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Research Article

PREPARATION AND EVALUATION OF MEFENAMIC ACID AND DICYCLOMINE HYDROCHLORIDE AS ORAL DISINTEGRATING TABLET BY DIRECT COMPRESSION METHOD

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ABSTRACT

A new dosage form, Oral disintegrating tablets (ODT's) as a replacement to conventional oral dosage forms. ODT's are dosage forms they disintegrate in mouth offering various advantages such as better mouth feel, dose accuracy, improved stability and convenient dosing as compared to oral liquids. So, there is need to designed oral disintegrating tablet to release the medicaments with an enhanced rate. Mefenamic acid is an anti- inflammatory drug while Dicyclomine HCl is anti-cholinergic drug. The combination of Mefenamic acid & Dicyclomine HCl controls pain very effectively, also relaxes bodily spasm which commonly arises during menstruation or intestinal colic spasm. This combination gives the quick onset of action and fast relief than conventional dosage form. For preparation of oral disintegrating tablet nine formulations were designed using Croscarmellose sodium and Crospovidone as superdisintegrants in varying concentration. All the formulations were prepared by direct compression method. Thus, all the formulations of Mefenamic acid and Dicyclomine HCl oral disintegrating tablets were investigated, in which F9 formulation was optimized. The % drug release of, Oral disintegrating tablet batch F9 has shown 96.98% of Mefenamic acid and 94.02 % of Dicyclomine HCl in 18 min, disintegration time in 40 sec and wetting time in 25sec.

KEYWORDS: oral disintegrating tablet, mefenamic acid, dicyclomine hydrochloride, direct compression, superdisintegrants.

INTRODUCTION

Generally, one-third of the patients need quick therapeutic action of drug, resulting in poor compliance with conventional drug therapy which leads to reduced overall therapy effectiveness. Orally disintegrating tablets (ODTs) are solid dosage form, which involves rapid disintegration and dissolution of dosage form into solution or suspension state when placed in the mouth. Because of its simplicity of self-administration, economy, and ease of manufacture, the oral route of administration is the most commonly accepted.[1] The major advantage of the ODTs formulation is that it has the advantages over both liquid and conventional tablet formulations, and also offering advantages over traditional dosage forms. This dosage form provides the convenience of a tablet formulation, and also allows the ease of swallowing. Compared to the primary alternative, oral liquids and others, ODTs allow for much more precise dosing.[2]

ODTs are strong dosage forms that include medicinal substances and appropriate excipients that disintegrate quickly when put on the tongue, in a matter of seconds (sec). ODTs in contrast to conventional dosage forms (tablets and capsules) which takes several minutes to dissolve in mouth, ODTs disintegrates and dissolves in the mouth in less than 60 sec, hence produce early action.[3] Pre-gastric (Oral cavity, Pharynx, and oesophagus), gastric (stomach), and post-gastric (small and large intestine) segments of the Gastro Intestinal Tract (GIT) release the medicament in the mouth for absorption by oral-mucosal tissue. The upcoming generation of ODTs can produce high robust, versatile tablets that overcome some of the limitations of previous ODTs. One of the main reasons why businesses prefer ODTs over other delivery systems is that they are relatively easy to develop and often less costly. The use of superdisintegrants such as Cross connected carboxymelhylcellulose (Crosscarmellose), crospovidone, and others is the basic concept behind the development of these tablets. which provide quick disintegration of tablet after administration.[4]

Superdisintegrants

Superdisintegrants are pharmaceutical excipients that are added to tablets and some encapsulated formulations to promote the disintegration of tablet and capsule "slugs" into smaller fragments in an aqueous environment there by increasing the availability of surface area and promoting a more rapid release of the drug substance.[5]

Selection of superdisintegrants [6]

While superdisintegrants mainly affect the rate of disintegration, they may also affect mouth feel, tablet hardness, and friability when used in large doses. As a result, there are many ideal considerations to consider when choosing suitable superdisintegrants for a specific formulation:

Produce rapid disintegration, when tablet comes in contact with saliva in the mouth/oral cavity.

Be compatible enough to produce less friable tablets.

Produce good mouth feel to the patients.

Small particle size is preferred to achieve patient compliance.

Have good flow, since it improves the flow characteristics of total blend.

MATERIALS AND METHODS

Dicyclomine HCl and Mefenamic acid was received as gift sample from blue cross industries, Goa, India and Ball pharma, Bangalore, India. resp., Croscarmellose sodium, Crosspovidone, Micro Crystalline Cellulose, Magnesium Stearate, Starch was received from and Karnataka antibiotics, Bangalore, India.

