International Journal of Pharmaceutical Research and Applications
Volume 9, Issue 5 Sep - Oct 2024, pp: 751-760 www.ijprajournal.com ISSN: 2456-4494

Formulation and Evaluation of Metoclopramide Orodispersible Tablet

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Date of Submission: 01-10-2024 Date of Acceptance: 10-10-2024

ABSTRACT: In the study all the formulation were subjected to physical parameters of tablets, like hardness, friability, weight variation, drug content of Metoclopramide hydrochloride. All the formulations resulted in acceptable limit except formulation MF3 and MF8 for hardness test marginally deviated. The final batch MF9 (contained Cross Carmellose Sodium 5.3%) can be considered as optimized batch as it has the disintegration time is minimum (26 sec) seems to be most promising formulation which gives the release up to **99.60**% in 3min. The drug-excipients interaction studies were carried out by FTIR. No significant interaction of drug with excipients was observed. The total weight of MF9 batch was 150 mg contained metoclopramide HCL-6.6%, croscarmellose sodium-5.3%, microcrystalline cellulose-33.3%, aspartame-4%, magnesium stearate-1%, talc-0.6%, aerosil-0.3%, pineapple flavor-0.6%, mannitol-48%. The Prefromulation study gives the following information of optimize batch Angle of Repose-$28^0.50^{''}$ Bulk density-0.520, Tapped density-0.627, Compressibility Index-16.08 good to flow, Hausner ratio-1.205. Post parameter evaluation of tablets Hardness-1.96, Friability-0.788, Thickness-2.590, Weight variation-150.11±, Dispersion time-29 sec, Water absorption ratio-61.65, Disintegration time-26 sec, Content uniformity-98.93%, In-vitro drug release studies- in 3 min. If the concentration of croscarmellose sodium is increases it gives quick the disintegration and dissolution was observed. So the results give information that Disintegration time in 26 sec and dissolution in 3 min. The optimized formulation of batch MF9 gave the best in-vitro release of 99.60% in3min in phosphate buffer pH 6.8. The release of drug followed matrix diffusion mechanism. Formulation MF9 gives the quick disintegration and better drug release. Hence it can be concluded that the formulation MF9 is a stable and effective for quick action and it is alternative to the conventional tablets.

KEYWORDS: Evaluation, Diffusion, Disintegration, Drug, Delivery.

I. INTRODUCTION:

Oral route of drug administration is the most common and preferred method of delivery as it is the simplest and easiest way of administering drugs. The rout offers ease of drugadministration in a convenient manner and patients are more familiar with this rout. So, patient compliance and thus drug treatment is typically more effective with orally given medications.[1]The tablet is most widely used dosage form existing today because of its convenience in term of self administration, compactness and ease in manufacturing. However, geriatric, paediatric and mentally ill patients experiences difficulty in swallowing conventional tablets, which is common among all age groups, especially in elderly which leads to poor patient compliance. To overcome these problem, scientists have developed innovative drug delivery system known as mouth dissolving or disintegrating tablets. This dosage forms dissolve and disintegrates in the oral cavity within minutes without need of water or chewing. This formulation is useful in administration of drug in paediatric and geriatric patients.[2]

The most popular solid dosage formsare being tablets and capsules, one important drawback of this dosage forms for some patients, is the difficulty to swallow. Drinking water plays an important role in the swallowing of oral dosage forms. Often times people experience inconvenience in swallowing conventional dosage forms such as tablet when water is not available, in the case of motion sickness (kinetosis) and sudden episodes of coughing during the common cold, allergic condition and bronchitis. For these reason, tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention. Orodispersible tablets are not only indicated for people who have swallowing difficulties, but also ideal for active people. Orodispersible tablets are also called as mouth-dissolving tablets, melt-in mouth tablets, fast dissolving tablets, rapimelts, porous tablets, quick

