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FORMULATION AND EVALUATION OF MOUTH DISSOLVING TABLET OF METOCLOPRAMIDE

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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 disintegrants 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 F4 were found to be satisfactory comparing to other formulations. F4 Formulation as processed excipient was found to be the best super disintegrants 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.

Keywords: *Metoclopramide, super disintegrates, FTIR Studies, direct compression technique, in-vitro drug release studies.*

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INTRODUCTION:

Solid dosage forms also present significant administration challenges in other patient groups, such as children, mentally challenged, bed ridden and uncooperative patients. Pediatric patients may suffer from ingestion problems as a result of underdeveloped muscular and nervous control.[1] Moreover, patients traveling with little or no access to water, limit utility of orally administered conventional tablets or capsules.[2] Therefore, to cater the needs of such patients, recent advancements in technology have resulted in development of viable dosage alternatives popularly known as orally disintegrating tablets (MDTS)[3]. These dosage forms are preferable alternative for oral medication in improving Sthe quality of life and patient acceptability. MDTS are also known as oro dispersible tablets, mouth dissolving tablets, rapimelts, melt-in-mouth tablets, fast disintegrating tablets and rapid dissolving tablets.MDTS are the solid unit dosage forms/entities containing medicinal substances which disintegrate[4] or dissolve rapidly in oral cavity usually within a few seconds even without the need of water or chewing. As the tablet disintegrates in mouth, this can enhance the clinical effect of drug through pregastric absorption from the mouth, pharynx and esophagus[5]. In such cases, bioavailability of drug is significantly enhanced by avoiding first pass hepatic metabolism than those observed with conventional tablets. MDTS also combine the advantages of both liquid and conventional tablet formulations allowing the ease of swallowing in the form of liquid.[6]The advantages of these dosage forms are continuously and increasingly being identified in both pharmaceutical industries as well as in academia. The objective of present work is to highlight the development of MDTS, their significance, ideal characteristics, various techniques and aspects related to design and formulation, marketed preparations and future prospectives[7].The objective of present study is to design and develop a stable solid oral dosage form of Metoclopramide mouth dissolving tablets to deliver with optimum concentration of drug at desired site at specific time comparable to the innovator product with better stability, high production feasibility, and excellent patient compatibility.

MATERIALS AND METHODS:

Metoclopramide was collected as a gift sample from Hetero labs, Hyderabad and various excipients and polymers were purchased from Synpharma Research Labs, HYD.

METHODOLOGY:

Formulation Development

Table-1: Formulation table

S.No	Ingredient	F1	F2	F3	F4
1	Metoclopramide	10	10	10	10
2	Croscarmellose sodium	50	100	-	-
3	Sodium starch glycolate	-	-	50	100
4	Mannitol	210	160	210	160
5	Micro crystalline cellulose	20	20	20	20
6	Magnesium stearate	2	2	2	2
7	Talc	3	3	3	3
8	Aspartame	5	5	5	5
8	Total wt	300	300	300	300

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 800mg using 12 mm round flat punches on 10-station rotary tablet machine (Rimek).

Fourier transform infrared spectroscopy [8]:

Fourier transform IR spectra were obtained on Shimadzu FT-IR spectrometer. Samples were prepared in KBr disks (2mg sample in 200mg KBr). The scanning range was 450-4000 cm^{-1} and the resolution was 4 cm^{-1}.

Evaluation of tablet [9,10,11,12]

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 then two of the individual tablet weight deviate from the average weight by more than the percentage.

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.

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.

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 loose more than 1% of their weight.

The percentage friability was measured using the formula,

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

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.

Wetting time:

A piece of tissue paper folded twice was placed in a small petridish 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.

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 $^0C \pm 1\ ^0C$. 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.

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±0.5^oC 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.

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 2-8°c for a period of 90 days. [13]

RESULTS & 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.

