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Research Article

Formulation and In -Vitro Evaluation of Metoclopramide Hydrochloride Chewable Tablets

Smitha B, Suresh V Kulkarni, K Manjunath, S.T. Bhagawati

Department of Pharmaceutics Sree Siddaganga College of Pharmacy, B H Road, Tumakuru-572102, Karnataka, India.

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Address for Correspondence: Smitha B
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Abstract:
The objective of the present research work was to develop a formulation of Metoclopramide HCl chewable tablets with efficacy and better palatability. Metoclopramide HCl belongs to the class of Anti-emetic which is used to treat nausea and vomiting. Metoclopramide HCl chewable tablets were prepared by the direct compression method. Chewable tablets were prepared and evaluated. The pre-formulation studies of FT-IR revealed that there was no significant interaction observed between the drug and excipients. Formulated chewable tablets were characterized for appearance, weight variation, hardness, friability, moisture content determination, drug content, in-vitro drug release studies and drug release kinetic studies. Formulation F3 released 98.167% drug at the end of 4th min better than other formulations and obeyed Korsmeyer peppa's drug release kinetics. Formulation F3 could be considered as best formulation based on drug release profile, physical texture and other properties. Metoclopramide HCl chewable tablets could be serve as promising drug delivery dosage form for geriatric and pediatric patients with improved palatability.
Keywords: Chewable, tablet, Metoclopramide HCl, Antiemetic.

Introduction

Chewable tablets are an oral dosage form intended to be chewed and then swallowed by the patient rather than swallowed whole. Chewable formulations are widely acceptable dosage form and its most suitable for paediatric and geriatric patients. This type of formulations is designed to be processed by chewing which facilitate the release of active pharmaceutical ingredient. Advantages of chewable formulations are ease of manufacturing, long term stability, dosing accuracy, portability, it also facilitates swallowing as the product is initially broken down into particles in the oral cavity, since water is not required for their administration of the formulation, it has the benefit of convenience when dosing mostly in the case of paediatric and geriatric.

Advantages of chewable tablets include the following, (i) improved patient acceptance due to the pleasant taste of the formulation (especially in pediatrics) (ii) they can be administered anytime and anyplace because it doesn't need water for swallowing and simple to handle (iii) possible to use as a substitute for

liquid indefinite quantity forms wherever fast onset of action is required and (iv) absorption of drug is quicker. However, there is need to consider the drawbacks of chewable tablets in their development such as (i) flavoring agents gift in a tender pill might cause ulceration in the mouth and (ii) chewable tablets are hygroscopic in nature needs to store in a dry place.

The materials which are used along with API in the particular formulation which mainly include excipients should be pure, safe, efficacious and stable for the suitable period of time. Sweetening agents which are mostly used in tablet formulation can also be applicable for the formulating of chewable formulation as the as such agents have the ability to provide some necessary properties of sweetness and chew-ability. Some commonly used sweeteners in the medicated formulations are Dextrose, Lactose, Sucrose (sugar), honey, mannitol, sorbitol, brown sugar, aspartame etc. These sweetening agents are categorized in two types natural and artificial sweeteners. In the evaluation of the chewable formulations, taste plays the important role in increasing the patient compliance and their acceptance towards the particular formulation. It's combination of Mouth –feel, sweetness and flavors. Sweetness, at an appropriate level, is a necessary background to any flavor. Different forms of flavoring agents are available such as emulsions, dry powders, oil bases, spray-dried beadlets, dry adsorbents and water- miscible solutions. Flavors can be characterized into different types i.e., sweet, sour, salty and bitter depending upon how our taste buds react it. However, different challenges come across while formulating paediatric formulation which includes taste masking, stability of the formulation i.e. physical stability, chemical stability, microbial growth, etc, achieving global regulatory acceptability, providing rapid patient access and accelerated development studies.

Chewable formulations are prepared in such a way that they can easily be crushed or smashed by chewing. They are usually formulated for patients who have difficulty in swallowing tablets. These classes of patients could also be adults with pathologically compromised throats or infants and youngsters who haven't learnt a way to properly swallow tablets with liquid. Chewable formulation can also be a way to mask the bitter taste of antiemetic which thereby helps in increasing the patient's compliance which is a forth coming challenge to formulate metoclopramide chewable tablet due to its bitter taste. [1-4] In the literature, it is observed that various formulations with some matrix bases and corrigents were examined for development of oral chewable tablets which suppressed the bitter taste of acetaminophen, often used as an antipyretic for infants.[5]

Metoclopramide hydrochloride has been approved by the FDA specifically to treat nausea and vomiting in patients with gastroesophageal reflux disease or diabetic gastroparesis by increasing gastric motility. It is also used to control nausea and vomiting in chemotherapy patients. It is a dopamine D2 antagonist but also acts as an agonist on serotonin 5-HT4 receptors and causes weak inhibition of 5-HT3 receptors in the chemoreceptor trigger zone (CTZ) which leads to decrease in the triggering for emesis. It has a higher bitter index with absolute oral bioavailability of 80 ± 15.5%, with half-life of about 6 hours where faster absorption of the drug is seen in mouth and stomach. Metoclopramide hydrochloride is available in the market under the different brand names like Reglan (tablets, injection), Maxolon (tablets, injection and syrup) and Gimoti (nasal spray) Metozolv ODT (orally disintegrating tablets).

Metoclopramide hydrochloride is available in different dosage forms in the market such as tablets, injections, syrup and oral disintegrating tablets, however, there are no chewable tablets of metoclopramide in the market and no research work is done till today on metoclopramide chewable tablets. In addition, metoclopramide possess a bitter taste, so it is challenging to convert it as successful taste

masking chewable tablets. Hence, in this study, we have selected metoclopramide drug to formulate into chewable tablet dosage forms.

