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Design, Formulation and Evaluation of Metoclopramide Hydrochloride Mouth Dissolving Tablets

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KEYWORDS

Metoclopramide, super disintegrates, FTIR Studies, Direct compression technique, In- vitro drug release studies.

ABSTRACT:

The objective of the study was to formulate and evaluate Mouth Dissolving Tablets of Metoclopramide. Direct compression method was used to formulate mouth dissolving tablet of Metoclopramide by employing different super disintegrates and magnesium stearate (lubricant), Talc. These prepared formulations were then evaluated. Dissolution and drug content tests were performed using USP apparatus II and ultraviolet spectrophotometry, respectively. All formulations showed compliance with pharmacopeia standards. The effect of super disintegrates concentration and direct compression method on drug release profile was studied. Release profile of F16 were found to be satisfactory comparing to other formulations. F16 Formulation as processed excipient was found to be the best super disintegrates for the preparation of Metoclopramide mouth dissolving tablets formulations. Due to it has exhibited faster disintegration time and best dissolution profile when compared to other formulations.

1.

INTRODUCTION

Mouth-dissolving tablets (MDTs are solid dosage forms designed to disintegrate or dissolve rapidly in the oral cavity with minimal water, forming a swallow able suspension.1 MDTs improve patient compliance in populations with dysphagia offer ease of administration during travel or when water is

unavailable, and can provide faster onset for drugs that are intended to act quickly or be absorbed from the oral mucosa.2 Metoclopramide hydrochloride (MCP) is a widely used antiemetic and prokinetic agent prescribed for nausea and vomiting associated with chemotherapy, gastroesophageal reflux disease, and postoperative conditions.3 This study aims to design, prepare, and perform in-vitro evaluation of metoclopramide hydrochloride mouth-dissolving tablets.4 The study outcomes will identify formulations that provide rapid disintegration, acceptable mechanical properties, effective taste masking, and favourable early-time dissolution suitable for rapid therapeutic action.5

2.MATERIALS

Metoclopramide hydrochloride was procured from Yarrow chem. Products Mumbai. Croscaramellose and Sodium alginate was obtained from Sun Pharma Pvt.Ltd, Dewas. Other chemicals and the reagents used were of analytical grade.

METHODOLOGY

Drug excipient compatibility

Compatibility studies of Metoclopramide and the disintegrates were carried out by using Fourier Transform Infrared Spectroscopy (FTIR). Fourier transform infrared spectra of the samples were obtained in the range of 4000 to 450 cm-1 using a FTIR by the KBr disc method.6

Formulation table:

Table-1: Composition of Metoclopramide Mouth dissolving tablets

STD	RUN	Metoclopramide	Croscaramellose	SSG	DT	DC	% DR
17	1	15	7.5	7.5	35	79.69	90.22
4	2	20	10	5	38	80.22	81.25

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15	3	15	7.5	7.5	40	76.39	86.27
16	4	15	7.5	7.5	35	82.25	85.31
7	5	10	10	10	28	78.45	91.58
20	6	15	7.5	7.5	30	63.89	90.25
2	7	20	5	5	25	71.25	85.24
12	8	15	11.7045	7.5	32	75.21	86.98
11	9	15	3.29552	7.5	26	72.1	95.37
19	10	15	7.5	7.5	22	65.39	97.42
9	11	6.59104	7.5	7.5	30	62.25	93.19
3	12	10	10	5	26	74.81	87.86
13	13	15	7.5	3.29552	22	78.9	90.12
10	14	23.409	7.5	7.5	25	83.33	95.21
18	15	15	7.5	7.5	29	65.23	88.63
5	16	10	5	10	39	68.15	98.5
14	17	15	7.5	11.7045	26	82.1	95.1
1	18	10	5	5	23	80.12	89.37
8	19	20	10	10	27	85.22	90.25
6	20	20	5	10	22	79.33	92.35

Variables and Constrains in Box Behnken experimental design

Table-2: Variables and Constrains in Box Behnken experimental design

Independent Variables	**Level**			**Constrains**
	-1	**0**	**1**	
X_1 : mg of Metoclopramide	**10**	**15**	**20**	**In the range**
X_2 : mg of Croscaramellose	**5**	**7.5**	**10**	**In the range**
X_3 : mg of SSG	**5**	**7.5**	**10**	
Dependent Variables				
Y_1 : DT				
Y_2 : DC				
Y_3 : % DR				