Direct Compression method

It is the simplest method of producing tablets. Direct compression uses standard equipment, widely available excipients, and a small number of processing steps. Furthermore, large doses can be accommodated, and the final tablet weight can easily surpass that of other manufacturing methods. The disintegration and solubilization of a directly compressed tablet are dependent on a single or combined action of disintegrants. Large and hard tablets require more time to disintegrate than is usually required. As consequences, products with optimal disintegration properties often have medium to small size and /or high friability and low hardness.[7]

Drug and Excipients Compatibility Studies

UV spectroscopy

The drugs Mefenamic acid and Dicyclomine HCl were scanned in a UV Spectrophotometer to detect the max and draw the drug calibration curve in 0.1N NaOH and 0.1N HCl as solvents, respectively.[8]

FTIR spectral studies

The infrared spectra of Mefenamic acid and Dicyclomine HCl were recorded by SHIMADZU 84005 FTIR spectrometer, equipped with an Inferometer detector. The samples were made using the KBr disc method (2 mg sample in 100 mg KBr) and analysed in transmission mode. Over a frequency range of 4000–400 cm1, each spectrum was measured.

DSC studies

On 2-5mg samples, DSC analysis was performed using a Shimadzu-Thermal Analyzer DSC 60. Sample was heated in an open nitrogen pan at a rate of 10°C/min conducted over a temperature range of 50 to 200°C for Mefenamic acid and Dicyclomine HCl under nitrogen flow of 2 bar pressure.[9]

METHOD OF PREPARATION OF POWDER BLEAND

Two excipients (Croscarmellose sodium and Crosspovidone) were used as superdisintegrants at three concentration levels. MCC is applied to maintain superdisintegrant concentration while also serving as a binder, and Mg stearate and starch are added at a constant stage. Formulations coded as F1 to F9 respectively. The composition of formula is as shown in Table 1. All of the ingredients were passed through sieve mesh 60#, and bleanding for 15 mins. Finally, the bleand was passed through mesh #40 and used for evaluation of flow characteristic.

***In vitro* evaluation of powder blend**

Angle of Repose[10]

Angle of repose is used to determine the flow properties of powders, pellets or granules. A glass funnel was secured with its tip at a given height (h) above a piece of graph paper placed on a horizontal surface to measure angle of repose. Powder was pumped through the funnel until the apex of the conical pile met the tip of the funnel. The angle of repose was calculated using the formula below. Standard values of angle of repose was shown in table 2.

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

Where, h = height of the heap, r = Radius of the heap

Apparent bulk density[11]

Weighed quantity of pre-sieved powder bleand was taken in a graduated cylinder and bulk volume was measured and weight of bleand was determined by using the formula

$$Db = M/ Vb$$

Where, M is the mass of powder, Vb is the bulk volume of the powder.

Tapped density

It was determined by placing a graduated cylinder, containing a known mass (i.e. 10gm) of powder sample on mechanical tapping apparatus, which was operated for fixed number of taps (around 100) until the powder bed volume reached a minimum. The tapped density was measured using the weight of powder in a cylinder and this minimum volume. Carr's index was determined using the bulk density and tapped density data.

$$Dt = M / Vt$$

Where, M =The mass of powder, Vt =The tapped volume of the powder.

Carr's index[12]

Carr's index was used to assess the powder bleand's compressibility index. Carr's index was determined using the bulk density and tapped density data.

The formula is given below

$$\text{Carr's index} = TD\text{-}BD \times 100 / TD$$

Where, TD is the tapped density of powder, BD is the bulk density of powder.

Hausner's Ratio

The Hausner's ratio is a measurement of a powder's or granular material's ability to flow. It is calculated by following formula.

$$\text{Hausner's Ratio} = \frac{TD}{BD}$$

***In vitro* evaluation of prepared tablets**

Tablet hardness and thickness[13]

The fracture strength, which is defined as the force required breaking a tablet by radial compression was measured with a tablet hardness tester (Monsanto hardness tester). It is usually expressed in kg/cm^2. Tablets were selected from each formulation. The mean and standard deviation values were calculated.

The thickness of the tablet calculated by using screw gauge, Vernier calliper which indicates the strength of withstand compression force applied during manufacturing process.

Friability

Friabilator is used to determine the friability test on ODTs. Six pre-weighed tablets were picked from each batch and loose dust was removed with the help of a soft brush. The tablets were then placed in a friabilator. For 4 minutes, the drum was rotated at 25 rpm. The minitablets were removed following the rotation. If any loose dust was removed from the minitablets as before and the tablets weighed again then the percentage friability was calculated by the following formula,

$$F\% = W_{initial} - W_{final} * 100 / W_{initial}$$

Where, W_{intial} = weight of 6 tablets before friability, W_{final}= weight of 6 tablets after friability.