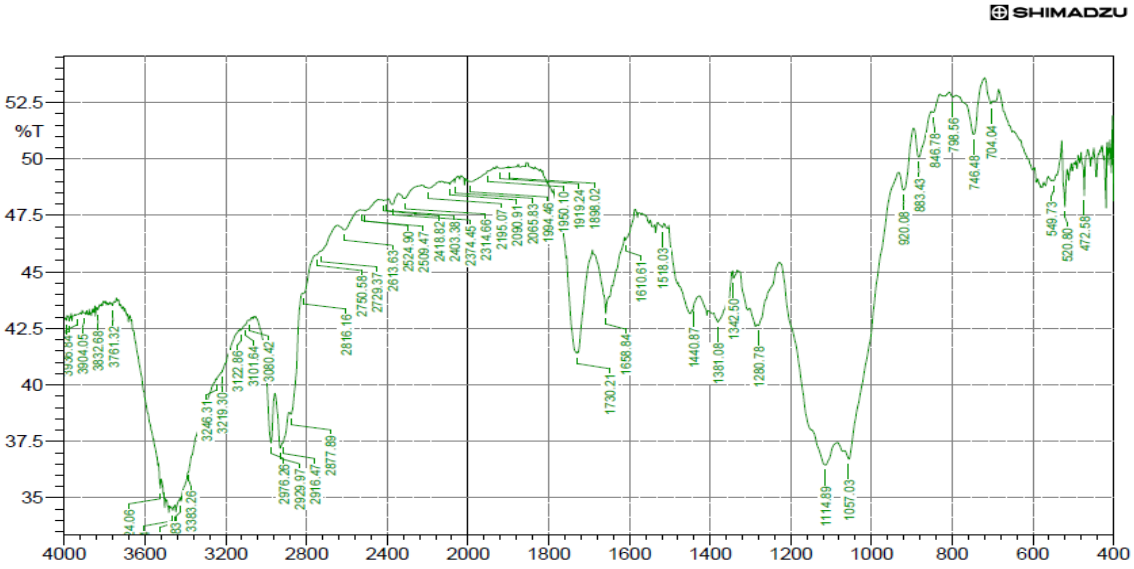

Fig-1: FT-IR Sample for Metoclopramide

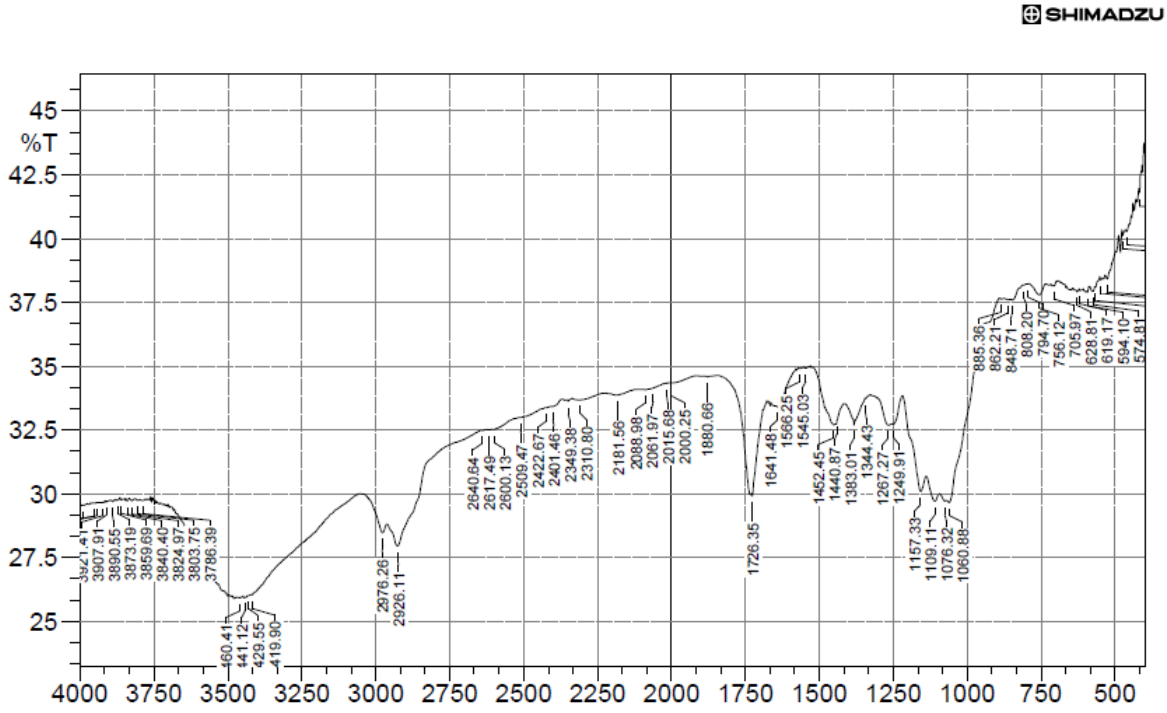

Fig-2: FT-IR Sample for physical mixture of drug and Excipients

Evaluation studies:

Pre compression parameters

a) **Bulk Density:** The Bulk density of various powder mixed blends prepared with different super disintegrants, was measured by graduated cylinder. The bulk density was found in the range 0.456 -0.472gr/ml.

b) **Tapped density:** The Tapped density of various powder mixed blends prepared with different super disintegrants, was measured by graduated cylinder. The Tapped density was found in the range 0.536-0.579 gr/ml.

c)Angle of repose: The angle of repose for the formulated blend was carried out. It concludes that all the formulations blend was found to be in the range of 26 to30^0

c) **Compressibility index:** The Compressibility index of various powder mixed blends, prepared with different super disintegrants, using bulk density and tapped density data, compressibility index was calculated. It was found in the range 25.60-30.19%.

d) **Hausner's ratio:** The Hausner's ratio of various powder mixed blends, prepared with different super disintegrants, using bulk density and tapped density data, Hausner's ratio was calculated. It was found in the range 1.34- 1.45.

The flow properties of powder blend in all formulations exhibit good flow and passable characteristics.