International Journal of Pharmaceutical Research and Applications
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dissolving etc. Orodispersible tablets are those when put on tongue, disintegrates instantaneously, releasing the drug, which dissolve or disperses in the saliva. The faster the drug into solution, quicker the absorption and onset of clinical effect. Some drugs are absorbed from the mouth, pharynx and oesophagus as thesaliva passes down into stomach. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablet dosage form. The advantages of mouth dissolving dosage forms are increasingly being recognized in both, industry and academics. Their growing importance was underlined recently when European pharmacopoeia adopted the term "Orodispersible tablet" as a tablet that to be placed in the mouth where it disperses rapidly before swallowing.[3] Orodispersible tablets are solid unit dosage forms like conventional tablets, but are composed of super disintegrants, which help them to dissolve the tablets within a minute in the mouth in the presence of saliva without any difficulty of swallowing. It offers several advantages with respect to its stability, administration without water, accurate dosing, easy manufacturing, small packaging size, and handling. Its ease of administration in the population especially for paediatric, geriatric, or any mentally retarded persons makes it a very popular dosage form. Due to the presence of superdisintegrants, it gets dissolved quickly, resulting in rapid absorption of drug which in turn provides rapid onset of action. Since the absorption taking place directly from the mouth, so, bioavailability of the drug increases. Drugs present in orodispersible tablets are also not suffering from first pass metabolism. This type of drug delivery is becoming popular day by day due to its numerous advantages.[4] The most important drug delivery route is undoubtedly the oral route. It offers advantages of convenience of administration and potential manufacturing cost savings. Today drug delivery companies are focusing on solid oral drug delivery systems that offer greater patient compliance and effective dosages. Over a decade, the demand for development of orally disintegrating tablets (ODTs) has enormously increased as it has significant impact on the patient compliance. Need to formulate orodispersible tablets. The need for non-invasive drug delivery systems continues due to patients poor acceptance and compliance with existing delivery regimes, limited market size for drug companies and drug uses coupled with high cost of disease management. ODT is one such dosage form which is useful for geriatric patients mainly suffering from conditions like hand tremors and dysphasia.

- Paediatric patients who are unable to swallow easily because their central nervous system and internal muscle are not developed completely.
- Travelling patients suffering from motion sickness and diarrhoea that do not haveeasy access to water.
- Especially for patients with persistent nausea for a long period of time are unable to swallow.
- Mentally challenged patients, bedridden patients, and psychiatric patients.
- Rapid onset of action and may offer an improved bioavailability.
- Improved patient compliance.
- Useful for paediatric, geriatric and psychiatric patients.
- Suitable during travelling where water may not be available.
- No specific packaging required, can be packaged in push through blisters.
- Smooth mouth feel and pleasant taste.
- Conventional manufacturing equipment.
- Cost effective.
- Good chemical stability as conventional oral solid dosage form.
- Convenience of administration and accurate dosing as compared to liquidformulations.
- More rapid drug absorption from the pre-gastric area i.e. mouth, pharynx and oesophagus which may produce rapid onset of action.
- Pre-gastric absorption can result in improved bioavailability, reduced dose and improved clinical performance by reducing side effects.
- Beneficial in case such as motion sickness, suede-episodes of allergic attack (or)coughing, where an ultra rapid onset of action required.
- Portable without fragility concern.

II. MATERIALS AND METHODS

MATERIALS: Metoclopramide, SSG, Crospovidone, CCS, MCC, Aspartame, Mannitol. All chemicals were formulation grade.

METHODS

Formulation of Metclopramide ODT

The superdisintegrants are incorporated in the formulation of ODTs like, Sodium starch glycolate, Crospovidone, Cross carmellose sodium. Before the tablet formulation the superdisintegrants was screened out and taken into formulation with

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other excipients for compression by direct compression method. The Metoclopramide hydrochloride tablets are available in 5mg and 10mg doses in the market. Dose of 10mg is selected for the present study.

Table 1: Formulation design of Metoclopramide HCL orodispersible tablets.