Weight variation[14]

The weight variation test of tablet was conducted by weighing 10 tablets randomly. Calculating the average weight and individual weight. By comparing the individual tablet to the average tablet. The percentage difference in the weight variation should be within the acceptable limits. The percent deviation was calculated using the following formula.

% Deviation = Individual weight – Average weight / Average weight x 100

The percentage deviation for weight variation of tablets as per IP limits is shown in table 3.

***Wetting time test*[15]**

Wetting time is relative to the inner structure of tablets and hydrophilicity of excipients. The USP does not have a monograph outlining the method for performing a wetting test. Usually wetting test utilizes tissue paper of 10 cm diameter are placed in a Petri dish. The tablet is placed on the tissue paper near the centre of the Petri dish and water is added. The tissue paper wicks the water and the tablet begin to uptake water. The wetting time is recorded as the time when complete wetting of the tablets occurs.

Water absorption ratio

A piece of tissue paper folded twice was placed in small Petri dish (6.5cm) containing 5 ml water. A tablet was placed on the tissue paper to allow complete wetting. After that, the wetted tablet was weighed. The following equation was used to calculate the water absorption ratio R. A tablet was put on the tissue paper and allows wetting completely. The wetted tablet was then weighed. The water absorption ratio R was determined using following equation.

R = Wa –Wb X 100 / Wa

Where; Wa = weight of a tablet after absorption, Wb = weight of a table before absorption

***In-vitro disintegration test*[16]**

The disintegration method of tablet used in the present study is a potential method.it was possible to determine the time until complete disintegration of each unit, which in turn made it possible to compare the disintegration times of different batches. The test was conducted for six tablets of each formulation at 37°C ± 0.5°C using disintegration apparatus. Distilled water was used as disintegration medium. A tablet was placed in each of six tubes of the apparatus which consist of 10-mesh sieve at the bottom end of the basket rack assembly and one disc was added to each tube, complete disintegration of the tablet with no mass remaining in the apparatus was measured in seconds, by using the conventional disintegration apparatus. Times for complete disintegration of each of the tablets were recorded thrice and the average value and standard deviation were reported.

Drug content uniformity

Twenty tablets were weighed accurately and crushed into a fine powder. Mefenamic acid tablet powder weighing 25 mg equivalent weight was accurately weighed and transferred to a 100 ml volumetric flask. After shaking for 10 minutes, 50 ml of phosphate buffer (pH7.4) was added. Then, the volume was made up to 100 with phosphate buffer. The solution in volumetric flask was filtered, diluted suitably and analysed spectrophotometrically at 285 nm. The amount of drug was estimated by using standard calibration. The percentage drug content was calculated.

***In-vitro dissolution studies*[17]**

An in-vitro drug release studies of the prepared nine formulations of oral disintegrating tablets were conducted for a period of 16 minutes using an eight station USP type 2 apparatus (paddle type) (LABINDIA-DISOTEST, 6 F 622). The agitation speed was 50 rpm. Prepared tablets were added to 900 ml of phosphate buffer 7.4 at 37 ± 0.5° C and stirred at 50 rpm .5 ml samples were withdrawn at time intervals of 2,4,6,8,10,12,14,14,16,18 min. and filtered through Whatman's No. 41 filter paper. To maintain the volume of dissolution medium, an equal volume of fresh dissolution medium was replaced. The filtered samples were tested at the zero-crossing point of the respective drugs. The cumulative percentage of the labelled amount of drug released was determined.

Stability Studies

Accelerated stability studies were performed for 6 months as per ICH guidelines. The optimized formulation was kept at 40 ± 2 °C and 75 ± 5 % RH. The parameters used to assess the effect of stress on tablets are as follows: Disintegration time, wetting time, drug content, and drug release percentage.

RESULT AND DISCUSSION

All batch tablets F1-F9 were successfully prepared using the direct compression process.

All the formulations were prepared by direct compression process to improve the solubility of drug and to mask the bitter taste of the drug, which is vital for preparation of oral disintegrating tablets for paediatric and geriatrics use.

Preformulation studies of Mefenamic acid and dicyclomine hydrochloride were carried out by determination melting point, solubility and λmax. The obtained results complied with IP standards, thus indicating the purity of drug.

