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Development and *in vitro* Evaluation of Meloxicam Mouth Dissolving Tablets

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Abstract
Mouth dissolving tablets (MDTs) are a modern form of tablets that when placed in the oral cavity, disperses rapidly. These tablets have advantages, particularly good applications for children and old patients who have a complication in chewing or swallowing solid dosage forms. Drug compatibility with excipients was checked by FTIR studies. In the present work, oral dispersible tablets of Meloxicam category of NSAIDS were prepared by direct compression method with a view to enhance patient's compliance. Drug and excipient compatibility studies measured by using FTIR studies. Eight formulations having different concentrations of super disintegrates such as Croscaramellose and Sodium starch glycolate were prepared. The pure drug and formulation blend was examined for angle of repose, bulk density, tapped density, Compressibility index and Hauser's ratio. These tablets were evaluated for drug content, weight variation, friability, hardness, wetting time and *in vitro* disintegration time. Among the formulations tablets of batch F4 containing croscarmellose showed superior organoleptic properties along with excellent *in-vitro* disintegration time and drug release as compared to other formulations. Hence Croscarmellose is recommended as suitable disintegrate for the preparation of direct compression mouth dissolving tablets of Meloxicam. It was concluded that the presence of a super disintegrate is desirable for orodispersion of tablets by direct compression method.

Keywords: Meloxicam, Croscarmellose, Sodium starch glycolate, FTIR Studies, Direct Compression Technique, *In vitro* Drug Release Studies

Introduction
Oral route is still the most effective approach to provide therapeutic agents because it is convenient to administer and has a cheap cost of therapy, which enhances patient compliance. Because of its firmness, self administration accessibility, and convenience of production, tablets are a frequently prescribed dose type [1]. Oral administration is the most common route due to relief of ingestion, flexibility, pain elimination and most importantly [2]. Solid oral delivery systems are doing not required sterile conditions and are, therefore, less expensive to manufacture. Mouth dissolving tablet (MDT) is moderately novel solid dosage form that includes rapid dissolution and disintegration in the mouth without require of drinking water. They are well-known as fast disintegrating, fast melt or fast dissolving tablet [3]. Nonsteroidal anti-inflammatory medication (NSAID) meloxicam (MLX) works by blocking prostaglandin production, mainly the cyclooxygenase-2 (COX-2) isoform of cyclooxygenase, making it an effective treatment for pain and inflammation, fluid retention, and fever [4]. Mouth dissolving tablets of Meloxicam were prepared by effervescent, superdisintegrant addition by direct compression method.

Materials
Meloxicam was obtained from Hetero lab, HYD. Sodium starch glycol ate and Croscarmellose sodium were procured from

Synpharma Research Labs, Hyderabad, and other chemicals, and the reagents used were of analytical grade.

Methodology

Fourier Transform Infrared Spectroscopy (FTIR)

Fourier Transform Infrared (FTIR) Spectroscopy FTIR spectra were obtained on Shimadzu FTIR Model 8400-S spectrometer. The spectra was recorded as a dispersion of the sample in potassium bromide in IR disk (2 mg sample in 200 mg KBr) with the scanning range of 400 to 4000 cm-1 and the resolution was 1 cm -1 [5].

Table 1: Formulation table

S. No	Ingredient (mg)	F1	F2	F3	F4	F5	F6	F7	F8
1	Meloxicam	5	5	5	5	5	5	5	5
2	Croscaramellose	5	10	15	20	-	-	-	-
3	Sodium starch glycolate	-	-	-	-	5	10	15	20
4	Lactose	75	70	65	60	75	70	65	60
5	Magnesium stearate	3	3	3	3	3	3	3	3
6	Talc	2	2	2	2	2	2	2	2
7	Aspartame	5	5	5	5	5	5	5	5
8	MCC	5	5	5	5	5	5	5	5
9	Total wt	100	100	100	100	100	100	100	100

Preparation method

Direct compression technique [6]

Meloxicam mouth dissolving tablets were prepared by direct compression method by using coprocessed superdisintegrants like Croscarmellose and Sodium Starch Glycolate and Lactose as a diluent, Aspartame as a sweetening agent, MCC used as a binder, Magnesium Stearate, Talc used as a lubricant and glidant. All the ingredients (except granular directly compressible excipients) were passed through # 44 mesh separately. Then the ingredients were weighed and mixed in geometrical order after sufficient mixing of drug as well as other components and compressed into tablets of 100mg using 6mm round flat punches on 12-station rotary tablet machine.