Matierals and Methods.[6]

Metoclopramide hydrochloride, Maize starch, Sodium starch glycolate, Cross carmellose sodium, Cross-povidone, sodium starch glycolate, Lactose, Aspartame, Vanilla, Citric acid, magnesium stearate, Talc and Aerosil.

The Chewable tablet of Metoclopramide hydrochloride were prepared by Direct compression method.

Preparation of chewable tablets containing Metoclopramide hydrochloride

Chewable tablets containing 10 mg Metoclopramide hydrochloride with a total weight of tablet 300 mg by Direct compression method. All powder compounds were accurately weighed, passed through a standard sieve (sieve no 80) and thoroughly blended for 5 min. After being mixed powders were evaluated for bulk density and tapped density, compressibility index (Carr's index), Housner ratio and angle of repose. Chewable tablets were prepared by direct compression using rotary tablet compression machine of light yellowish tablets with an average mass of 300 mg were obtained. Completed composition of the tablets of nine batches.

Evaluation of chewable tablets containing Metoclopramide hydrochloride Pre-Compression Parameters:

Angle of Repose; In order to determine the flow property, the angle of repose was determined using the standard procedure. It is the maximum angle that can be obtained between the freestanding surface of the powder heap and the horizontal plane.

$$\theta = \tan^{-1}(h/r)$$

Determination of Bulk Density and Tapped Density ;A quantity of 5gm of the powder (W) from each formula was introduced into a 25 ml measuring cylinder. After the initial volume was observed, the cylinder was allowed to fall under its own weight onto a hard surface from the height of 2.5 cm at 2 sec intervals. The tapping was continued until no further change in volume was noted. The bulk density, and tapped density were calculated using the following formulae.

Bulk density = W / V_o Tapped density = W / Vf
Where, W = weight of the powder, Vo = Initial volume, Vf = Final volume
Compressibility Index (Carr's Index) It was identified using the formula
$C.I = 100 (V0 – Vf) / v$

Hauser's Ratio: It indicates the flow properties of the powder and is measured by the ratio of tapped density to the bulk density.

Hauser's Ratio = $(W / Vf) / (W / V0)$
Where, W / Vf= Tapped density, $W / V0$ =Bulk density

Post-Compression Parameters: [7]

Shape of Tablets: The Compressed tablets were examined under the magnifying lens for the shape of the tablet. Tablet Dimensions: Thickness and diameter were measured using a calibrated vernier caliper. Five tablets of each formulation were taken randomly and thickness was measured individually.

Hardness: Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablet was determined using Monsanto hardness tester. It is expressed in kg/cm^2 . Five tablets were randomly picked and hardness of the tablet was determined.

Friability Test: The friability of tablets was determined using Roche friabilator. It is expressed in percentage (%). Twenty tablets were initially weighed (w0 initial) and transferred into friabilator was operated at 25rpm for 4 mins or run up to 100 revolutions. The Tablets were weighed again (w). The friability was then calculated by

Friability = $100 (1-w/w0)$

Weight Variation Test: Twenty tablets were selected at random and the average weight was determined.

% Maximum positive deviation = (WH –A/ A) x 100
% Minimum negative deviation = (A-WL/ A) x 100

Where, WH = Highest weight in mg, WL=Lowest weight in mg, A= Average weight of tablet.

Drug Content Estimation: Five tablets were weighed individually and powdered. The powder equivalent to average weight of the tablet was weighed and drug was extracted in 0.1(N) HCl pH 1.2, the drug content was determined measuring the absorbance at 249 nm and 310 nm after suitable dilution using UV visible spectrophotometer.[47]

Disintegration Test: Disintegration test was carried out by using disintegration test apparatus. One tablet is placed in each tube, and the basket rack was positioned in a 1 ltr beaker of water, at 37°C ±2°C. A standard motor-driven device is used to move the basket. assembly containing the tablets up and down through a distance of 5 to 6 cm at a frequency of 28 to 32 cycles per mins. The time taken for the tablet to disintegrate completely wasnoted.

***In-Vitro* Drug Release Study:** In vitro drug release studies were performed to provide the amount of drug that is released at a definite time period. In these release studies for all formulations were carried out using tablet dissolution USP type II (paddle method). The dissolution media used was phosphate buffer, pH 6.8 maintained at 37±0.50C and rotated 50 rpm. Aliquots were withdrawn at different time intervals and the same volume of fresh medium was replaced to maintain sink conditions. The samples were analyzed against phosphate buffer pH 6.8 as blank at λ max 272.6 nm using UV spectrophotometer. [8]

Table No 1: Dissolution studies condition.

Apparatus	**USPII apparatus**
Dissolution medium	900ml of pH6.8 Phosphate buffer
Temperature	37 ± 0.5^0C
Rotating speed of thepaddle	50rpm
Sample time intervals	1,2,3,4,5,6,7,8,9and10minutes
Detection	UV-Visble spectrophotometer
Wavelength	272.6nm(λ_{max})
SamplingVolume	5 Ml

The graph of percentage cumulative drug release Vs Time plotted.

In-vitro drug release analysis:
In–vitro drug release dissolution data subjected to drug release kinetics studies.

➢ **Kinetic Analysis of In-Vitro Release Rates of Metoclopramide HCL :**
The results of in-vitro release profile obtained for all the formulations were plotted in modes of data treatment as follows:
1. Zero order kinetic model - Cumulative % drugs released versus T.
2. First order kinetic model - Log cumulative percent drug remaining versus T.
3. Higuchi" s model-Cumulative percent drug released versus square root of T.
4. Korsmeyer equation/ Peppa's model-Log cumulative percent drug released versus log T.