FTIR and DSC study revealed that there was no chemical interaction between the drug (Mefenamic acid and dicyclomine hydrochloride) and superdisintegrants (excipients) when they are combined together.

The λmax of Mefenamic acid and Dicyclomine HCl were measured at 284.8 nm and 213 nm, respectively, and the calibration curve was built using concentration ranges of 2-10 ppm and 100-500 ppm. equation was found to be y = 0.043X + 0.01, y =0.005 X + 0.090 respectively and the regression coefficient R2 = 0.998, R2= 0.993 respectively. Spectra and calibration curve were showed in Figure 1, 2, 3, 4.

FTIR spectra of Mefenamic acid, Dicyclomine HCl and the optimized formulations are shown in Figures 5, 6 and 7. The FTIR spectrum of Mefenamic acid exhibited at3346.53 cm^{-1}, 1650.85 cm^{-1}, 3314.86 cm^{-1}, 2924 cm^{-1}, 1453 cm^{-1}, 2858 cm^{-1}, (NH group, C=O Stretching, O-H Stretching, C-H Stretching C-H bending, CH group,).

FTIR spectrum of Dicyclomine HCl exhibited at 1134.07 cm^{-1}, 1193.85 cm^{-1}, 2929.67 cm^{-1}, 1719.45 cm^{-1}, 1712.85 cm^{-1}, (C-N stretching, C-O stretching, C-H stretching, C=O (ester) group, C=C stretching, C-H bending).

The IR spectra of combination showed prominent absorption band at 3350.48 cm^{-1}, 3311.89 cm^{-1}, 2928.04 cm^{-1}, 1712.95 cm^{-1}, 1615.12 cm^{-1}, 2858.60 cm^{-1} (NH stretching, OH stretching, C-H stretching, C=C stretching, C=O stretching, C-H group).All of these distinct bands were retained in formulations, indicating that there is no interaction between the drug and the polymers.

Figures 8 and 9 show DSC thermograms of Mefenamic acid, Dicyclomine HCl, and Mefenamic acid exhibited a strong endothermic peak at 224.77°C, which corresponded to its melting point. While Dicyclomine HCl showed sharp endothermic peak at 167.97°C corresponding to its melting point.

The DSC curve of Mefenamic acid and Dicyclomine HCl tablet (physical mixture) shows sharp endothermic peak at 234.62°C and 163.28°C respectively. The drug does not undergo decomposition following its melting. This indicates that no

chemical interaction between the drug and excipients mixture is likely. Thermograms is as shown in Figure 10.

The powder bleands were prepared by mixing of various ingredients mentioned in Table 1 and used for characterization of various flow properties of powder. Table 4 reports the values for Compressibility Index (CI) and Hausner's ratio (HR) for all prepared batches. According to the literature, powders with CI values below 15% are suitable for producing the tablets and those with a Hausner's ratio values below 1.25 and angle of repose values in between 20-40˚ indicate good flow properties of powders. The results are shown in Table 4.

Tablets were evaluated for hardness, thickness, friability, contents of active matter, weight variation, wetting time, weight absorption and disintegration time as procedure mention in method. The results were within the specified limits. All the studies were performed in triplicate, and results are expressed as mean ± SD. The results are shown in Table 5 and 6.

The in-vitro release of drug (Mefenamic acid and dicyclomine hydrochloride) from oral disintegrating tablets was found to vary according to the type and concentration of disintegrants used. The drug release was increased, due to the higher concentrations of superdisintegrants (Croscarmellose sodium and crospovidone) which enhance the tablet disintegration and improves dissolution. Among all the formulation, the F9 showed significantly higher drug release than other formulations.

In-vitro dissolution studies of ODT were within limit and drug release profile was found to be 98.97 % and 96.99 % in 18 min. Which shown in Table 7 and 8.

Stability studies were carried out with selected formulation i.e. F9 and the results of studies indicated the formulation was stable at 400C / 75%RH as presented in Table 9.

