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Review

Formulation and Evaluation of Duloxetine Hydrochloride Enteric Coated Tablets

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Abstract

Objective of the current study is to develop colon targeted drug delivery systems for Duloxetine Hydrochloride. Sodium alginate and Carbopol 940 is used as polymers in this drug delivery system. The colon targeted tablet was prepared by direct compression technique. Study of the preformulation characteristics and FTIR studies indicates that there was no interaction between Duloxetine Hydrochloride and excipients used. The formulated tablets were tested for both pre-compression parameters and post compression parameters as per requirements of standards. Pre-compression parameters such as bulk density, tapped density, compressibility index, Hausner's ratio and compressibility index. The results obtained indicate that it has good flow property for direct compression. From among the entire batches, formulation F4 showed 98.81% drug release at 24 hrs. Since it provide greater protection to the core under acidic condition while at the same time show the fastest drug release under intestinal pH. So the trial F4 was considered as best formulation.

Keywords: Duloxetine Hydrochloride, Sodium alginate, Carbopol 940, and colon targeted drug delivery systems.

1. INTRODUCTION: [1-4]

Oral drug delivery has been known for decades as the most widely utilized route of administration among all the routes that have been explored for systemic delivery of drugs via pharmaceutical products of different dosage forms. Oral route is considered most natural, uncomplicated, convenient and safe due to its ease of administration, patient acceptance and cost effective manufacturing process. The reasons that the oral route achieved such popularity may be in part attributed to its ease of administration, belief that by oral administration of the drug iswell absorbed.

All the pharmaceutical products formulated for systemic delivery via the oral route of administration irrespective of the mode of delivery and the design of dosage forms must be developed within the intrinsic characteristics of GIT physiology, pharmacokinetics and pharmacodynamics and formulation design to achieve a systemic approach to the successful development of an oral pharmaceutical dosage form.

TABLETS: [5]

Tablets are solid dosage forms each containing a unit dose of one or more medicaments. They are intended for oral administration. Some tablets are swallowed whole or after being chewed, some are dissolved or dispersed in water before administration and some are retained in the mouth where the active ingredient is liberated. Because of their composition, method of manufacture or intended use, tablets present a variety of characteristics and consequently there are several categories of tablets.

Tablets are usually solid, the end surfaces of which are flat or convex and the edges of which may be bevelled. They may exist in other shapes like triangular, rectangular, etc also.They may have lines or break-marks and may bear a symbol or other markings. They are sufficiently hard to withstand handling without crumbling or breaking.

Advantages of Tablets: [6]

- They are unit dosage form and offer the greatest capabilities of all oral dosage form for the greatest dose precision and the least content variability.
- They are in general the easiest and cheapest to package and strip of all oral dosage forms.
- They may provide the greatest ease of swallowing with the least tendency for "hang-up" above the stomach, especially when coated, provided that tablet disintegration is not excessively rapid.
- They lend themselves to certain special release profile products, such as enteric or delayed release products.
- They are better suited to large-scale production than the other unit oral forms.
- They have the best-combined properties of chemical.
- Cost is low.
- Lighter and compact.
- Easy to swallowing with least tendency for hang-up.
- Sustained release product is possible by enteric coating.
- Objectionable odour and bitter taste can be masked by coating technique.
- Suitable for large scale production.
- Greatest chemical and microbial stability over all oral dosage form.
- Product identification is easy and rapid requiring no additional steps whenemploying an embossed and or monogrammed punch face.

Disadvantages of the tablets:

- Some drugs resist compression in to dense particles, owing to their amorphous nature or flocculent, low density character.
- Drugs with poor wetting, slow dissolution properties, intermediate to large dosages, optimum absorption high in the GIT or any combination of these features are very challenging for the formulators.
- Difficult to swallow in case of children and unconscious patients.
- Bitter tasted drugs, drugs with an objectionable odour or drugs that are sensitive to oxygen may require encapsulation or coating. In such cases, capsule may offer the best and lowest cost.

7. METHODOLOGY

IMPORTANT PARAMETERS EVALUATED DURING PREFORMULATION STUDIES:

1. Evaluation of API

The Evaluation of Duloxetine Hydrochloride was done according to IP. Following are some of the important parameters evaluated during Preformulation studies and results are tabulated in Table.

A. Description

It is the initial evaluation during Preformulation studies which assess the colour of the substance. This was only a descriptive test.