S. No.	Ingredients (mg)	MF1	MF2	MF3	MF4	MF5	MF6	MF7	MF8	MF9
1.	Metoclopramide HCL	10	10	10	10	10	10	10	10	10
2.	Sodium starch Glycolate	4	6	8	_	_	_	_	_	_
3.	Crospovidone	_	_	_	4	6	8	_	_	_
4.	Cross carmellose Sodium	_	_	_	_	_	_	4	6	8
5.	Microcrystalline Cellulose	50	50	50	50	50	50	50	50	50
6.	Aspartame	6	6	6	6	6	6	6	6	6
7.	Magnesium Stearate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
8.	Talc	1	1	1	1	1	1	1	1	1
9.	Aerosil	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
10	Pineapple flavour	1	1	1	1	1	1	1	1	1
11	Mannitol	76	74	72	76	74	72	76	74	72
	Total	150	150	150	150	150	150	150	150	150

III. RESULTS AND DISCUSSION

PREFORMULATION STUDIES

a. Melting Point :

The melting point of the metoclopramide HCL was found to be 184^0C, which complieswith given in the official reference.

b. UV Spectroscopic analysis:

The λ_{max} of pure Metoclopramide HCL was found to be 273 nm after scanning on the spectrophotometer, which complies with the reference spectra of metoclopramide HCL.

c. Solubility :

The Metoclopramide Hydrochloride was found to be freely soluble in water and alcohol.

Drug and Excipients Compatibility Study :

Fourier transformed infra-red (FTIR) spectra of Metoclopramide HCL and the physical mixture of drug with excipients was taken by using IR Spectrophotometer.

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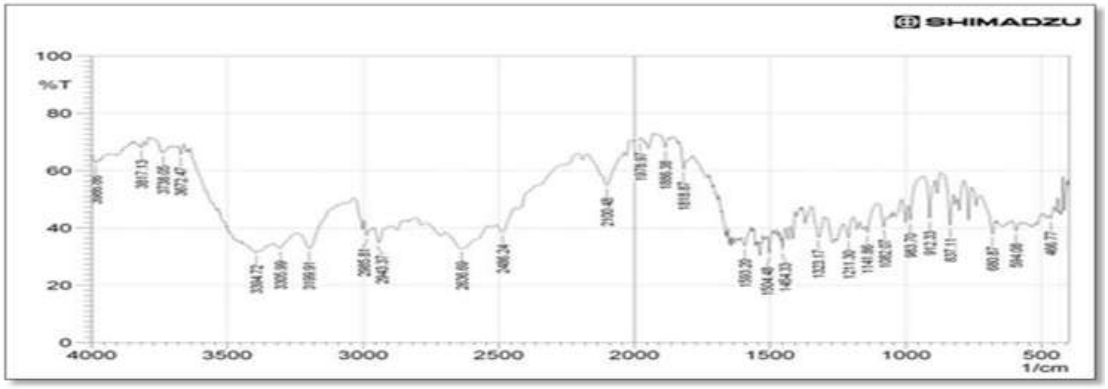

