10
F6	24.080±0.16	0.33±0.02	0.37±0.21	11.58 ± 0.18	1.13 ± 0.10
F7	24.860±0.13	0.34±0.01	0.38±0.08	11.21 ± 0.13	1.18 ± 0.11
F8	25.290±0.14	0.41±0.03	0.46±0.07	10.68 ± 0.21	1.20 ± 0.10
F9	23.210 ±0.017	0.32±0.06	0.38±0.01	10.69 ± 0.25	1.17 ± 0.06

Evaluation of Post Compression Characteristics of Tablets:

TABLE 7: EVALUTION OF TABLET FOR FORMULATION BATCHES

Batch	Weight variation	Thickness	% Drug Content	Hardness (kg/cm^2)	%Friability	Wetting Time (sec)	%water absorption ratio
F1	passes	6.24±0.15	99.6±0.05	7.43±0.20	0.1262±0.06	60±0.12	91.67±0.054
F2	Passes	6.22±0.12	100.79±0.035	7.19±0.20	0.2688±0.06	85±0.13	85.99±0.06
F3	Passes	6.41±0.10	99.23±0.003	7.7±0.21	0.1704±0.07	80±0.08	80.93±0.023
F4	passes	6.39±0.11	99.94±0.003	7.17±0.17	0.3829±0.02	60±0.06	91.53±0.05
F5	passes	6.46±0.12	99.35±0.004	7.61±0.22	0.1097±0.10	68±0.07	93.49±0.033
F6	passes	6.34±0.13	98.62±0.054	7.73±0.12	0.1566±0.02	85±0.08	90.32±0.041
F7	passes	6.32±0.15	99.36±0.020	7.54±0.11	0.1384±0.06	40±0.09	91.30±0.042
F8	passes	6.41±0.14	99.38±0.067	7.55±0.10	0.1893±0.03	45±0.06	90.33±0.05
F9	passes	6.38±0.12	99.45±0.983	7.19±0.08	0.2883±0.05	40±0.12	91.93±0.06

TABLE 8: DISINTEGRATION TEST FOR FORMULATION BATCHES

Batch no.	Disintegration time
F1	152±0.20
F2	163±0.19
F3	159±0.14
F4	156±0.11
F5	156±0.09
F6	151±0.13
F7	159±0.12
F8	159±0.14
F9	160±0.08

TABLE 9: DRUG RELEASE PROFILE OF CORE TABLET FORMULATION BATCHES

Time(min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	15.89±0.19	14.89±0.16	15.86±0.10	11.10±0.14	14.09±0.10	18.72±0.11	12.54±0.08	12.34±0.21	17.02±0.13
2	32.08±0.15	32.90±0.18	36.93±0.12	36.91±0.11	37.89±0.18	39.91±0.16	28.90±0.11	35.39±0.22	32.01±0.15
3	61.00±0.18	69.75±0.18	70.09±0.12	63.15±0.10	70.61±0.09	61.88±0.20	62.00±0.10	70.00±0.15	60.98±0.09
4	86.81±0.20	87.65±0.13	93.79±0.12	88.45±0.08	93.17±0.06	86.09±0.21	85.49±0.13	86.82±0.12	86.89±0.13
5	98.00±0.17	99.98±0.11	98.21±0.15	97.48±0.05	98.87±0.12	98.89±0.13	98.31±0.12	97.78±0.13	98.02±0.11

TABLE 10: POST COATING EVALUATION OF FORMULATION BATCHES

Batch code	% Weight gain	Coat thickness (mm)
F1	20.25±0.04	0.86±0.06
F2	19.54±0.04	0.93±0.03
F3	19.89±0.09	0.91±0.03
F4	20.62±0.07	0.85±0.08
F5	19.38±0.02	0.88±0.06
F6	20.25±0.04	0.94±0.05
F7	20.12±0.07	0.88±0.09
F8	19.75±0.02	0.96±0.03
F9	20.32±0.06	0.98±0.06