Evaluation of tablet

Weight variation

Twenty tablets are randomly selected from the batch and weighed separately to check for weight variation [7].

Hardness

The hardness of a tablet is defined as the amount of force required to shatter it across its diameter. When handled before use and during storage transition, the tablet's hardness influences how resistant it is to breaking, chipping, or abrasion. Hardness can be assessed using a Monsanto, Erweka, Pfizer, or Schleuniger hardness tester [8].

Friability

Friability may be assessed using the Roche Friabilator. This device subjects the tablet to the combined effects of abrasion and stress in a plastic container that rotates at a speed of 25 revolutions per minute and drops a tablet from a height of 6 inches with each revolution. The friabilator rotates a sample of tablets that have been pre-weighed 100 times [38]. The following formula provides the friability [9]

(F): = W int. − W fin / W int. × 100

Where,

W int = Initial weight of tablets before friability;
W fin = Final weight of tablets after friability.

Wetting time

The dosage form's wetting time and contact angle are related. It has to be assessed to provide light on the tablet disintegration properties; a shorter wetting time means a tablet will disintegrate more quickly. This is accomplished by placing a tablet in a tiny Petri dish with an internal diameter of 6.5 cm, 6 ml of water, and measuring how long it takes for the tablet to get totally wet [10].

Disintegration test

Mouth dissolving tablets need to have their disintegration times adjusted since they must dissolve without water for the test to be accurate. A 10 ml of water are placed inside a 10 cm diameter Petri dish for this purpose. The tablet is placed gently in the center of Petri dish, and the duration till it totally crumbles into tiny pieces can be noticed [11].

In vitro dissolution test

To perform *in vitro* dissolution studies, the USP paddle technique at 50 rpm in 900 ml of dissolving fluid kept at a temperature of 37±0.5 may be employed. You can select a dissolution medium based on a monograph. After staining the sample through Whatman filter paper and performing a spectrophotometric analysis at a specific wavelength, the sample should be taken out at the designated intervals. To maintain the same volume throughout the test, an equal amount of freshly heated medium heated to 37 °C is added back into the dissolution media after each sampling [12].

Kinetics of drug release [13]

To study kinetices data obtained from invitro relesase were plotted in various kinetic models.

Zero-order equation

% R = Kt

This model represents an ideal release profile in order to achieve the pharmacological prolonged action. This is applicable to dosage forms like transdermal systems, coated forms, osmotic systems, as well as matrix tablets with low soluble drugs.

First order equation

Log % unreleased = Kt / 2.303

This model is applicable to study hydrolysis kinetics and to study the release profiles of pharmaceutical dosage forms such as those containing water soluble drugs in porous matrices.

Higuchi equation

$\% R=Kt^{0.5}$

This model is applicable to systems with drug dispersed in uniform swell able polymer matrix as in case of matrix tablets with water soluble drug.

Korsmeyer-Peppas equation

$\%R=Kt^{n}$

This model is widely used, when the release phenomenon could be involved.

Stability testing of drug (temperature dependent stability studies) [14]

The mouth disintegrating tablets should be put in the proper packaging and stored under the following conditions for a period of time in accordance with ICH guidelines for stability studies.

Results and Discussion

Fourier Transformation Infra-Red (FTIR) analysis:

Infra-red spectroscopy analysis was performed by Fourier Transformation Infrared Spectrophotometer Alpha Brooker FTIR (Tokyo, Japan). In the present study, it has been observed that there is no chemical interaction between Meloxicam and the superdisintegrants used. From the figure it was observed that there were no changes in these main peaks in IR spectra of mixture of drug and polymers, which show there were no physical interactions because of some bond formation between drug and polymers. This further confirms the integrity of pure drug and compatibility of them with excipients.