Fig. 1: FTIR Spectrum of Metoclopramide HCL

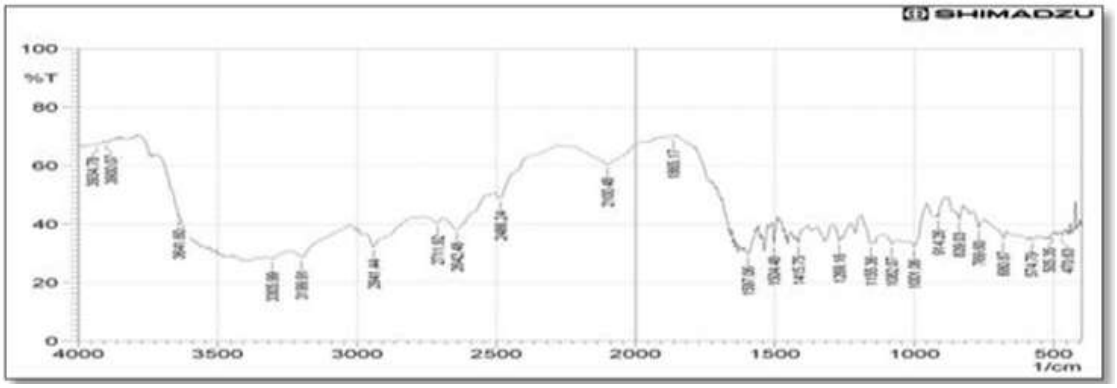

Fig. 2: FTIR Spectrum of Metoclopramide HCL with all excipients

These obtained results indicate that there was no positive evidence for the interaction between Metoclopramide HCL and super disintegrants or Metoclopramide HCL and excipients.

Standard Calibration Curve of Metoclopramide HCL :

Preparation of standard calibration curve in hydrochloric acid buffer pH 1.2:

The standard calibration curve of Metoclopramide HCL was prepared by using hydrochloric acid buffer pH 1.2 as solvent. The curve was found to be linear in the concentration range of 2-10 µg/ml at 273.0 nm. Thus the standard curve followed the Beer- Lamberts Law.

Table 2: Absorbance values for standard calibration curve of Metoclopramide HCLin hydrochloric acid buffer pH 1.2

S. No.	Concentration(µg/ml)	Absorbance
1	0	0
2	2	0.097
3	4	0.184
4	6	0.238
5	8	0.322
6	10	0.399

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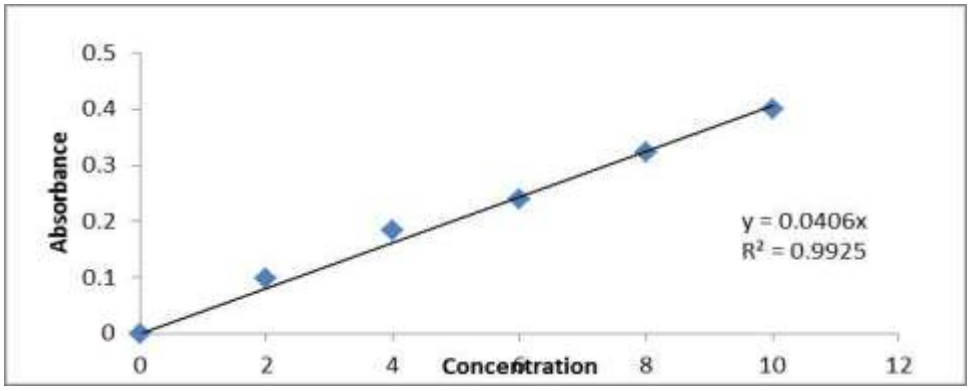

Fig. 3: standard calibration curve for Metoclopramide HCL at 273.0 nm. inHydrochloric acid buffer pH 1.2

Calibration curve of Metoclopramide HCL in phosphate buffer pH 6.8:

1) UV Spectra of drug in phosphate buffer pH 6.8:

50 µg/ml solution of Metoclopramide HCL was prepared in phosphate buffer pH 6.8 and was subjected to scanning under UV visible spectrophotometer, between the range 200- 400nm. The λ_{max} was found to be at 272 nm. (Fig. 8.8)