Table 1: Formula for oral disintegrating tablet of Mefenamic Acid and Dicyclomine HCl

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Mefenamic acid	250	250	250	250	250	250	250	250	250
Dicyclomine HCl	10	10	10	10	10	10	10	10	10
MCC	24	21	18	15	24	21	21	15	9
CCS	3	6	9	-	-	-	3	6	9
Crospovidone	-	-	-	3	6	9	3	6	9
Starch	9	9	9	9	9	9	9	9	9
Mg stearate	4	4	4	4	4	4	4	4	4
Flavouring agent	q,s	q,s	q,s	q,s	q,s	q,s	q,s	q,s	q,s

Table 2: Standards of Angle of Repose

Angle of Repose (◦)	Type of Flow
< 25	Excellent
25-30	Good
30-40	Passable
>40	Poor

Table 3: Standards of Weight variation

Average weight of tablet	Percentage deviation
80 mg or less	±10
More than 80 mg and less than 250 mg	±7.5
250 mg or more	±5

Table 4: Evaluation of powder blend containing drug and Excipients

Formulations	Bulk density (g/cm3)	Tapped density (g/cm3)	Hauser's ratio	Compressibility index (%)	Angle of repose
F1	0.421±0.024	0.423±0.012	1.17	13.25	33.15
F2	0.326±0.041	0.483±0.034	1.02	14.09	28.45
F3	0.351±0.038	0.442±0.025	1.23	13.06	35.26
F4	0.302±0.012	0.480±0.021	1.05	14.12	31.21
F5	0.400±0.25	0.485±0.023	1.42	14.26	30.32
F6	0.374±0.036	0.458±0.045	1.56	13.36	26.12
F7	0.384±0.041	0.461±0.032	1.23	13.28	28.42
F8	0.364±0.013	0.462±0.031	1.24	13.42	25.23
F9	0.314±0.023	0.492±0.025	1.14	13.16	29.15

Table 5: Results of thickness, hardness, friability, weight variation and wetting time of F1- F9

Formulation batches	Thickness (mm) (±SD) (n=3)	Hardness (Kg/c2) (± SD) (n=3)	Friability (%) (±SD) (n=30)	Weight variation (±SD) (n=20)	Wetting time (sec.) (± SD) (n=3)
F1	4.52±0.012	3.97±0.013	0.61±0.035	0.442±0.085	46±2.3
F2	4.23±0.005	4.25±0.023	0.45±0.015	0.435±0.025	43±1.2
F3	4.29±0.013	4.52±0.017	0.55±0.025	0.441±0.054	42±0.6
F4	4.64±0.031	4.36±0.006	0.37±0.014	0.444±0.013	35±1.5
F5	4.45±0.04	4.18±0.015	0.53±0.016	0.436±0.007	41±2.5
F6	3.98±0.058	4.96±0.016	0.46±0.012	0.437±0.018	41±0.65
F7	4.72±0.014	4.75±0.014	0.48±0.004	0.446±0.045	38±2.1
F8	4.15±0.036	4.89±0.025	0.52±0.023	0.448±0.032	36±0.89
F9	4.82±0.032	4.85±0.012	0.45±0.017	0.445±0.019	25±1.2

Table 6: Results of disintegration time, water absorption ratio and drug content of F1-F9

Formulation batches	Disintegration Time (sec.) (±SD) (n=3)	% Drug content Of MA (± SD) (n=3)	% Drug content Of DIC (±SD) (n=3)	Water absorption ratio (±SD) (n=3)
F1	47±2.51	93.25±0.63	94.21±0.87	75.42±1.45
F2	45±095	95.41±0.12	91.21±0.56	74.11±1.63
F3	55±0.51	97.23±0.45	92.25±0.64	72.61±2
F4	58±2.58	96.78±1.25	95.35±1.23	65.12±0.5
F5	52±3.12	96.89±0.63	93.01±1.56	77.2±0.35
F6	69±4.12	97.23±0.45	94.98±0.48	67.05±1.25
F7	67±1.56	96.04±0.54	89.08±0.45	69.36±2.45
F8	42±2.93	97.34±0.34	95.19±0.14	75.32±1.05
F9	40±1.54	98.13±0.05	96.18±0.25	76.82±0.84

Table 7: *In-vitro* drug release study of mefenamic acid

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
2	27.25	29.36	33.25	21.58	27.56	25.19	25.56	28.45	32.28
4	35.89	37.67	45.95	23.83	33.42	33.91	32.42	33.12	38.63
6	39.18	41.28	49.57	27.11	36.11	37.77	39.11	37.45	46.33
8	45.75	48.19	55.26	35.49	40.28	41.92	42.28	41.29	55.15
10	51.38	53.29	68.98	42.19	51.48	53.24	51.48	52.64	62.39
12	59.49	60.58	74.12	50.66	60.34	61.99	61.34	61.91	70.85
14	66.47	72.95	82.69	61.28	74.98	73.28	72.98	75.24	79.21
16	74.33	85.52	88.35	74.64	82.33	83.55	81.33	84.94	88.55
18	87.53	91.50	93.45	88.45	89.62	92.48	89.02	90.37	96.98