TABLE 11: DRUG RELEASE PROFILE OF COATED TABLET OF FORMULATION BATCHES

Time (h)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0
3	0.13±0.11	0.72±0.12	0	0	0	0	0	0	2.83±0.10
4	0.21±0.12	2.26±0.12	1.33±0.12	0	0	0	0	7.60±0.14	10.44±0.13
5	1.93±0.115	8.82±0.13	6.14±0.12	10.01±0.11	9.49±0.10	0	9.72 ±0.08	18.14±0.06	19.81±0.11
6	6.28±0.12	24.89±0.17	21.68±0.11	17.82±0.15	19.85±0.14	10.80±0.13	21.88±0.14	23.69±0.11	28.25±0.14
7	19.28±0.10	38.78±0.14	35.13±0.12	33.18±0.13	27.63±0.13	38.62±0.07	23.57±0.11	33.62±0.14	38.54±0.07
8	33.81±0.09	49.79±0.11	49.77±0.14	46.72±0.07	49.83±0.08	45.59±0.09	37.32±0.13	49.95±0.11	48.57±0.10
9	48.89±0.08	54.62±0.11	73.41±0.12	59.31±0.14	59.24±0.10	63.01±0.14	56.89±0.08	69.78±0.07	57.80±0.08
10	68.90±0.11	63.15±0.12	88.19±0.05	68.24±0.09	68.13±0.06	76.63±0.11	75.22±0.06	70.10±0.08	69.12±0.09
11	81.18±0.12	78.41±0.17	93.71±0.09	83.22±0.10	88.70±0.14	87.11±0.14	92.09±0.09	80.48±0.11	81.48±0.14
12	98.45±0.15	98.61±0.13	98.56±0.08	97.62 ±0.13	98.16±0.09	98.99±0.09	97.70±0.11	98.30±0.14	94.67±0.11

TABLE 12: STABILITY STUDY FOR FORMULATION BATCH F6

Stability (40±20, 75±5% RH)	Physical appearance	% Drug content	% Cumulative Drug release	Lag time
0 Day	No colour change	99.4±0.03	98.99±0.01	5
1 week	No colour change	99.4±0.11	98.99±0.03	5
2 week	No colour change	99.39±0.05	98.90±0.09	5
3 week	No colour change	98.97±0.06	98.89±0.04	5
4 week	No colour change	98.93±0.06	98.87±0.10	5

After getting all the physical parameter satisfactory for all the batches from F1 - F9 dissolution of these batches were tested. Dissolution study for coated tablet of satranidazole was carried out which give release 97.62 ± 0.05 - 98.99 ± 0.11 (%). For combination study of eudragit L100: eudragit S100 formulation batch F1 - F9, in conc. 1:9, 2:8, 3:7, 4:6, 5:5, 6:4, 7:3, 8:2, 9:1 were coated on core

tablet of satranidazole. The drug release study was done on coated batches and lag time of which were studied. From the combination study of eudragit L100: eudragit S100 of batch F6 (6:4) concentration shows satisfactory result. These formulations give 5 hrs of lag time to target tablet to the colon and also give release of drug upto 98.99 within 12 hrs.

CONCLUSION: From the results obtained of the executed experiments it can be conclude that, From the above IR Study and physical observation it can be concluded that there is no significant Drug-Excipient interaction. So we can conclude that drug and other excipients are compatible with each other. The prepared tablets were developed to a satisfactory level, in terms of hardness, thickness, weight variation, *In-vitro* disintegration, and content uniformity. It was shown that coating formulation consisted of Eudragit L100: Eudragit S100 in ratio of 6:4 at 10% coating level has potential for the required lag time of 5 h.

The release of drug from coated tablet was found to be proportional to the concentration of the polymer; where the % coating increases lag time increases. On the basis of *in vitro* release studies and effective lag time, F6 was selected as an optimized formulation for designing repturable coating device. *In-vitro* release study was shown after effective lag time. Accelerated stability studies, proved that the formulation is quite stable.

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