Characterization of Formulation:

Table-2: Pre compression parameters of Metoclopramide Mouth dissolving tablets

S. no	**Bulk density**	**Tapped density**	**Compressibility index**	**Hausner ratio**	Angle of repose(0)
F1	0.456	0.536	25.60	1.34	28^0c
F2	0.472	0.574	28.20	1.36	25^0c
F3	0.463	0.568	30.19	1.45	26^0c
F4	0.465	0.579	29.87	1.43	30^0c

Post compression parameter

Weight variation:

All the formulated (F1 to F4) tablets passed weight variation test as the % weight variation was within the 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 F4 formulations and were found to be in the range of 2.3 mm to 2.8 mm.

Hardness:

The measured hardness of tablets of each batch ranged between 4.2to 4.8 kg/cm^2. 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 tablets were tested for drug content by UV method, the percentage drug content was found to be in between 86.59 to 91.26 %

Disintegration Time:

Tablets were evaluated for disintegration time in the disintegration apparatus. The disintegration time was found in the range 10- 19 sec.

Wetting Time:

Tablets were evaluated for wetting time test. The wetting time was found in the range 105 – 134. 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	300	2.9	4.3	0.46	86.59	19	126
F2	299	2.6	4.1	0.53	88.96	17	134
F3	301	2.8	4.7	0.49	90.25	13	125
F4	300	3.1	4.6	0.50	91.26	10	105

Dissolution studies:

All the four formulation 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 all formulations

Time	F1	F2	F3	F4
0	0	0	0	0
5	25.19	27.39	28.10	29.86
10	38.13	37.15	38.14	39.47
15	55.56	58.49	57.43	58.42
20	67.19	68.10	67.48	69.82
25	81.39	82.15	80.25	83.25
30	95.50	94.36	96.38	97.82

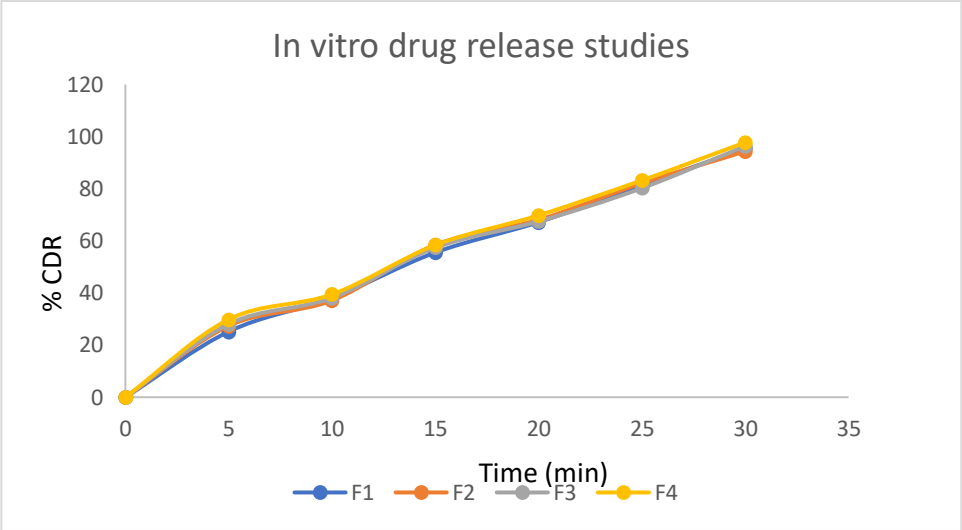

Table-3: Dissolution Profile of F1 to F4 formulations

Stability Study

There was no significant change in physical and chemical properties of the tablets of formulation F-4 after 3 months. Parameters quantified at various time intervals were shown.

Table-5: Stability studies of all formulations

Formulation Code	Parameters	Initial	1st Month	2nd Month	3rd Month	Limits as per Specifications
F-4	**25^{0}C/60%RH % Release**	97.82	96.37	95.48	94.69	**Not less than 85 %**
F-4	**30^{0}C/75% RH % Release**	97.82	96.50	95.28	94.35	**Not less than 85 %**
F-4	**40^{0}C/75% RH % Release**	97.82	96.43	95.32	94.02	**Not less than 85 %**

CONCLUSION:

The aim of the present study was to develop an optimized formula for Mouth dissolving tablet containing Metoclopramide After pre-formulation studies it was decided to prepare Mouth dissolving tablets prepared by direct compression method. In the formulation of sodium starch glycolate and croscaramellose sodium were used as super disintegrates.

Prior to compression the granules were evaluated for angle of repose, bulk density, tapped density, compressibility index, Hausner's ratio. The compressed tablets were also evaluated for weight variation, hardness, friability, drug content, disintegration time and invitro drug release. Mouth dissolving tablet is a promising approach with a view of obtaining rapid action of the drug and would be advantageous in comparison to currently available conventional dosage forms. The selection of an ideal batch of Mouth dissolving tablets was made after consideration of the evaluation parameters by dissolution study, disintegration time and wetting time. From the data obtained, it is observed from the formulation containing sodium starch glycolate in Formulation F4, shows Disintegration time in 10 seconds and the Percentage drug release is of 97.82 % at the end of 30 min which satisfied all the tablet evaluation parameters for Mouth dissolving tablet Hence looking at all the satisfactory parameters F4 formulation is selected as the optimized formulation.

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