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Procedure

Direct compression technique

Fast dissolving tablets of Metoclopramide were prepared by direct compression. All the ingredients were passed through 40-mesh separately. Then the ingredients were weighed and mixed in geometrical order and compressed into tablets of 300mg using 12 mm round flat punches on 10-station rotary tablet machine (Rimek). 7

Evaluation of tablet Weight variation

Twenty tablets were randomly selected form each batch and individually weighed. The average weight and standard deviation of 20 tablets was calculated. The batch passes the test for weight variation test if not more than two of the individual tablet weight deviates from the average weight by more than the percentage.8

Thickness

Twenty tablets were randomly selected form each batch and there thickness was measured by using vernier caliper. Thickness of three tablets from each batch was measured and mean was calculated.9

Hardness

Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablets was determined using Pfizer hardness tester. It is expressed in kg/cm2. Three tablets were randomly picked and hardness of the tablets were determined.10

Friability

Friability test is performed to assess the effect of friction and shocks, which may often cause tablet to chip, cap or break. Roche friabilator was used for the purpose. This device subjects a number of tablets to the combined effect of abrasion and shock by utilizing a plastic chamber that revolves at 25 rpm dropping the tablets at distance of 6 inches with each revolution. Twenty tablets were weighed and placed in the Roche friabilator, which was then operated for 25 rpm for 4 min. After revolution Tablets were dedusted and reweighed. Compressed tablets should not lose more than 1% of their weight.11

The percentage friability was measured using the formula,

$\% F = \{1-(Wo/W)\} \times 100$

Where,

% F = friability in percentage Wo = Initial weight of tablet

W = weight of tablets after revolution

Content Uniformity

Powder equivalent of Metoclopramide was dissolved in phosphate buffer pH 6.8. Sufficient dilutions were made to obtain 10 mcg/ml solution. Absorbance of the resulting solution was measured using a T60 model UV/VIS spectrophotometer. From the absorbance values, amount of drug present in the given tablet was calculated. Procedure was repeated by using four more tablets from the same formulation and the average value of all five tablets was calculated.12

Wetting time

A piece of tissue paper folded twice was placed in a small Petri dish containing ten milliliters of distilled water and water-soluble die. A tablet was placed on the paper and the time required for complete tablet wetting was measured. Complete wetting can be taken as the time at which colored water covered the entire tablet.13

In vitro disintegration time

Tablet disintegration experiment was carried out using tablet disintegration test apparatus on six tablets according to the pharmacopoeial guidelines for immediate release tablets. One tablet was placed in each of six tubes of the basket containing phosphate buffer (pH 6.8), maintained at 37 0C ± 1 0C. The tablet was considered disintegrated completely when all the particles passed through the screen. The disintegration time and standard deviation of 6 individual tablets were recorded.14

In- Vitro Release study

The release rate of Metoclopramide from mouth dissolving tablets was determined using dissolution testing apparatus II (paddle method). The dissolution test was performed using 900 ml of phosphate buffer pH 6.8 as a dissolution medium, at 37±0.5oC and 50 rpm. A sample (5 ml) of the solution was withdrawn from the dissolution apparatus at different time interval (minutes). The samples were filtered through a 0.45m membrane filter. Absorbance of these solutions was measured using a instrument T60 model UV/VIS spectrophotometer. Cumulative percentage of drug release was calculated using an equation obtained from a standard curve.15

Kinetics of drug release studies 16

The quantitative elucidation of the values obtained in the dissolution study is facilitated by the usage of a generic equation that mathematically translates the dissolution curve in function of some parameters related to the microspheres. For understanding the mechanism of drug release and release rate kinetics of the drug 45 from dosage form, the Invitro drug dissolution data of

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optimized formulations obtained was fitted to various mathematical models such as zero order, First order, Higuchi matrix and Korsmeyer-Peppas models.