B. Determination of Duloxetine Hydrochloride Solubility

Determination of solubility of drug by visual observation. An excess quantity of Duloxetine Hydrochloride was taken separately and adds in 10 ml of different solutions. These solutions were shaken well for few minutes. Then the solubility was observed and observations are shown in the Table.

Determination of Duloxetine Hydrochloride Melting point

The melting point of Duloxetine Hydrochloride was determined by capillary tube method according to the USP. A sufficient quantity of Duloxetine Hydrochloride powder was introduced into the capillary tube to give a compact column of 4-6 mm in height. The tube was introduced in electrical melting point apparatus and the temperature was raised. The melting point was recorded, which is the temperature at which the last solid particle of Duloxetine Hydrochloride in the tube passed into liquid phase**.**

Analytical method development:

Dissolution media Preparation:

Preparation of 0.1N HCl - 8.5 ml of concentrated HCl was added to 1000 ml of purified water and the pH is 1.2.

Preparation of pH 7.4 phosphate buffer-

Dissolved 6.8g of potassium Dihydrogen phosphate in 1000 ml of purified water and adjusted the pH to 7.4 by using 0.1 N sodium hydroxide solutions.

a) Determination of absorption maxima:

A solution containing the concentration 10 µg/ mL drug was prepared in 0.1N HCL UV spectrum was taken using Double beam UV/VIS spectrophotometer. The solution was scanned in the range of 200 – 800 nm.

b) Reparation calibration curve:

10 mg Duloxetine Hydrochloride pure drug was dissolved in 10ml of methanol (stock solution1) from stock solution 1ml of solution was taken and made up with10ml of 0.1N HCL (100 µg/ml). From this 1ml was taken and made up with 10 ml of 0.1N HCL (10 µg/ml). The above solution was subsequently diluted with 0.1N HCL to obtain series of dilutions Containing 2, 4, 6, 8, 10 µg /ml of per ml of solution. The absorbance of the above dilutions was measured at 290 nm by using UV-Spectrophotometer taking 0.1N HCL as blank. Then a graph was plotted by taking Concentration on X-Axis and Absorbance on Y-Axis which gives a straight line Linearity of standard curve was assessed from the square of correlation coefficient (R^2) which determined by least-square linear regression analysis.

Table 7.3: FORMULATION CHART

S. No	INGREDIENTS	QUANTITY OF INGRIDIENTS (mg/tab)					
		F1	F2	F3	F4	F5	F6
1	Duloxetine Hydrochloride	30	30	30	30	30	30
2	Sodium alginate	100	200	300	-	-	-
3	Carbopol 940	-	-	-	100	200	300
4	Lactose	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
5	Talc	20	20	20	20	20	20
6	Magnesium stearate	25	25	25	25	25	25
Total weight (mg)		500	500	500	500	500	500

COATING FORMULA:

Composition of Ingredient for Enteric Coating

6 % coating has been given for all the formulations to protect the drug from acidic environment.

Table 7.4:

S. No	Ingredients	Quantity/450 Tablet (gm)
1	Eudragit FS 30 D	130
2	Triethyl citrate	1.875
3	Talc	20.12
4	Purified water	120

Preparation of Enteric Coating solution:

A required quantity of Eudragit FS 30 D was weighed accurately and stirred. Meanwhile Triethylcitrate was added to it, purified talc were triturated separately in a mortar. And added to the solution and stirred. Finally the volume was making up to required quantity with purified water**.** Filtered the above solution with #100 mesh.

RESULTS & DISCUSSION

The present study was carried out to formulate colon targeted matrix tablet of Duloxetine Hydrochloride using direct compression method. In this method, the powder blend was subjected to various evaluation studies such as bulk density, tapped density, compressibility index and Hausner's ratio and was compressed into tablets. The compressed tablets were evaluated such as thickness, hardness, friability, weight variation, assay, *in-vitro* dissolution studies, and accelerated stability studies. The tablets are coated using Enteric coating polymers (Eudragit FS 30 D) to target the release of pH 7.4.

EVALUATION OF DULOXETINE HYDROCHLORIDE (API)

Table 8.1: PHYSICAL CHARACTERISTICS OF API

S. No	Tests	Specification	Results
1	Colour	off-white to tan powder	off-white to tan powder
2	Solubility	Practically insoluble in water, freely solublein Acetonitrile and methanol.	Complies
3	Moisturecontent	NMT 0.2 w/w%	0.1% w/w

Discussion:

The colour, solubility and moisture content of the API were evaluated. It was found to be within the range of the monograph.