Table 8: *In-vitro* drug Release Study of Dicyclomine HCl

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
2	19.15	21.6	24.59	11.65	14.52	22.45	25.11	27.0	24.36
4	25.68	28.4	29.48	19.12	20.48	31.17	32.05	33.35	36.4
6	32.81	36.8	38.05	28.95	29.84	39.28	39.99	40.08	49.86
8	39.5	41.91	42	34.56	36.66	47.54	45.28	47.53	58.45
10	45.15	49.25	50.69	46.32	48.55	54.27	56.17	57.18	65.12
12	51.98	53.67	56.16	52.48	55.28	61.52	63.48	64.28	77.47
14	60.35	61.71	65.30	60.08	62.39	70.08	71.95	72.59	86.91
16	67.95	68.11	74.08	66.58	69.17	75.22	78.62	80.27	91.54
18	73.89	79.43	85.10	74.00	77.25	82.95	88.52	91.78	94.02

Table 9: Accelerated stability studies for optimized formulation F9

Temperature and RH	Parameters	Duration in months			
		0	**2**	**4**	**6**
40 ± 2˚C/75% **40±2˚C and 75±5%**	Wetting time	25.00	24.97	24.93	24.89
	Disintegration time	40.00	40.95	40.92	40.88
	% Drug content of MA	98.13	98.10	98.07	98.03
	% Drug content of DiH	96.18	96.15	96.12	96.08
	% CDR of MA	96.98	96.95	96.91	95.88
	% CDR of DiH	94.04	94.02	93.98	93.94

Where, DiH – Dicyclomine Hydrochloride, MA – Mefenamic acid, CDR – Controlled drug release.