- **Zero order kinetics:**

Zero order release would be predicted by the following equation:
$At = A_o - K_o t$ ---------- (22)
Where, At- Drug release at Time t
A = Initial drug concentration
Ko = Zero-order rate constant (hr-1).
When the data is plotted as cumulative percent drug release versus T. if the plot is linear then the data obeys Zero-order release kinetics, with a slope equal to Ko

- **First Order Kinetics:**

First order release would be predicted by the following equation:

Log C= log Co-Kt/2.303----------(23)

Where,

C= Amount of drug remained at T't'.C_o = Initial amount of drug.

K=First order rate constant (hr^{-1}).

When the data is plotted as log cumulative percent drug remaining versus T

yields a straight line, indicating that the release follow first order kinetics. The constant 'K' can be obtained by multiplying 2.303 with the slope values.

- **Higuchi's model:**

Drug release from the matrix devices by diffusion has been described by following Higuchi's classical diffusion equation.

Q=[D/(2 A-Cs) Cst]1/2---------- (24)

Where. Q=Amount of drug released at T't'.

D = Diffusion coefficient of the drug in the matrix.

A Total amount of drug in unit volume of matrix. Cs the solubility of the drug in the matrix.

s =Porosity of the matrix.

t = Tortuosity.

T = T (hrs) at which 'q' amount of drug is released.

Above equation may be simplified if one assumes that D, Cs, and A, are constant. Then equation becomes:

Q=Ktl/2 .....(25)

When the data is plotted according to equation i.e., cumulative drug release versus square root of T yields a straight line, indicating that the drug was released by diffusion mechanism. The slope is equal to K (Higuchi's 1963).

- **Korsmeyer equation / Peppa's model:**

To study the mechanism of drug release from the BUD pulsin cap, the release data were also fitted to the well-known exponential equation (Korsmeyer equation/Peppa's law equation), which is often used to describe the drug release behaviour from polymeric systems.

Mt/Ma= Ktn (26)

Where, Mt/Ma the fraction of drug released at T't'.

K = Constant incorporating the structural and geometrical characteristics of the Drug/polymersystem.

N- Diffusion exponent related to the mechanism of the release.

Above equation can be simplified by applying log on both sides, and we get:

Log Mt / Ma= Log K+n Logt (27)

When the data is plotted as log of drug released versus log T, yields a straight line with a slope equal to 'n' and the 'K' can be obtained from y intercept. For Fickian release 'n' = 0.5 while for anomalous (non-Fickian) transport 'n' ranges between 0.5 and 1.0.

Table 2: **Formulation of Metoclopramide hydrochloride chewable tablet**

Weight in mg									
Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Metoclopramide Hcl	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**
Cross carmellose sodium	**10**	**20**	**30**	-----	-----	-----	------	------	------
Sodium starch glycolate	**-----**	------	-----	**10**	**20**	**30**	------	------	------
Cross povidone	**-----**	------	-----	-----	-----	-----	**10**	**20**	**30**
Maize starch	**63**	**63**	**63**	**63**	**63**	***63***	***63***	**63**	**63**
Aerosil	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**
Lactose	**190**	**180**	**170**	**190**	**180**	**170**	**190**	**180**	**170**
Aspartame	**3**	**3**	**3**	**3**	**3**	**3**	**3**	**3**	**3**
Vanilla flavour	**5**	**5**	**5**	**5**	**5**	**5**	**5**	**5**	**5**
Citric acid	**5**	**5**	**5**	**5**	**5**	**5**	**5**	**5**	**5**
Magnesium stearate	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**
Talc	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**
Total	**300**	**300**	**300**	**300**	**300**	**300**	**300**	**300**	**300**

Results and Discussion

Pre-compression parameters of Metoclopramide hydrochloride.

Table No. 3: Physical properties of drugs

Sl.No.	Physical property	Observation	Inference
1.	Color	Light yellowish	Complies
2.	Odour	Odorless	Complies
3.	Taste	Bitter	Complies
4.	Appearance	Amorphous powder	Complies

Melting point determination

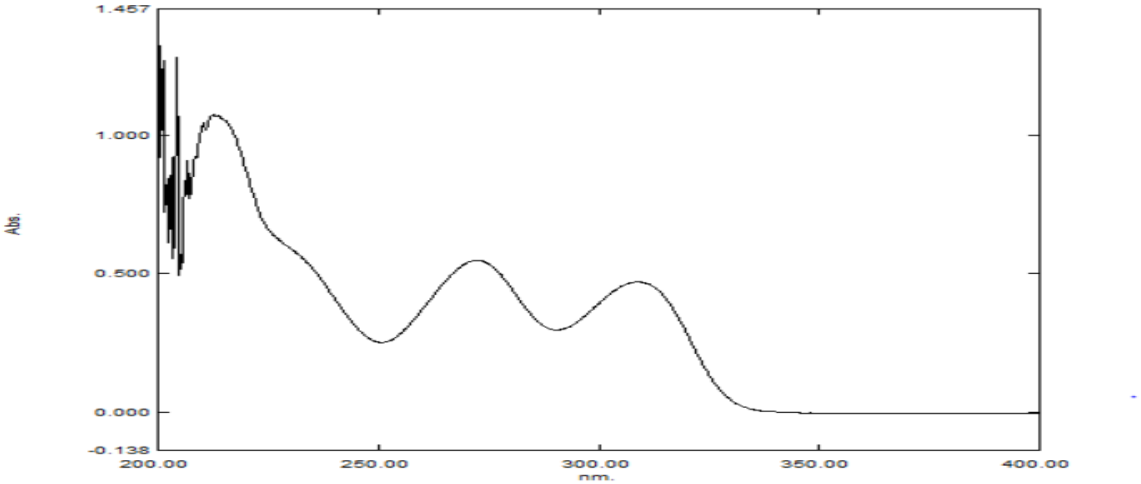
Melting point of Metoclopramide Hcl	183±1.100 C

Solubility studies

Solubility of Metoclopramide Hcl	In Acetone Soluble In methanol Partially Soluble In Hcl Soluble.