Formulation and evaluation of Duloxetine Hydrochloride tablets for colon drug delivery systems:

Analytical Method

Graphs of Duloxetine Hydrochloride were taken in 0.1N HCL and in pH 6.8 phosphate buffer at 290 nm and 290 nm respectively.

Table 8.2: Observations for graph of Duloxetine Hydrochloride in 0.1N HCL

Concentration (µg/ml)	Absorbance
0	0
5	0.118
10	0.247
15	0.355
20	0.454
25	0.572

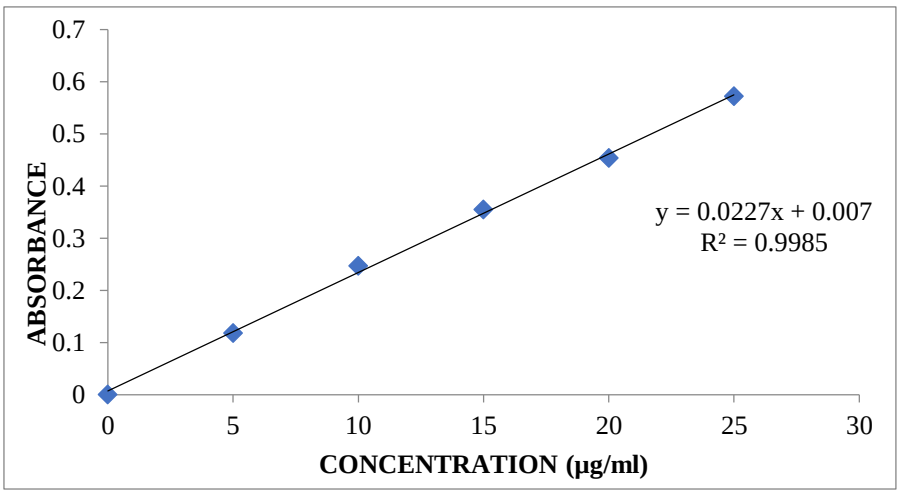

Figure 8.1: Standard curve of Duloxetine Hydrochloride

Table 8.4: Standard graph values of Duloxetine Hydrochloride at 290 nm in pH 7.4 phosphate buffer

Concentration (µg/ml)	Absorbance
0	0
5	0.139
10	0.247

15	0.365
20	0.468
25	0.572

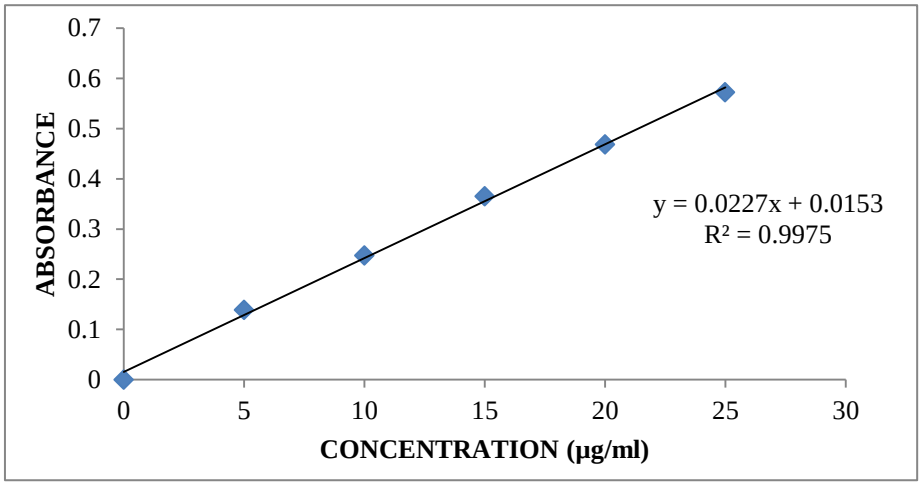

Figure 8.2: Standard curve of Duloxetine Hydrochloride

DRUG - EXCIPIENTS COMPATIBILITY STUDIES:

It was determined as per procedure given in material and method part

Table 8.5: DRUG - EXCIPIENTS COMPATIBILITY

Composition	Initial	After 15days At 25°C	After 30days At 25°C	Conclusion
Duloxetine Hydrochloride	off-white to tan powder	NCC	NCC	Complies
Duloxetine Hydrochloride + Excipients	off-white to tan powder	NCC	NCC	Complies

NCC- No Characteristic Change.

From the drug excipients compatibility study, it was observed that there was no characteristic change or interaction between drug and excipients. Thus it was concluded that the excipients selected for the formulation were compatible with Duloxetine Hydrochloride.