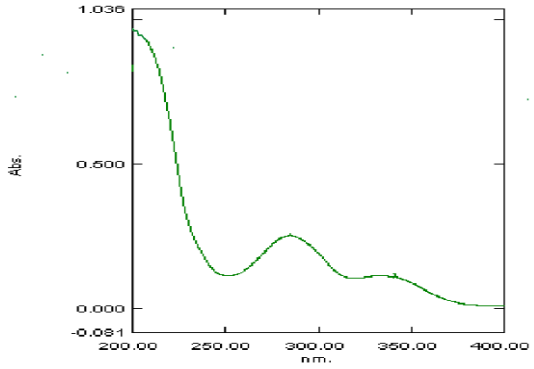


Fig 1: UV spectrum of Mefenamic acid

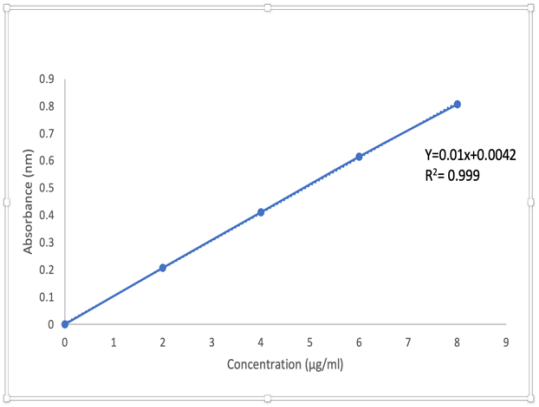


Fig 2: Calibration curve of Mefenamic acid

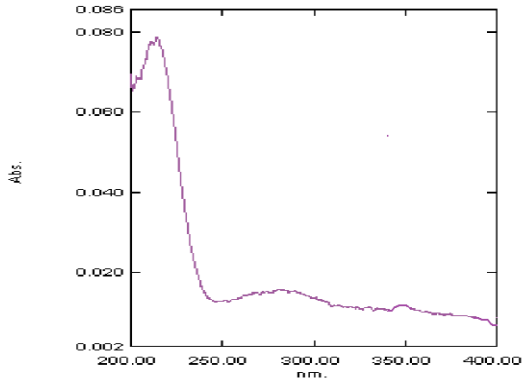


Fig 3: UV spectrum of Dicyclomine Hydrochloride

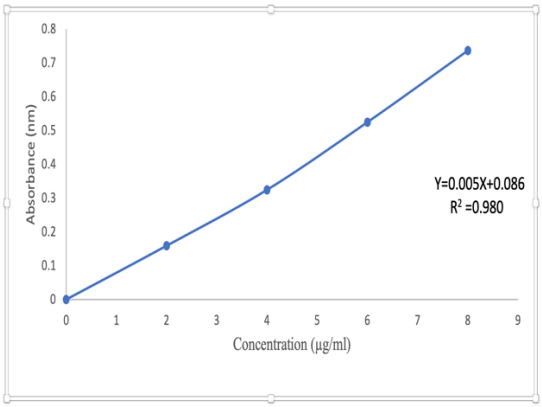


Fig 4: Calibration curve of Dicyclomine Hydrochloride

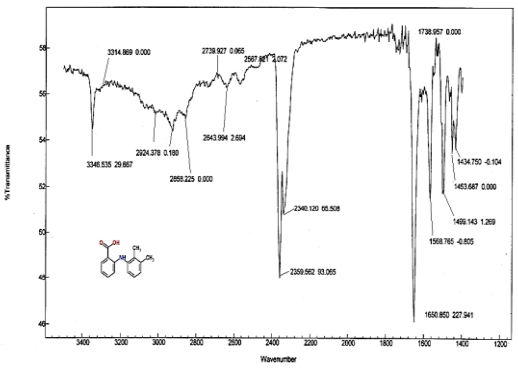


Fig 5: FTIR spectra of Mefenamic acid

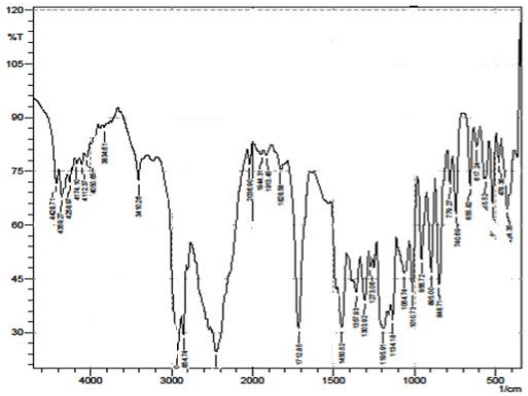


Fig 6: FTIR spectra of Dicyclomine Hydrochloride

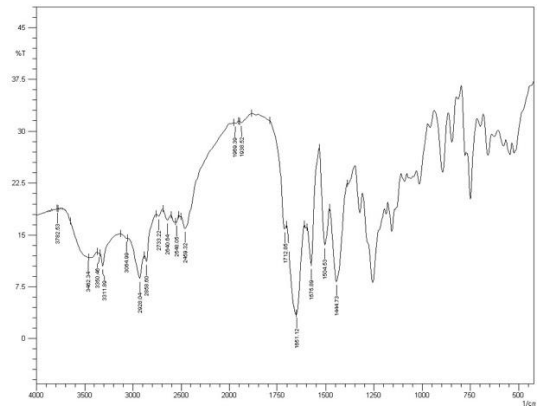


Fig 7: FTIR spectra of pysical mixture of drug and polymer

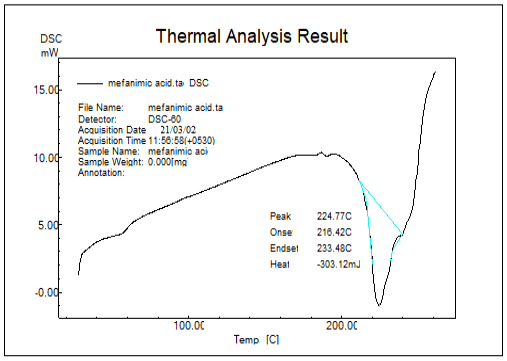


Fig 8: DSC of Mefenamic acid

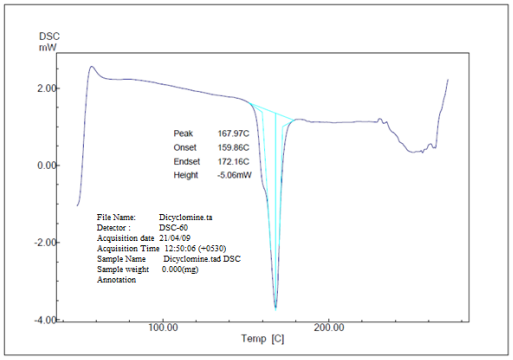
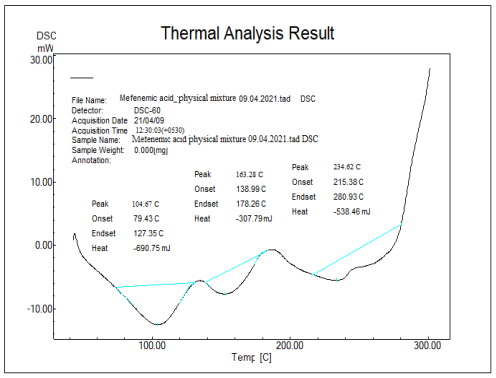