Zero order kinetics

Drug dissolution from pharmaceutical dosage forms that do not disaggregate and release the drug slowly can be represented by the following equation:

Q0 - Qt = K0t

Arrangement of equation yields: Qt = Q0 + K0t Where Qt is the amount of drug dissolved in time t,

Q0 is the initial amount of drug in the solution (most times, Q0 = 0)

and K0 is the zero-order release constant expressed in units of concentration/time.

To study the release kinetics, data obtained from in vitro drug release studies were plotted as cumulative amount of drug released versus time.

First order Kinetics

The equation for first order release is given below Log Qt = log Q0+ K1t/2.303

Where Qt is the amount of drug released in time t, Q0 is the initial amount of drug in the solution and K1 is the first order release constant.

A graph of the decimal logarithm of the released amount of drug versus time will be linear. Microspheres following this dissolution profile release the drug in a way that is proportional to the amount of drug remaining in its interior, in such way, that the amount of drug released by unit of time diminishes.

Higuchi model

Higuchi described drug release as a diffusion process based on the Fick's law, square root time dependent. The simplified Higuchi equation is represented as

Qt=Kt ½

Where Qt = amount of drug released in time t, K = Higuchi's constant

A linear relationship between amount of drug released (Q0 versus square root of time (t½) is observed if the drug release from the microspheres is diffusion controlled.

Korsmeyer-Peppas model

This mathematical model, also known as the Power Law, has been used, very frequently; to describe the drug release from several different pharmaceutical modified release dosage forms. The Korsmeyer- Peppas model relates drug release exponentially to time. It is described by the following equation

Mt/M∞ =atn

Where 'a' is a constant incorporating structural and geometric characteristics of microspheres, 'n' is the release exponent, indicative of the drug release mechanism, and the function of 't' is Mt/ M∞ (fractional release of drug).

Stability studies

The success of an effective formulation can be evaluated only through stability studies. The prepared disintegration tablets of Metoclopramide were placed on plastic tubes containing desiccant and stored at ambient conditions, such as at room temperature, 40±2oc and refrigerator 2-8oc for a period of 90 days.17

3.RESULTS AND DISCUSSION

FT-IR Spectrum of Metoclopramide

All the formulations were uniform in drug content and the FTIR spectra of Metoclopramide and its mouth dissolving tablets are identical. The principle FTIR absorption peaks of Metoclopramide mouth dissolving tablets were observed and found to be identical with the spectra of Metoclopramide pure drug. Thus, from the spectra it was understood that there was no interaction between Metoclopramide and the disintegrates used in the preparation of tablets.

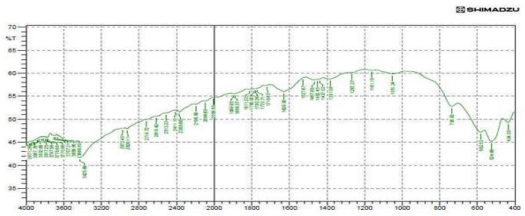

Fig-1: FT-IR Sample for Metoclopramide

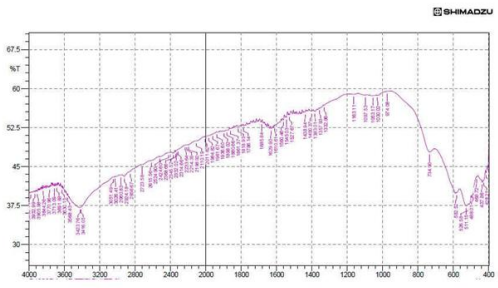

Fig-2: FT-IR Sample for physical mixture of drug and Excipients

Evaluation parameters Weight variation:

All the formulated (F1 to F20) tablets passed weight variation test as the % weight variation was within the

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pharmacopoeial limits of 7.5% of the weight. The weights of all the tablets were found to be uniform with low standard deviation values.

Thickness:

Tablets mean thickness were uniform in F1 to F20 formulations and were found to be in the range of

2.2 mm to 3.1 mm.

Hardness:

The measured hardness of tablets of each batch ranged between 2.2 to 3.9 kg/cm2. This ensures good handling characteristics of all formulations.