IR SPECTRAL ANALYSIS:

The FTIR studies of Duloxetine Hydrochloride and Duloxetine Hydrochloride with Excipients

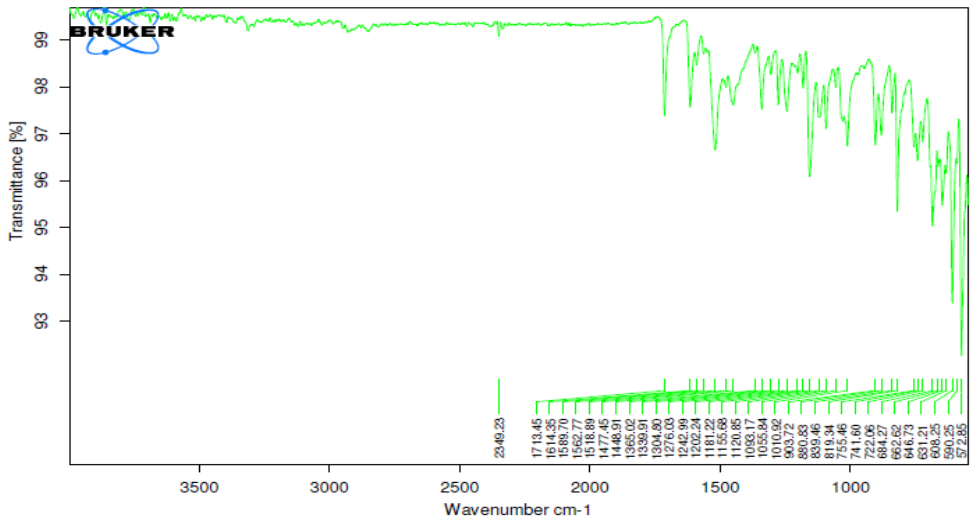

Figure 8.3: FT-TR Spectrum of Duloxetine Hydrochloride pure drug

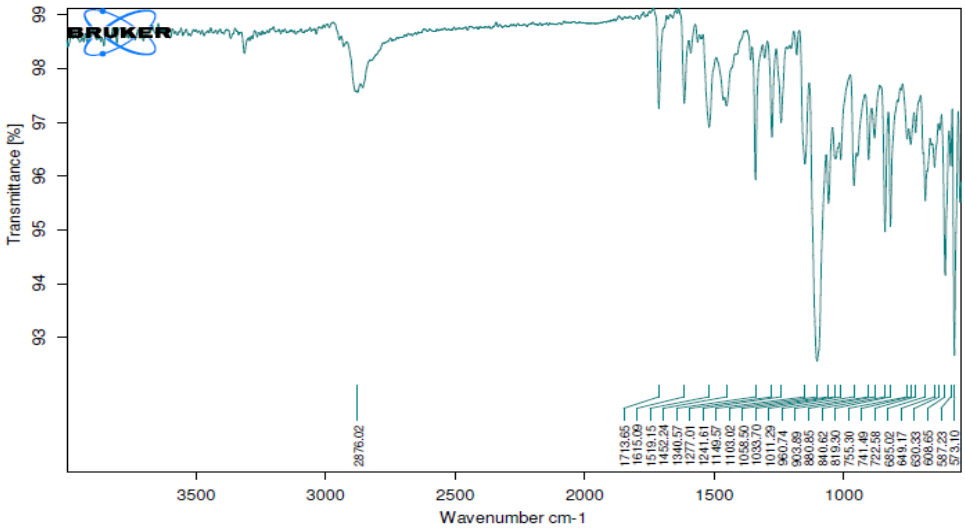

Figure 8.4: FT-IR Spectrum of Optimised Formulation

Pure Duloxetine Hydrochloride spectra showed sharp characteristic peaks. These peaks are also prominent in the FTIR spectra's of the physical mixtures containing Duloxetine Hydrochloride and other excipients in the final formula. This indicates that there is no interaction between the drug and excipients from both Physical observation and FT-IR studies.