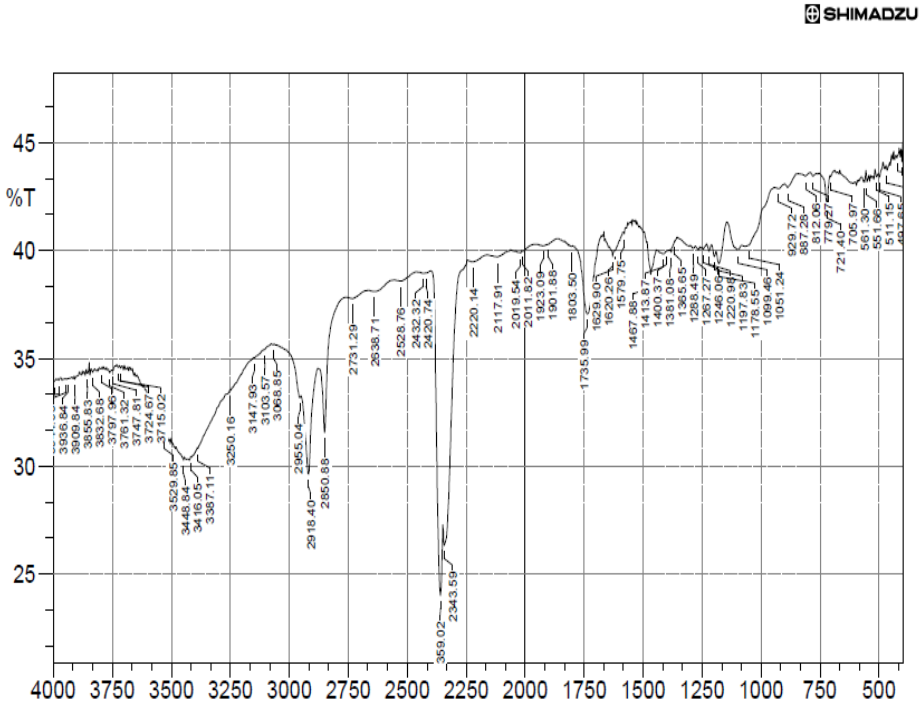

Fig 1: FTIR Studies of Meloxicam

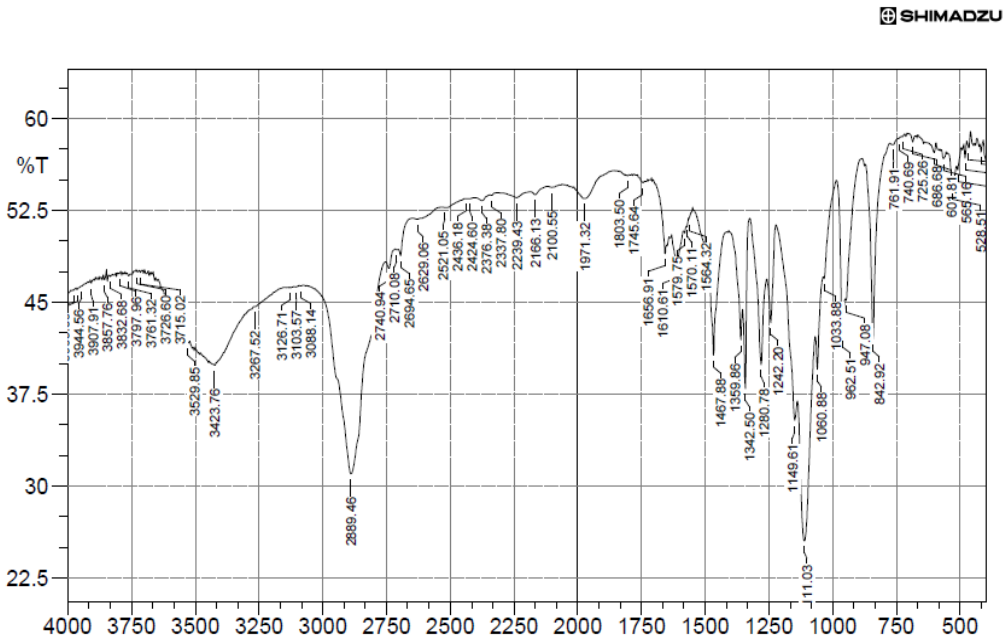

Fig 2: FTIR Studies of optimized formulation

Evaluation parameters

Table 2: Evaluation Parameters for Meloxicam mouth dissolving tablets

Parameter	F1	F2	F3	F4	F5	F6	F7	F8
Weight variation(mg)	99±1.25	100±1.30	100±1.62	100±1.58	99±1.59	100±1.67	100±1.54	99±1.17
Thickness (mm)	2.8±2.20	2.6±2.18	2.1±2.36	2.4±2.58	2.7±2.61	2.3±2.56	2.0±2.41	2.5±2.18
Hardness (kg/cm^2)	3.5±1.86	3.2±1.56	3.4±1.53	3.6±1.60	3.9±1.29	2.9±1.35	2.5±1.46	3.5±1.58
Friability (%)	0.35±0.68	0.50±0.42	0.49±0.45	0.46±0.53	0.43±0.47	0.39±0.49	0.37±0.43	0.40±0.45
Disintegration time(Sec)	43±1.56	42±1.53	38±1.60	36±1.80	39±1.52	43±1.62	40±1.48	44±1.73
Drug content (%)	78.95±1.82	79.82±1.56	80.25±1.50	81.57±1.27	80.22±1.20	78.96±1.27	79.80±1.30	79.15±1.52
Wetting time	53±1.56	56±1.28	58±1.30	57±1.23	49±1.52	50±1.46	53±1.34	58±1.50

Uniformity of weight

All the prepared mouth dissolving tablets of Meloxicam were evaluated for weight variation. The weight of all the tablets was found to be uniform with low values of standard deviation and within the prescribed IP limits of ± 5%.

Hardness and friability

The hardness of the tablet formulations was found to be in the range of 2.5±1.46-3.9±1.29 kg/cm^2. The friability values were found to be in the range of 0.35±0.68 to 0.50±0.42 %.