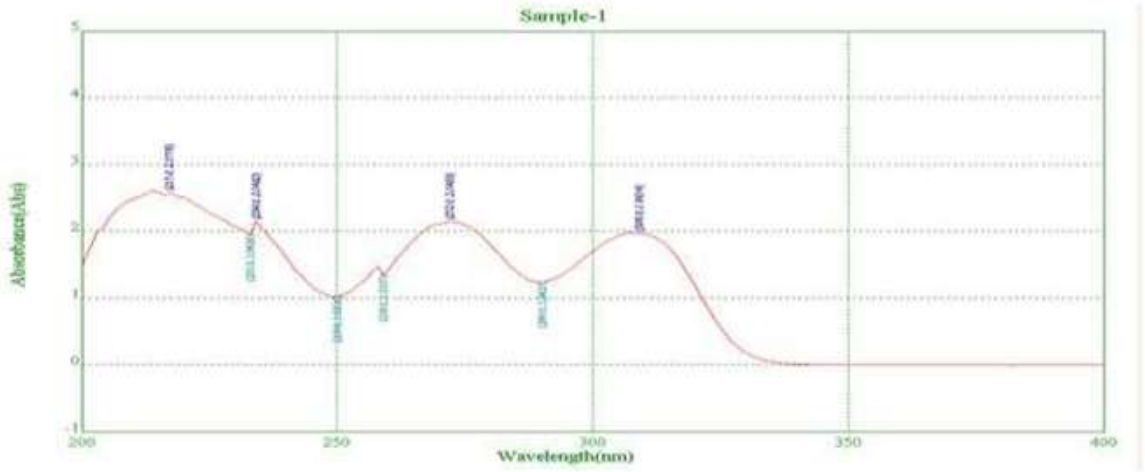

Fig. 4: UV Spectrum of Metoclopramide HCL in phosphate buffer pH 6.8

2) Preparation of standard calibration curve in phosphate buffer pH 6.8:

The curve was found to be linear in the concentration range of 2-10 µg/ml at 273.0 nm. Thus the standrad curve followed the Beer-Lamberts Law.

Table 3: Absorbance values for standard calibration curve of MetoclopramideHCL in phosphate buffer pH 6.8

S. No.	1	2	3	4	5	6
concentration	0	2	4	6	8	10
Absorbance	0	0.081	0.168	0.248	0.314	0.378

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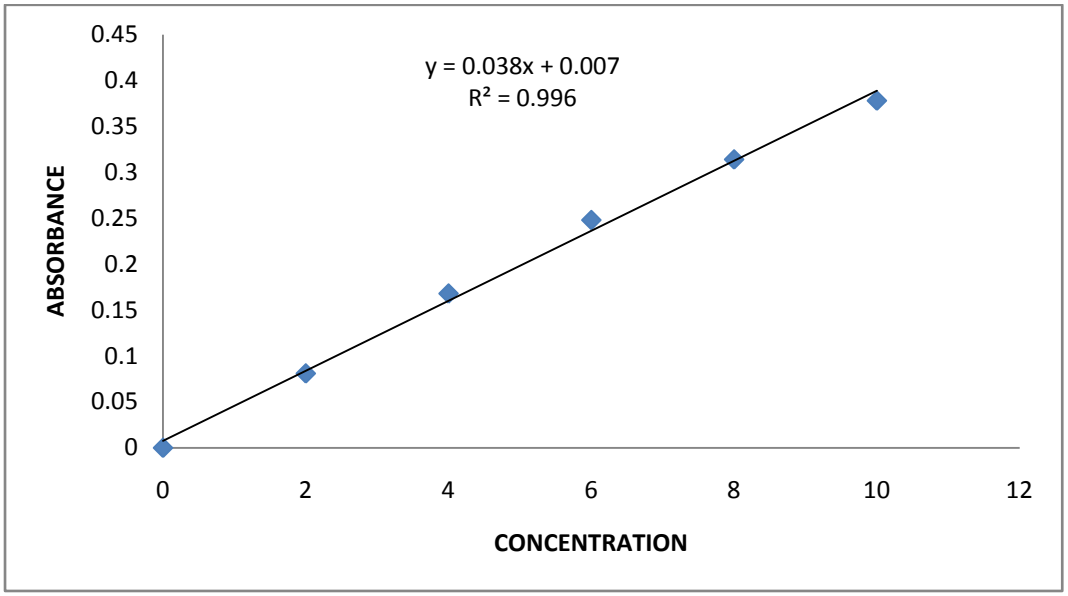

Fig. 5: Standard calibration curve of Metoclopramide HCL in pH 6.8 buffer.