Preformulation parameters of powder blend

Table 8.6: Pre-formulation parameters of Core blend

Formulation code	Angle of repose (Θ)	Bulk density (gm/cm^3)	Tapped density(gm/cm^3)	Carr's index (%)	Hausner's ratio
F1	22.6±2.5	0.56±0.08	0.68±0.11	13.2±1.12	1.17±0.17
F2	20.7±1.9	0.52±0.06	0.69±0.16	14.1±1.3	1.18±0.23
F3	20.8±1.8	0.51±0.03	0.67±0.13	14.2±1.24	1.25±0.19
F4	20.7±2.3	0.53±0.04	0.64±0.09	15.9±1.23	1.15±0.18
F5	20.8±1.7	0.50±0.02	0.67±0.17	15.1±1.24	1.23±0.22
F6	20.6±2.1	0.53±0.04	0.63±0.12	13.2±1.12	1.16±0.11

Tablet powder blend was subjected to various pre-formulation parameters. The angle of repose values indicates that the powder blend has good flow properties. The bulk density of all the formulations was found to be in the range showing that the powder has good flow properties. The tapped density of all the formulations powders has good flow properties. The compressibility index of all the formulations was found to be below 15.9 which show that the powder has good flow properties. All the formulations have shown the Hausner ratio below 1.25 indicating the powder has good flow properties.

Table 8.7 : EVALUATION OF FINISHED PRODUCT (UNCOATED)

Formulations	Parameters					
	Weight variation (mg)	Thickness (mm)	Hardness (kg/cm2)	Friability (%)	Disintegration time (min)	Assay (%)
F1	496.41	6.42	4.8	0.19	6.54	97.59
F2	498.62	6.50	4.9	0.28	8.21	99.35
F3	500.63	6.74	4.2	0.85	15.37	98.52
F4	499.95	6.90	4.6	0.64	4.42	95.29
F5	501.26	6.71	4.2	0.38	6.09	97.36
F6	400.19	6.82	4.9	0.75	10.72	99.56

The tablets are evaluated for different parameters are given in ***Table:***

- The thickness of the tablets was in the range of 6.42 to 6.90 mm. This is due to the upper and lower punch adjustments during compression process.
- The prepared tablets in all the trials possessed good mechanical strength with sufficient hardness in the range of 4.2 to 4.9 kg/cm^2.

- The friability of the tablets was found to be within 1%. All the above trail formulations have passed the friability test.
- The weight variation of all the formulations was found to be within the permissible range.
- The percentage of drug content was found among different batches of the tablets and ranged from 97.59 to 99.56 which were within the acceptable limits.

EVALUATION PARAMETERS OF DULOXETINE HYDROCHLORIDE ENTERIC COATED TABLETS

Table 8.8:

Formulation	Thickness (mm)	Weight variation(mg)	Disintegration time(min)	Assay (%)
F4	6.12 ± 0.01	599.05±0.42	212.52±1.50	99.82 ± 0.19

Duloxetine Hydrochloride tablet of the above trial (F4) was satisfied of all the parameters. It was coated by using enteric coating method. The coated tablets were evaluated for the following parameters including thickness, weight variation, and Disintegration assay and *in-vitro* studies.

COMPARATIVE DATAS OF UNCOATED AND ENTERIC COATED DULOXETINE HYDROCHLORIDE TABLETS

Table 8.9:

Formulation	Thickness (mm)	Weight variation (mg)	Assay (%)
F4 Un coated	6.81± 0.24	499.12	97.95±0.21
F4 Enteric coated	6.52 ± 0.01	596.43	99.01 ± 0.23

All values are expressed as mean ± standard deviation, n=3

Discussion:

Duloxetine Hydrochloride Enteric coated tablets were compared with the same trial of uncoated Duloxetine Hydrochloride tablets. The thickness of enteric coated tablets was found to be more than uncoated tablets. Weight variation was increased in enteric coated tablets than the uncoated tablets. This is due to the coating of core tablet.

Table 8.10: *In-Vitro* Dissolution profile of Enteric coated Tablets

TIME (H)	CUMULATIVE % OF DRUG RELEASE					
	F1	F2	F3	F4	F5	F6
In dissolution media 0.1 N HCL						
0	0	0	0	0	0	0
2	1.08	1.80	1.31	2.10	1.14	1.10
In dissolution media Simulated Intestinal Fluid (7.4pH Phosphate buffer)						
5	7.14	9.09	11.10	13.23	15.11	12.28
8	12.85	15.14	18.60	30.71	22.60	20.10
12	29.42	31.20	46.14	58.80	52.95	45.37
16	47.20	50.29	52.36	65.46	61.21	58.05
20	64.12	71.50	78.71	92.25	87.70	83.83
24	78.96	83.15	84.44	98.81	97.41	92.95