Fig 9: DSC of Dicyclomine Hydrochloride



Fig, 10: DSC of Physical mixture

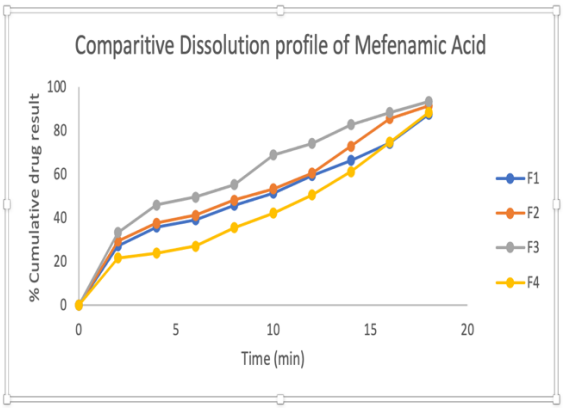


Fig 11: *In vitro* release profile of Mefenamic acid of Formulations F1-F4

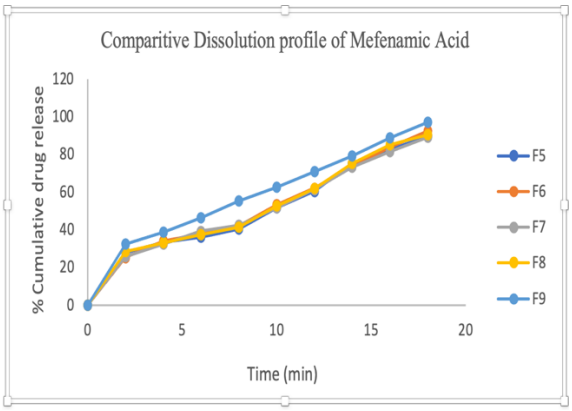


Fig 12: *In vitro* release profile of Mefenamic acid of Formulations F5-F9

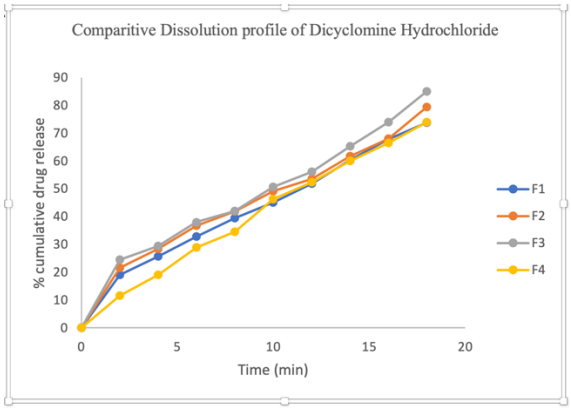


Fig 13: *In vitro* release profile of Dicyclomine Hydrochloride of Formulations F1-F4

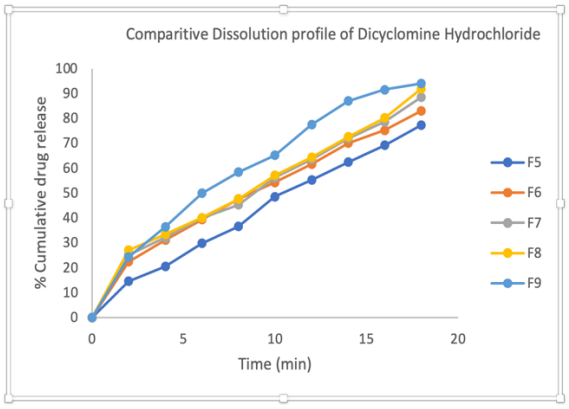


Fig 14: *In vitro* release profile of Dicyclomine Hydrochloride of Formulations F5-F9

CONCLUSION

Oral disintegrating tablets are a promising approach for achieving faster drug action and would be preferable to currently available conventional dosage forms. The ODT dosage form struck a good balance between disintegration time and patient comfort. The prime objective of the study was to develop an oral disintegrating tablet by mefenamic acid and dicyclomine hydrochloride using commonly available excipients and conventional technology (direct compression). All tablets prepared, were uniform in thickness, hardness and weight variation. They also show good % drug release and drug content. The % drug release of, Oral disintegrating tablet batch F9 has shown 96.98% of Mefenamic acid and 94.02 % of Dicyclomine HCl in 18 min, disintegration time in 40 sec and wetting time in 25sec. wetting time in 25 second. Thus, oral disintegrating tablet of Mefenamic acid and Dicyclomine HCl F9 batch was optimized and stability studies were conducted.

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