Pre-compression Evaluation of tablet blend:

Nine formulations were prepared by using 2.6%, 4%, 5.3% concentration of super disintegration of superdisintegrants sodium starch glycolate, crospovidone and croscarmellose sodium. For each designed formulation, powder mixed blend of drug and excipients was prepared and evaluated for various parameters as follows.

Angle of Repose (θ):

The angle of repose of various powders mixed blend, prepared with different superdisintegrants, was measured by cylinder method. Angle of repose was found in the range from 25.80 to 32.36 the good flowability of powder blend was also evidenced with angle of repose which is indicated a good flowability. The result are given in table.

Table 4: Angle of Repose

Formulation	F1	F2	F3	F4	F5	F6	F7	F8	F9
Angle of repose	30.61	2.12	31.60	29.60	32.20	32.36	31.16	25.80	28.50

Bulk density: The bulk density of various powder mixed blends. Prepared with different superdisintegrants was measured by graduated cylinder. The bulk density was found in the range from 0.5 to 0.520. The result are given in table.

Table 5: Bulk Density

Formulation	F1	F2	F3	F4	F5	F6	F7	F8	F9
Bulk density	0.500	0.510	0.500	0.500	0.508	0.520	0.518	0.519	0.520

Tapped density: The tapped density of various powder mixed blends prepared with different superdisintegrants, was measured by measuring cylinder. The tapped density was found in the range from 0.606 to 0.628. The result are given in table.

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Table 6: Tapped Density

Formulation	F1	F2	F3	F4	F5	F6	F7	F8	F9
Bulk density	**0.608**	0.625	0.625	0.606	0.617	0.609	0.621	0.628	0.627

Compressibility Index: The compressibility index of various powder mixed blends prepared with different superdisintegrants using bulk density and tapped density data, compressibility index was calculated. It was found in the range 14.61 to 20.00. The result are given in table.

Table 7: Compressibility Index

Formulation	F1	F2	F3	F4	F5	F6	F7	F8	F9
CI	17.76	18.04	20.00	17.49	17.66	14.61	16.58	17.35	16.08

Hausner ratio: The Hausner ratio of various powder mixed blends prepared with different superdisintegrants, it was calculated by using bulk density and tapped density data. It was found in the range of 1.17 to 1.25. The result are given in table.

Table no . 8: Hausner ratio

Formulation	F1	F2	F3	F4	F5	F6	F7	F8	F9
HR	1.216	1.225	1.250	1.212	1.214	1.171	1.198	1.210	1.205

Evaluation of orodispersible tablets of Metoclopramide HCl:

Hardness: Tablets were evaluated by using hardness tester. Hardness of the tablets was found in the range 1.90 to 2.20. The result are given in table.

Table no. 9: Evaluation parameters of ODT

Formul. code	Hardness	Friability	Thickness	Wt. variation	Dispersion time	WAR	Disint. time	Content uniformity
F1	1.98	0.650	2.571	150.85	35	62.65	31	98.96
F2	1.98	0.771	2.552	149.25	37	91.03	33	99.02
F	2.02	0.589	2.558	150.75	40	67.76	32	100.30
F4	1.95	0.718	2.573	148.20	36	62.60	31	99.16
F5	1.96	0.819	2.568	150.30	42	67.56	32	97.91
F6	2.0	0.705	2.568	151.48	45	97.10	36	98.95
F7	1.90	0.489	2.571	150.30	33	83.81	28	99.03
F8	2.20	0.533	2.574	149.60	32	84.10	27	99.30
F9	1.96	0.788	2.590	150.11	29	61.65	26	98.93

In-vitro release studies:

The Comparative analysis of each formulation was based on in vitro kinetic parameters, which elucidated the release profile. The in-vitro drug release of orodispersible tablets ofMetoclopramide HCL for all formulation is given as follows. Comparative in vitro drug release profile of orodispersible tablets of Metoclopramide HCL in pH 6.8 buffer.