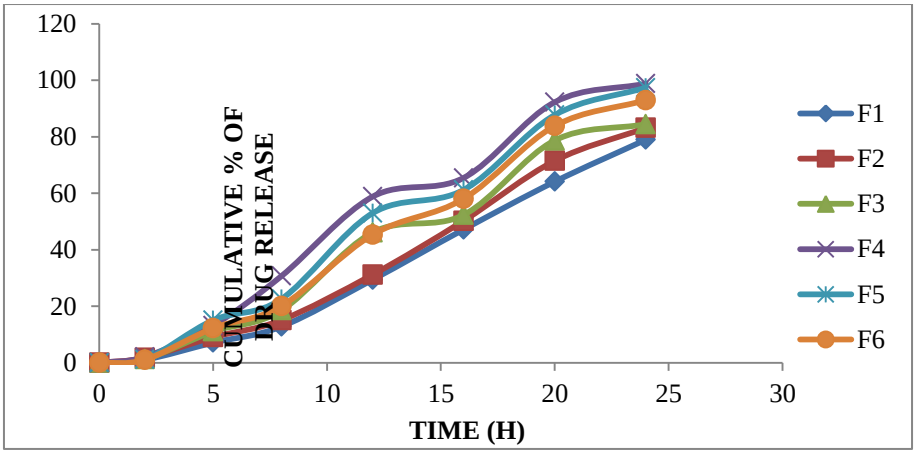

Figure 8.5: Graphical representation of *in-vitro* drug release

Discussion:

F1: The method used in this trial is direct compression. The concentration of Sodium alginate used was 100 mg/unit, and the concentration of Talc and magnesium stearate used. The hardness of the tablet were crossed the specification limit.

F2: Same as procedure of F1. But in this formulation the concentration of Sodium alginate and was increased to 200 mg/unit. The hardness of this formulation were better than the above formulation but the time required to disintegrate tablets were crossed the specification limit.

F3: The hardness was achieved. But the time required to disintegrate tablets were crossed the specification limit. In this formulation the concentration of Sodium alginate was increased to 300 mg/unit.

F4: In trial 4 the concentration of Carbopol 940was further decreased to 100mg/unit and the disintegration time of tablet was better than the above formulations limits. The tablets were subjected to *in-vitro* dissolution study. The tablets are subjected to *in-vitro* dissolution study. The percentages of drug release were found to be 98.81 at 24 hrs. It was better than the earlier trials.

F5: The concentration of Carbopol 940was further increased to 200mg/unit. The disintegration time of tablet was found to be within the limit. The tablets are subjected to *in-vitro* dissolution study. The percentages of drug release were found to be 97.41 at 24 hrs. It was better than the earlier trials.

F6: The concentration of Carbopol 940 was further increased to 300mg/unit. The tablets of this trial are subjected to *in-vitro* dissolution study. The percentage of drug release showed 92.95 at 24 hrs.

Hence from the above dissolution data it was concluded that F4 formulation was considered as optimised formulation because good drug release (98.81 %) in 24 hours.

Table 8.11: Release Kinetics:

CUMULATIVE (%) RELEASE Q	TIME (T)	ROOT (T)	LOG (%) RELEASE	LOG (T)	LOG (%) REMAIN	RELEASE RATE (CUMULATIVE % RELEASE/t)	1/CUM% RELEASE	PEPPAS log Q/100	% Drug Remaining	Q01/3	Qt1/3	Q01/3-Qt1/3
0	0	0			2.000				100	4.642	4.642	0.000
2.1	2	1.414	0.322	0.301	1.991	1.050	0.4762	-1.678	97.9	4.642	4.609	0.033
13.23	5	2.236	1.122	0.699	1.938	2.646	0.0756	-0.878	86.77	4.642	4.427	0.214
30.71	8	2.828	1.487	0.903	1.841	3.839	0.0326	-0.513	69.29	4.642	4.107	0.534
58.8	12	3.464	1.769	1.079	1.615	4.900	0.0170	-0.231	41.2	4.642	3.454	1.188
65.46	16	4.000	1.816	1.204	1.538	4.091	0.0153	-0.184	34.54	4.642	3.257	1.385
92.25	20	4.472	1.965	1.301	0.889	4.613	0.0108	-0.035	7.75	4.642	1.979	2.663
98.81	24	4.899	1.995	1.380	0.076	4.117	0.0101	-0.005	1.19	4.642	1.060	3.582