Determination of Absorption Maxima (Λ_{max}) of Metoclopramide Hcl by Uv-Visible Spectrophotometer

The λ_{max} of Metoclopramide Hcl in phosphate buffer pH 6.8 was found to be 272.6 nm as show in the figure below.



Standard Calibration Cure

Concentration µg/ml	Absorbance @272.6nm
4	0.150
8	0.306
12	0.464
16	0.630
20	0.789
24	0.964

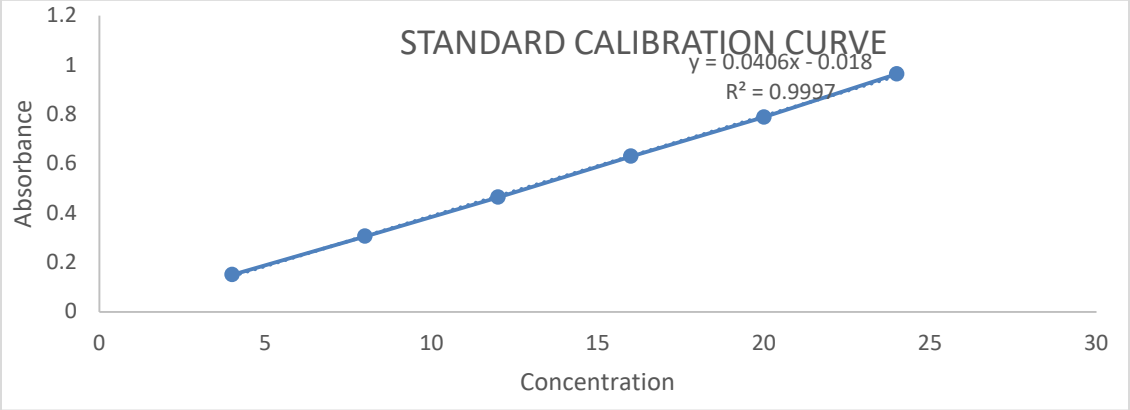


Figure No.1: Standard Calibration Curve of Metoclopramide Hcl

The standard calibration curve was constructed in the concentration range of 10-50µg/ml. The Beer's law was obeyed within the above concentation range.The regression equation obtained was y =coeiffient r^2= 0.0406x-0.018with r^2 value equal to 0.9997.

FTIR spectroscopy

The IR spectrum of the drug sample was recorded. Characteristic peaks (table No5.2)were observed and compared with the standard spectra in the I.P. All characteristic speaks were matching with standard spectra.