Friability:

Tablets were evaluated by using Roche friabilator and friability of tablets was observed in the range 0.42-0.46%

Content Uniformity:

The Metoclopramide mouth dissolving tablets were tested for drug content by UV method, the percentage drug content was found to be in between 62.25 to 85.22 %

Disintegration Time:

Tablets were evaluated for disintegration time in the disintegration apparatus. The disintegration time was found in the range 19- 39 sec.

Wetting Time:

Tablets were evaluated for wetting time test. The wetting time was found in the range 30– 60. sec.

Table-3: Evaluation parameters of Metoclopramide mouth dissolving tablets

F. No.	Weight variation (mg)*	Thickness (mm)*	Hardness (kg/cm^2) *	Friability (%)	Drug content (%)	Disintegration Time (sec)	Wetting time (sec)
F1	100	2.5	3.2	0.38	79.69	35	43
F2	100	2.4	3.8	0.51	80.22	38	58
F3	101	2.2	2.7	0.42	76.39	40	60
F4	100	2.9	3.1	0.32	82.25	35	37
F5	99	2.3	3.6	0.26	78.45	28	30
F6	100	2.7	2.2	0.37	63.89	30	36
F7	101	2.6	3.5	0.37	71.25	25	35
F8	99	2.4	3.4	0.38	75.21	32	46
F9	100	2.9	2.9	0.42	72.1	26	38
F10	100	3.1	2.8	0.49	65.39	22	30
F11	99	2.3	3.1	0.52	62.25	30	37
F12	100	2.9	2.5	0.5	74.81	26	35
F13	101	2.8	3.6	0.48	78.9	22	32
F14	100	2.2	3.7	0.56	83.33	25	35
F15	99	2.8	3.9	0.48	65.23	29	36
F16	100	2.2	3.2	0.54	68.15	19	29
F17	100	2.5	3.1	0.52	82.1	26	37
F18	99	2.9	3.5	0.53	80.12	30	42
F19	101	2.3	3.6	0.49	85.22	32	38
F20	100	2.7	3.3	0.42	79.33	39	45

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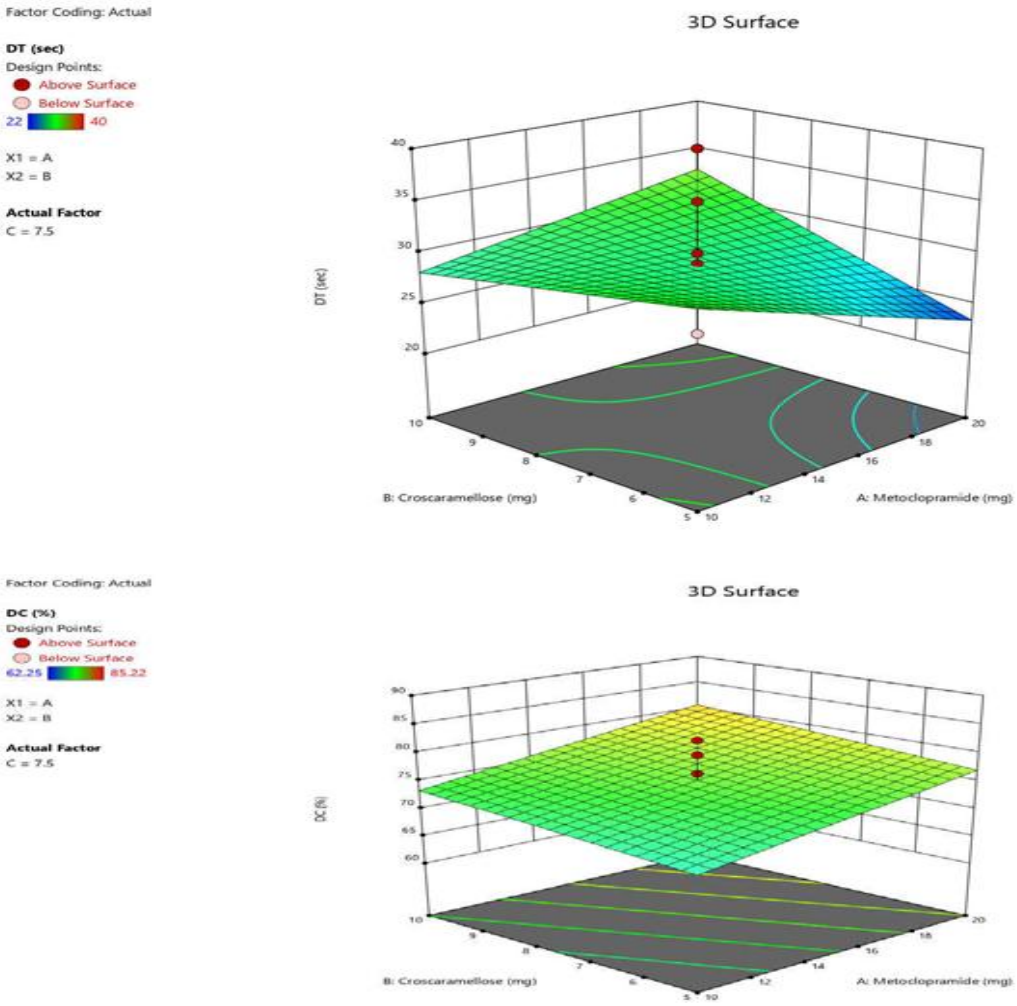