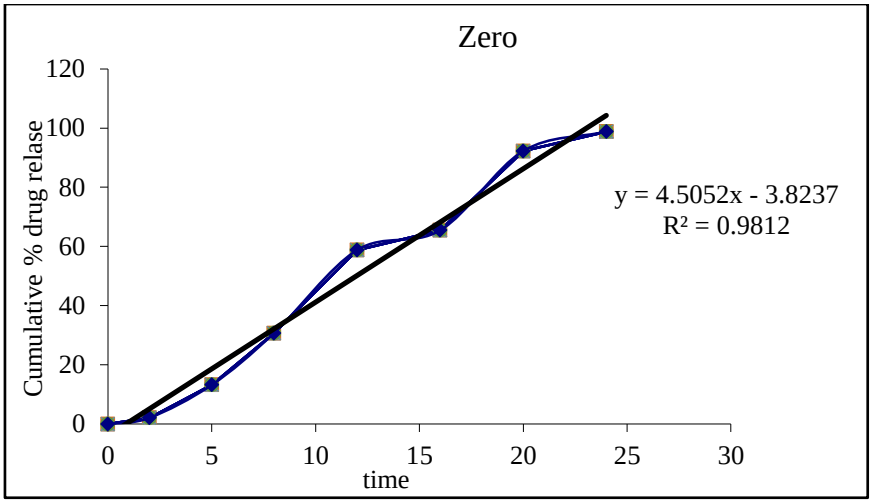

Figure 8.6: Zero order release kinetics graph

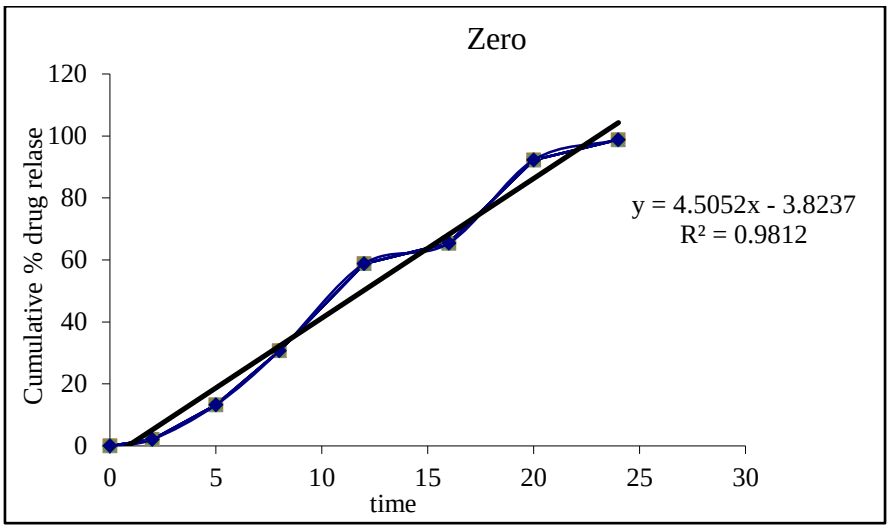

Figure 8.7: Higuchi release kinetics graph

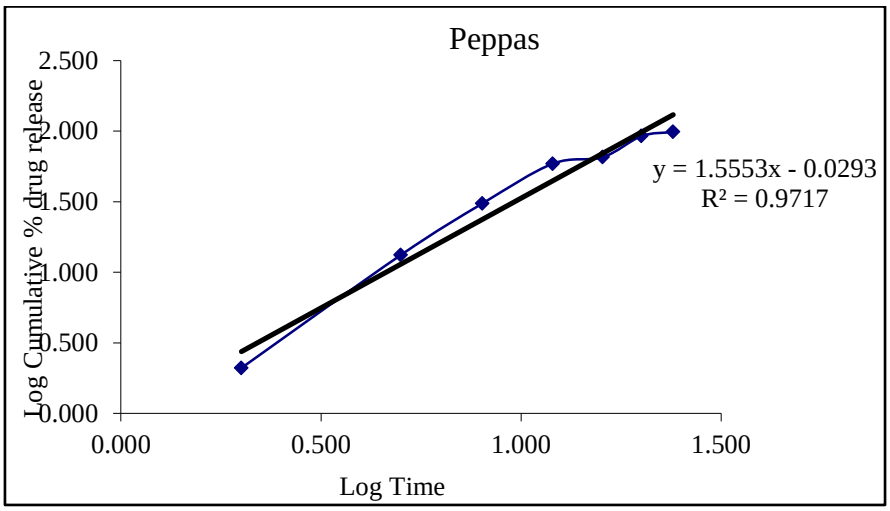

Figure 8.8: Peppas release kinetics graph

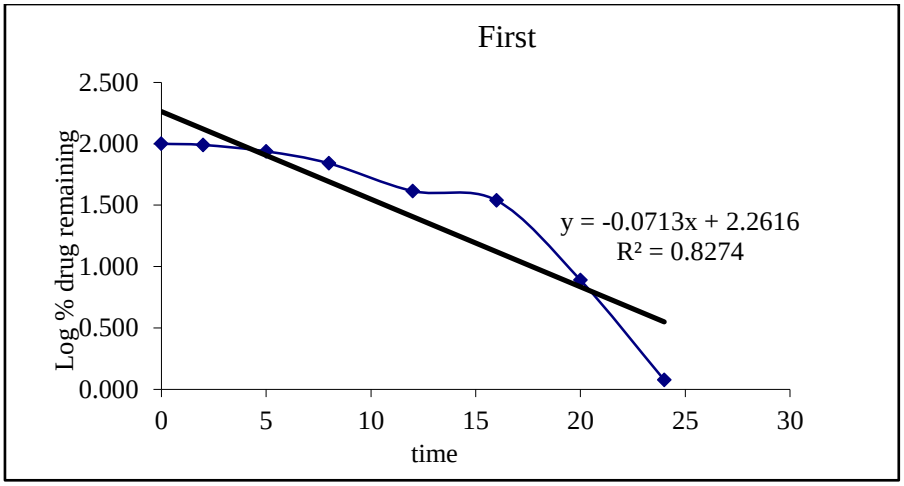

Figure 8.9: First order release kinetics graph

Optimised formulation F4 was kept for release kinetic studies. From the above graphs it was evident that the formulation F4 was followed **Zero order release** kinetics mechanism.

9. SUMMARY AND CONCLUSION

The present work involves the formulation of colon targeted matrix tablet of Duloxetine Hydrochloride by using direct compression method. Literatures regarding, Duloxetine Hydrochloride tablet dosage form preparation, excipients selection, manufacturing method, etc., has been collected and reviewed.

In this work, selection of excipients was done based on a literature review. Excipients include Sodium alginate, Carbopol 940, Lactose, Talc, Magnesium stearate. Quantities of the excipients were selected by performing FT-IR method.

Preformulation studies have also been performed to study the nature of API and compatibility of API with excipients by physical observation and FT-IR studies. The result showed that API was compatible with all the excipients selected.

The tablets were formulated by direct compression method using the selected excipient quantities. The formulated tablets were tested for both pre-compression parameters and post compression parameters as per requirements of standards. Pre-compression parameters such as bulk density, tapped density, compressibility index, Hausner's ratio and compressibility index. The results obtained indicate that it has good flow property for direct compression.

The formulated Duloxetine Hydrochloride matrix tablets were coated with enteric polymer Eudragit FS 30D by pan coating method. The prepared tablets were evaluated for weight variation, hardness, thickness, friability, drug content, and disintegration time and *in-vitro* dissolution studies. All these parameters were found to be within the standard limits.