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Table 10: Comparative in-vitro drug release profile of all batches

S. No.	Time (Min.)	PERCENT DRUG RELEASE								
1		F1	F2	F3	F4	F5	F6	F7	F8	F9
2	0	0	0	0	0	0	0	0	0	0
3	1	16.39	22.39	22.39	20.96	20.96	22.39	21.51	32.39	52.63
4	2	32.62	39.62	49.62	32.15	32.15	39.62	42.70	53.58	72.63
5	3	56.39	52.39	78.39	55.09	55.09	68.39	62.35	75.86	99.60
6	4	69.53	76.56	92.50	77.59	77.59	77.5	97.15	98.97	
7	5	79.36	93.65	99.79	85.35	88.62	92.36			
8	6	94.35			91.35	98.96				
9	7				99.25					

From the above observation we can conclude that, as concentration of sodium starch glycolate, crospovidone, and cross carmellose sodium increase the disintegration time also increase. But the superdisintegrant cross carmellose sodium gives the minimum disintegrating time as compare to sodium starch glycolate or crospovidone. In the batch of cross carmellose sodium gives minimum disintegrating time and drug release in 3mins. at the concentration of 5.3% of cross carmellose sodium. And the batch of sodium starch glycolate and crospovidone (at the same conc. of superdisintegration i.e. 5.3%) gives the more disintegration time.

STABILITY STUDIES:

Stability studies were carried out on optimized formulation (MF9) as per ICH guidelines. There was not much variation in the tablets at all the temperature conditions. There was no significant changes in drug content, physical stability, hardness, friability, drug release for the optimized formulation MF9 after 90 days at $25^{o}C\pm 2^{0}C$ / 60% ± 5% RH, and $40^{0}C \pm 2^{0}$ / 75% ± 5% RH.

IV. SUMMARY AND CONCLUSION

The aim of present work was to prepare a suitable orodispersible tablet of Metoclopramide hydrochloride; once a day Metoclopramide hydrochloride dosage form could reduce the dosing frequency and improve patient compliance. All the formulations resulted in acceptable limit except formulation MF3 and MF8 for hardness test marginally deviated. The final batch MF9 (contained Cross Carmellose Sodium 5.3%) can be considered as optimized batch as it has the disintegration time is minimum (26 sec) seems to be most promising formulation which gives the release up to **99.60**% in 3min. The drug-excipients interaction studies were carried out by FTIR. No significant interaction of drug with excipients was observed. During stability studies, no significant variation in drug release was observed, indicating that formulation batch MF9 was stable over the chosen condition for 3 months. The optimized formulation batch MF9 showed better drug release profile with other formulations. From the present study carried out on metoclopramide HCL orodispersible tablet using by direct compression method, the following conclusion can be drawn. The total weight of MF9 batch was 150 mg contained metoclopramide HCL-6.6%, croscarmellose sodium-5.3%, microcrystalline cellulose-33.3%, aspartame-4%, magnesium stearate-1%, talc-0.6%, aerosil-0.3%, pineapple flavor-0.6%, mannitol-48%. The Prefromulation study gives the following information of optimize batch Angle of Repose-$28^{0}.50^{"}$ Bulk density-0.520, Tapped density-0.627, Compressibility Index-16.08 good to flow, Hausner ratio-1.205. Post parameter evaluation of tablets Hardness-1.96, Friability-0.788, Thickness-2.590, Weight variation-150.11±, Dispersion time-29 sec, Water absorption ratio-61.65, Disintegration time-26 sec, Content uniformity-98.93%, In-vitro drug release studies- in 3 min. So the results give information that Disintegration time in 26 sec and dissolution in 3 min. Croscarmellose sodium is the optimize batch on basis of disintegration time and in-vitro drug release. The optimized formulation of batch MF9 gave the best in-vitro release of 99.60% in3min in phosphate buffer pH 6.8. The release of drug followed matrix diffusion mechanism. Formulation MF9 gives the quick disintegration and better drug release. Hence it can be concluded that the formulation MF9 is a stable and effective.

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