Fig-3: Effect on independent variables of Drug content and Disintegration time

Dissolution studies

All the 20 formulations of Metoclopramide mouth dissolving tablets were subjected to in vitro release studies these studies were carried out using dissolution apparatus. The dissolution medium consisted of 900 ml of Standard buffer pH 6.8 for period of time.

Table-4: Drug release studies of F1-F7 formulation

Time	F1	F2	F3	F4	F5	F6	F7
0	0	0	0	0	0	0	0
5	24.39	25.63	27.69	29.86	25.65	28.85	26.37
10	37.50	37.15	38.14	39.47	35.49	36.74	4025
15	52.36	58.49	55.43	58.42	60.22	58.90	50.25

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20	75	68.10	67.48	69.82	75.25	70.26	61.49
25	81.39	72.36	72.39	76.98	86.92	81.21	76.98
30	90.22	81.25	86.27	85.31	91.58	90.25	85.24

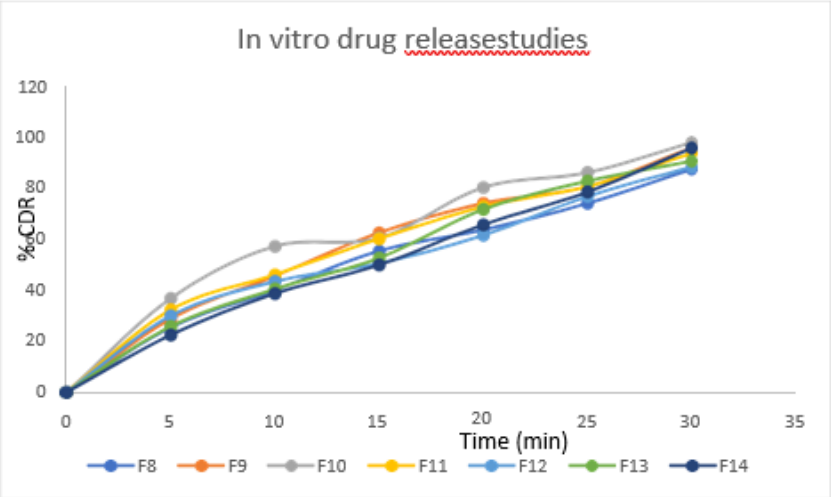

Fig-4: Drug release studies of F1-F7 formulation

Table-5: Drug release studies of F8-F14 formulation

Time	F8	F9	F10	F11	F12	F13	F14
0	0	0	0	0	0	0	0
5	25.25	28.60	36.58	32.16	29.82	25.69	22.36
10	39.80	45.36	56.93	45.87	43.18	40.25	38.49
15	55.10	62.22	60.15	59.86	50.25	52.39	49.68
20	63.37	73.69	79.86	72.39	61.25	71.29	65.37
25	73.69	80.25	85.69	80.25	76.39	82.36	78.10
30	86.98	95.37	97.42	93.19	87.86	90.12	95.21