Comparative studies of coated Duloxetine Hydrochloride tablets and uncoated Duloxetine Hydrochloride tablets are evaluated for the hardness, thickness and disintegration time.

Out of six formulations, the formulation F6 showed 92.95 % drug release at 24 hrs. Since it provide greater protection to the core under acidic condition while at the same time show the fastest drug release under intestinal pH. So the formulation F4 was considered as the optimized formulation.

CONCLUSION

Preformulation studies were performed to study the nature of Duloxetine Hydrochloride and compatibility of Duloxetine Hydrochloride with excipients by physical observation and FT-IR studies. The results showed that there was no interaction between Duloxetine Hydrochloride and all the excipients selected.

The Duloxetine Hydrochloride matrix tablets were successfully formulated by direct compression method using the selected excipient quantities. The formulated tablets were evaluated for both pre-compression and post-compression parameters as per requirements of standards. And the results were complied with the pharmacopoeia specification. The formulated Duloxetine Hydrochloride matrix tablets were coated with enteric polymer Eudragit FS 30D and Ethyl cellulose by pan coating method.

From among the entire batches, formulation F4 showed 98.81% drug release at 24 hrs. Since it provide greater protection to the core under acidic condition while at the same time show the fastest drug release under intestinal pH. So the trial F4 was considered as best formulation. From the results obtained, it can be concluded that formulation F4 containing enteric coated matrix tablet of Duloxetine Hydrochloride would be a promising

formulation to achieve the purpose which treat inflammatory bowel diseases (ulcerative colitis) without any gastric irritation.

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