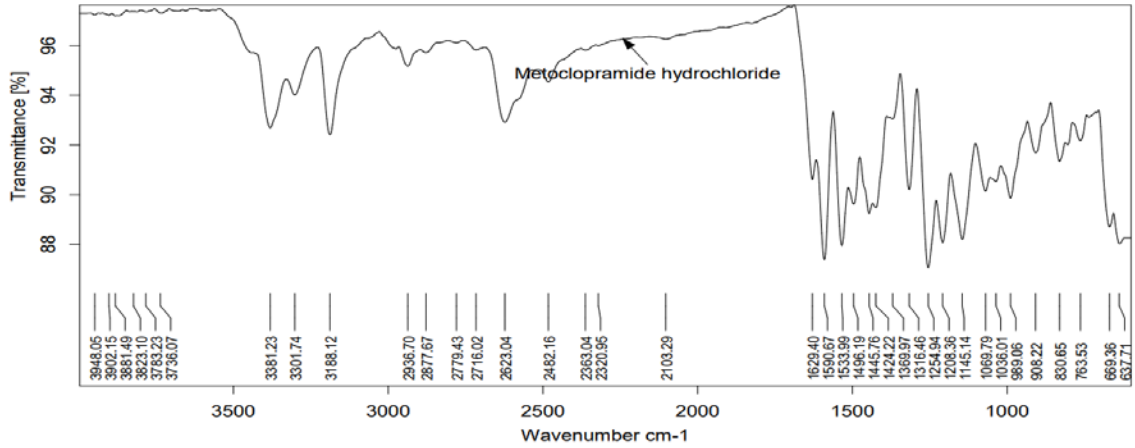


Figure No. 2: FTIR spectra of Metoclopramide Hcl

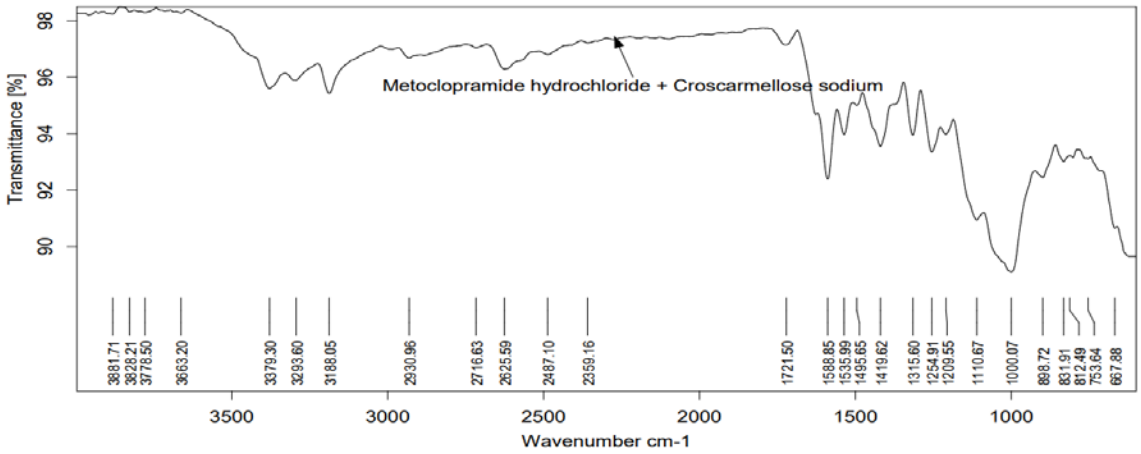


Figure No 3: FTIR spectra of Formulation (F3) i.e., Metoclopramide Hcl and croscarmellose sodium.

Table no.4: FTIR data

Sl no.	Name of the compound	range in cm^{-1} (literature value)	Peaks in cm^{-1} (obtained value)	Functional group
1	Metoclopramide Hcl	3500cm^{-1} (asymmetric) 3400 cm^{-1}(symmetric)	3500cm^{1}(asymmetric) 3400 cm^{-1}(symmetric)	N-H (stretching)
		1270-1230cm^{-1}	1269cm^{-1}	OCH3
		1650-1580 cm^{-1}	1596 cm^{-1}	N-H (bending)
		1220-1020 cm^{-1}	1215 cm^{-1}	C-N (stretching)
		1500 cm^{-1}	1501 cm^{-1}	C=C
2	Metoclopramide Hcl and croscarmellose sodium	3500 cm^{-1} (asymmetric) 3400 cm^{-1} (symmetric)	3500 cm^{-1} (asymmetric) 3400 cm^{-1} (symmetric)	N-H (stretching)
		1270-1230 cm^{-1}	1269 cm^{-1}	OCH3
		1650-1580 cm^{-1}	1596 cm^{-1}	N-H (bending)
		1220-1020 cm^{-1}	1215 cm^{-1}	C-N (stretching)
		1500 cm^{-1}	1501 cm^{-1}	C=C
		1050-1000 cm^{-1}	1008 cm^{-1}	Hydroxyl group

4. Evaluationoftheprepared Formulation

Formulation Code	Bulk density (gm/cm^3)	Tap density (gm/cm^3)	Carr's index (%)	Hausner's ratio	Angle of repose(θ)
F1	0.42±0.01	0.42±0.02	15.79±1.12	1.19±0.03	26.62±0.45
F2	0.44±0.02	0.44±0.05	8.33±0.66	1.09±0.02	27.13±0.56
F3	0.53±0.04	0.53±0.04	13.33±0.35	1.15±0.07	26.65±1.23
F4	0.44±0.05	0.44±0.03	8.33±0.56	1.09±0.04	25.50±0.46
F5	0.43±0.01	0.43±0.02	13.51±1.24	1.16±0.05	26.91±1.45
F6	0.42±0.03	0.42±0.01	13.16±0.25	1.15±0.03	27.37±0.64
F7	0.44±0.05	0.44±0.02	16.67±1.23	1.20±0.07	26.70±1.30
F8	0.50±0.02	0.50±0.04	12.50±0.55	1.14±0.05	26.55±0.24
F9	0.50±0.04	0.50±0.04	6.25±1.11	1.07±0.04	27.32±1.10

Table No. 5: Flow properties of powder of formulations F1-F9

Formulation Code	Diameter (mm)	Thickness (mm)	Hardness (kg/cm^2)	%Weight variation
F1	6.60±0.02	1.80±0.11	4.12±0.42	0.231±1.11
F2	7.00±0.05	1.80±0.21	3.91±0.14	0.342±1.04
F3	7.00±0.06	2.00±0.05	4.54±0.43	0.465±0.34
F4	6.80±0.04	1.60±0.05	4.43±0.16	0.453±1.53
F5	7.00±0.06	1.60±0.14	4.84±0.11	0.53±1.10
F6	6.80±0.05	1.60±0.04	4.27±0.28	0.347±0.26
F7	7.00±0.02	1.60±0.11	3.72±0.68	0.642±1.43
F8	7.00±0.05	1.60±0.24	4.3±0.34	0.224±1.37
F9	6.80±0.02	1.60±0.02	4.87±0.45	0.456±1.04

Diameter, thickness, hardness and %Weight variation of formulation F1-F9

Table No. 6: Diameter, thickness, hardness and %Weight variation of formulations F1-F9

Formulation Code	Disintegration time (in sec)	Drug content of Metoclopramide
F1	125±0.03	97.447±0.00
F2	108±0.01	96.170±0.004
F3	143±0.04	99.640±0.003
F4	90±0.03	97.872±0.006
F5	85±0.05	98.723±0.005
F6	110±0.03	98.979±0.002
F7	78±0.01	98.043±0.016
F8	74±0.04	96.213±0.004
F9	69±0.06	96.043±0.002

In-vitro drug release study

The percent cumulative drug release of the formulations F1 to F9 are shown inthe below table.