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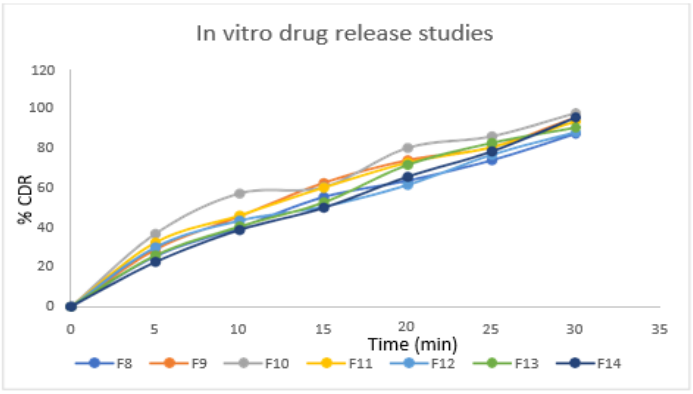

Fig-5: Drug release studies of F8-F14 formulation

Table-6: Drug release studies of F15-F20 formulation

Time	F15	F16	F17	F18	F19	F20
0	0	0	0	0	0	0
5	26.38	33.36	30.12	32.36	29.68	25.16
10	42.3	49.8	41.59	42.16	36.82	32.68
15	55.28	65.15	60.36	55.98	54.72	55.58
20	65.34	79.98	75.82	63.36	65.69	67.82
25	78.98	86.39	82.36	75.69	87.46	85.9
30	88.63	98.5	95.1	89.37	90.25	92.35

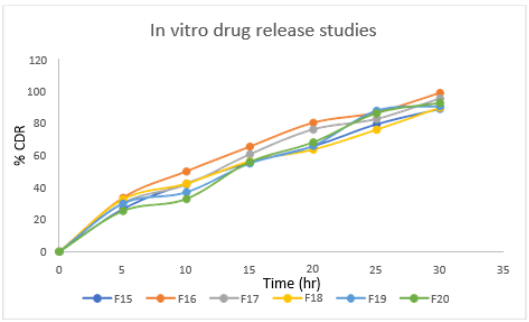

Fig-6: Dissolution Profile of F15 to F20 formulations

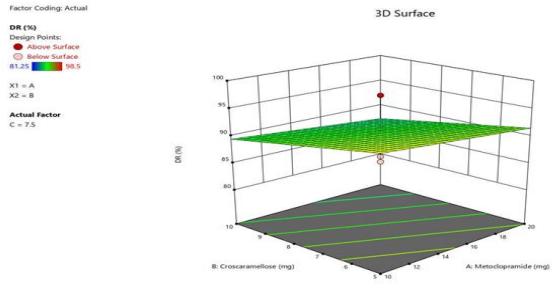

Fig-7: Effect on independent variables of Drug release studies

Kinetic modelling of drug release

All the 20 formulations of prepared mouth dissolving tablets were subjected to in vitro release studies these studies were carried out using dissolution apparatus.

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The results obtaining in vitro release studies were plotted in different model of data treatment as follows:

1. Cumulative percent drug released vs. time (zero order rate kinetics)

2. Log cumulative percent drug retained vs. time (First Order rate Kinetics)

3. Cumulative percent drug released vs. square root of time (Higuchi's

Classical Diffusion Equation)