Formulation code	Time (min)	% CDR
F1	7	100.138
F2	6	95.1596
F3	4	98.1672
F4	9	100.58
F5	7	97.924
F6	4	96.438
F7	7	96.762
F8	6	94.445
F9	5	96.264

TableNo.7: Dissolution profile of formulation F1-F9

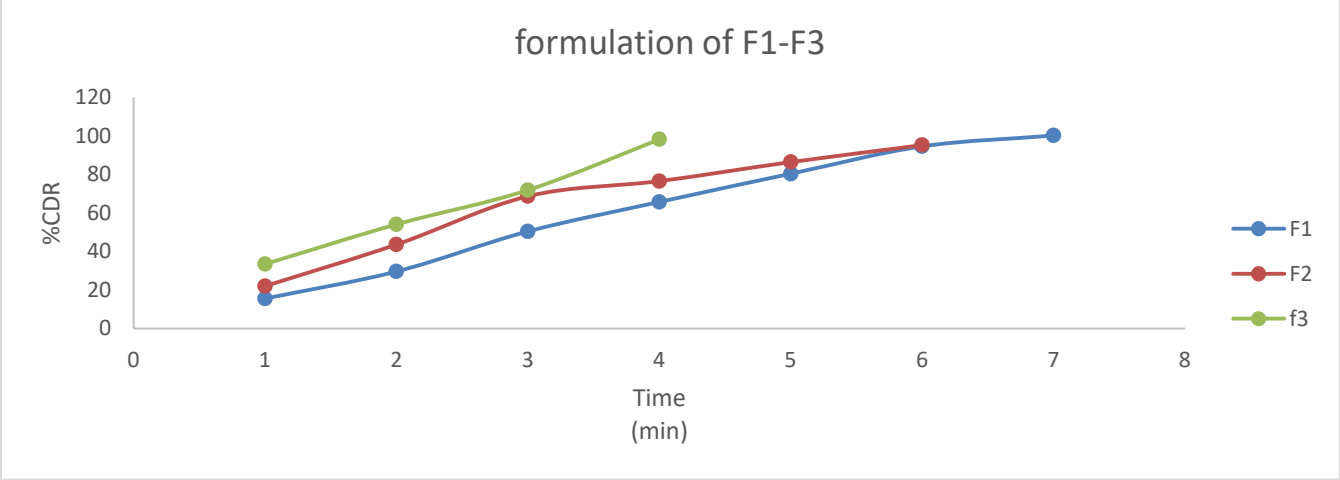


Figure No.4: Plot of %Cumulative Drug Release v/s Time(min) of F1-F3

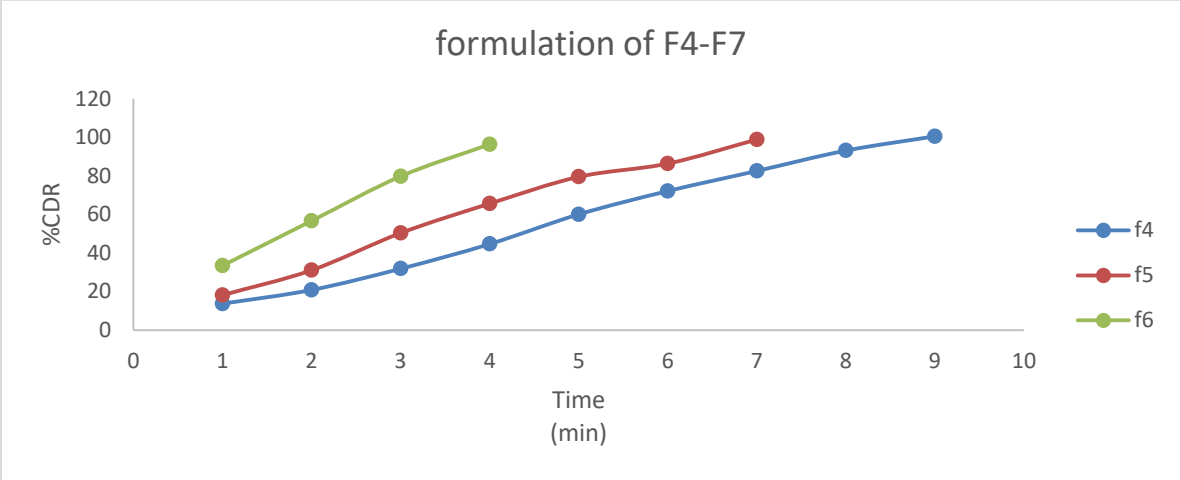


Figure No.5: Plot of %Cumulative Drug Release v/s Time(min)of F4-F7

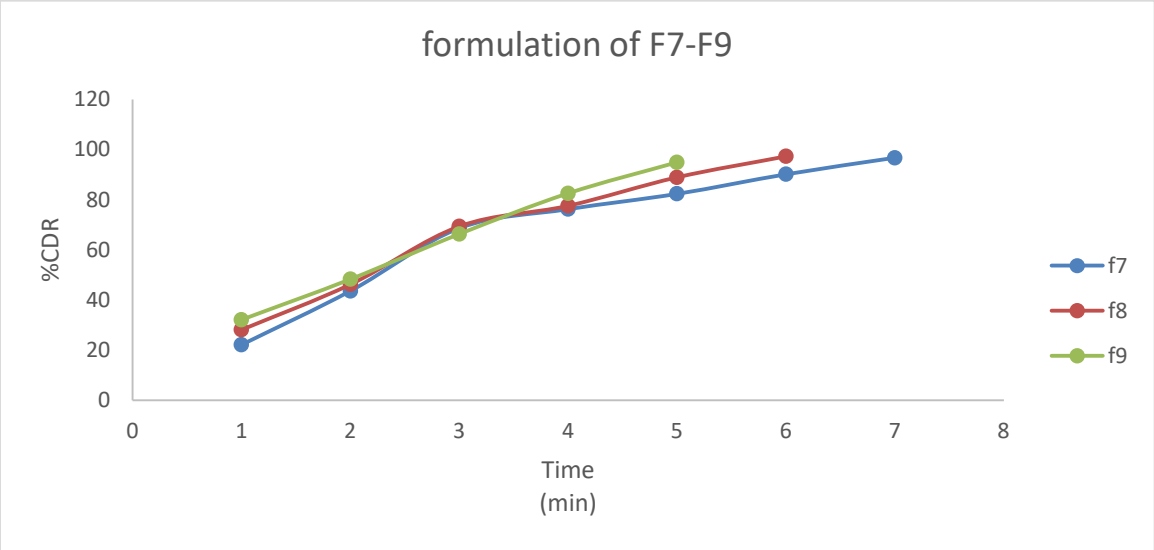


Figure No.6: Plot of %Cumulative Drug Release v/s Time (min) of F7-F9 Drug Release Kinetic:

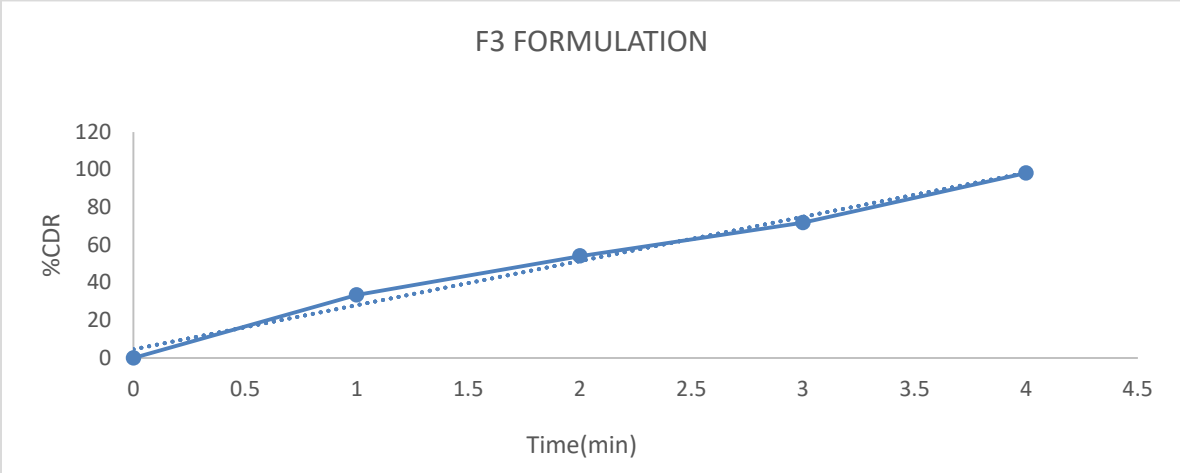


Figure No.7: Plot of Zero Order for Formulation F3

First Order Plot

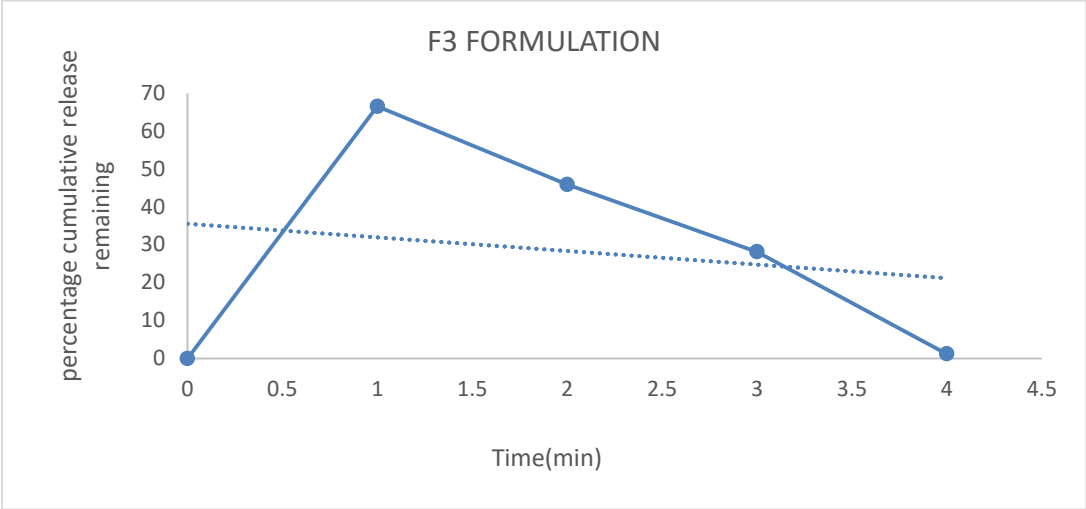


Figure No.8: Plot of First Order for Formulation F3

Higuchi's Plot

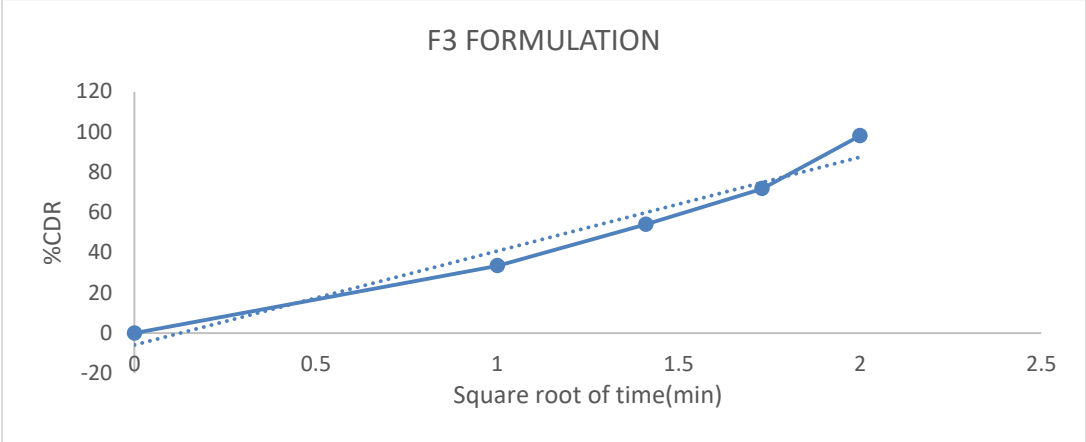


Figure No 9: Plot of Higuchi's for FormulationF3

Korsmeyer Equation/Peppa's Model

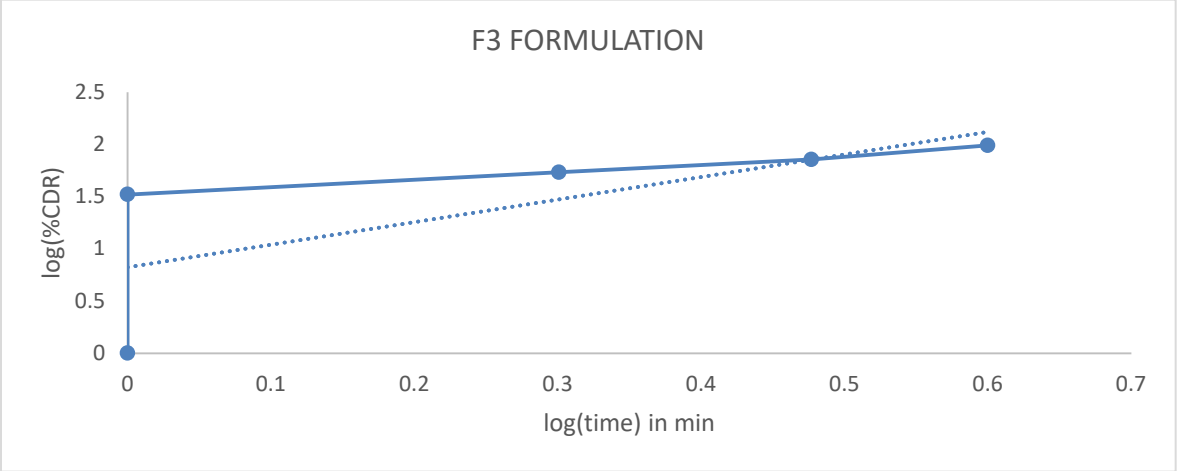


Figure No. 10: Plot of Peppa's model for FormulationF3

Table No 8: Statistical analysis data of medicated Metoclopramide Hydrochloride chewable tablets.

Formulation code	Zero Order	First Order	Higuchi Model	Korsmeyer Peppa's	
	R^2	R^2	R^2	R^2	n
F3	0.987	0.707	0.956	0.930	1.457

Stability studies

Table No 9: Stability studies

Characteristics	15 days	1 month
Physical appearance	Light yellowish smooth faced flat	Light yellowish smooth faced flat
Weight variation	0.465±0.34	0.485±0.35
Drug content	99.640±0.003	99.845±0.004
In-vitro release	98.1672	98.587

Conclusion

The present investigation was aimed to develop chewable tablets of Metoclopramide Hcl with a flavoring agent to mask the bitter taste of the drug for treatment of nausea and vomiting , for the pediatrics and geriatric patients who has difficulty in swallowing.

The preformulation studies of the Metoclopramide Hcl drug sample were carried out. The drug sample was characterized for its physiochemical properties such as appearance, melting point, solubility, absorption maxima and FTIR studies.

FTIR studies confirmed that there was no interaction between the drug and excipient (croscarmellose sodium), hence the selected excipient were found to be compatible with the drug.