4. Log of cumulative % release Vs log time (Pappas Exponential Equation)

Zero order kinetics

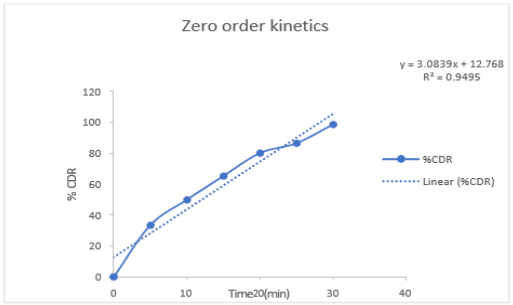

Fig-8: Zero order kinetics of optimized formulation

First order kinetics

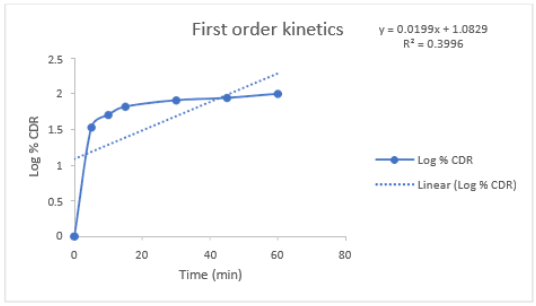

Fig-9: First order kinetics of optimized formulation

Higuchi model

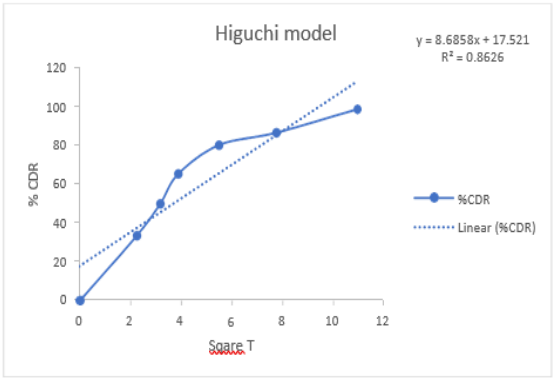

Fig-10: Higuchi model of optimized formulation

Korsmeyer Peppas

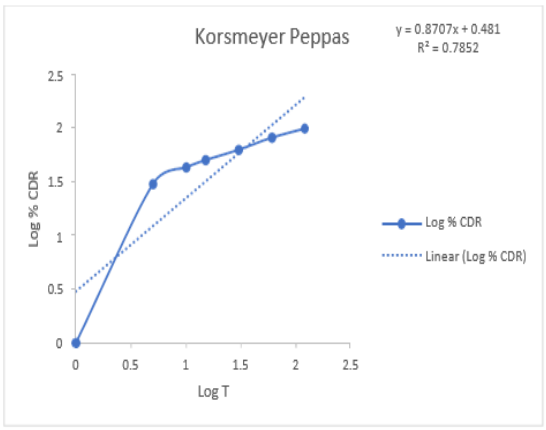

Fig-11: Korsmeyer peppas of optimized formulation

The kinetic values obtained for formulation F16 were shown. The values of in vitro release were attempted to fit into various mathematical models.

Regression values are higher with Zero order release kinetics. Therefore, all the Metoclopramide tablets Zero order release kinetics. Therefore, all the Metoclopramide tablets follow first order release kinetics.

Table-7: Regression equations of mouth dissolving tablets F16

F. code	In vitro release in phosphate buffer P^H 6.8 Regression values			
	Zero order	First order	Higuchi Plot	Korsmeyer peppas

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F16	0.949	0.399	0.862	0.785

The table indicates that r2 values are higher for Higuchi's model compared for all the tablets. Hence drug release from all the tablets followed diffusion rate-controlled mechanism.

Stability Study: There was no significant change in physical and chemical properties of the tablets of formulation F-16 after 3 months. Parameters quantified at various time intervals were shown.

Table-8: Stability studies of all formulations

Formulation Code	Parameters	Initial	1st Month	2nd Month	3rd Month	Limits as per Specifications
F-16	**25^0C/60%RH % Release**	98.50	97.69	96.39	95.82	**Not less than 85 %**
F-16	**30^0C/75% RH % Release**	98.50	97.62	96.52	95.37	**Not less than 85 %**
F-16	**40^0C/75% RH % Release**	98.50	97.06	96.37	95.28	**Not less than 85 %**

4.CONCLUSION

The study successfully demonstrated the feasibility of formulating Metoclopramide Hydrochloride Mouth Dissolving Tablets by direct compression technique using suitable superdisintegrants. The optimized formulation exhibited excellent physicochemical properties, rapid disintegration, and fast drug release, making it highly beneficial for patients with swallowing difficulties, pediatric and geriatric patients, as well as in emergency conditions requiring quick onset of action.

Thus, the developed MDTs of Metoclopramide Hydrochloride not only improve patient compliance but also enhance therapeutic efficacy by ensuring rapid onset of antiemetic action. This approach can serve as a valuable platform for the development of mouth dissolving dosage forms of other drugs with similar therapeutic needs.

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