Total nine different formulations of Metoclopramide Hcl loaded tablet were formulated in using different concentration and types of the excipients. The formulated Metoclopramide Hcl loaded chewable tablet exhibits the spherical shape in appearance. The weight variation test, hardness, friability and percent moisture content of the chewable tablets were within the standard limits. The drug content of the chewable tablets are within the limits.

The *in-vitro* dissolution studies of all the four formulation was carried out in the phosphate buffer pH 6.8 for the 10min. Formulation F3 containing compound croscarmellose sodium have better drug release at the end of 4 min i.e. 98.18% compared to the nine formulation.

From the statistical analysis data (i.e. R^2 value) of medicated Metoclopramide Hcl chewable tablet it is concluded that formulation F3 follows korsmeyer peppa's model followed by zero order kinetics.

Formulation F3 could be considered as the best formulation compare to other nine formulations.

stability studies were also conducted for optimized formulation there is no changes in their results , hence the tablet were in stable condition.

The successful attempt was made in formulate Metoclopramide Hcl loaded chewable tablets using different excipients. From the present studies it could be concluded that formulation F3 was the best formulation in terms of general appearance, weight variation, hardness, friability, disintegration time, moisture content determination, drug content and *in-vitro* drug release (98.18%) and drug release kinetic studies.

The Metoclopramide Hcl loaded chewable tablets formulation could be promising drug delivery dosage form which mask the bitter taste of Metoclopramide Hcl . Due to sweet in taste and palatability of the formulation, it may be accepted by pediatric as well as geriatric patients.

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