Uniformity of drug content

The low values of standard deviation indicates uniform drug content within the tablets The percent drug content of all the tablets was found to be in the range of 78.95±1.82 to 81.57±1.27 percent (which was within the acceptable limits of ±5%.).

All Formulations tested for Physical parameters like Hardness, thickness, Weight Variation, Friability and found to be within the Pharmacopoeial limits. The results of the tests were tabulated. The drug content of the formulation was determined and was found to be within the permissible limit. This study indicated that all the prepared formulations were good.

***In-vitro* dissolution Profiles for tablets**

Table 3: *In vitro* drug release studies of all formulations

Time (min)	% Drug Release							
	F1	F2	F3	F 4	F5	F6	F7	F8
0	0	0	0	0	0	0	0	0
5	25.86±2.18	28.25±1.68	29.82±1.25	30.71±1.69	27.54±2.19	26.34±1.69	28.93±1.52	27.82±1.34
10	37.14±1.59	38.92±2.13	37.54±1.17	39.10±2.10	38.52±3.10	37.42±2.10	36.74±1.36	35.81±1.30
15	48.80±2.17	50.13±2.45	52.60±2.34	53.17±2.38	54.10±2.85	55.47±1.23	54.15±1.49	52.10±1.56
30	56.92±1.58	61.24±1.58	65.85±2.16	66.80±1.69	68.12±2.46	67.18±2.06	66.50±1.28	65.14±1.50
45	72.15±2.13	79.82±1.67	78.50±2.19	79.85±2.34	80.48±3.02	76.80±1.53	74.15±1.34	76.95±1.49
60	90.12±2.19	92.46±2.13	93.68±2.38	96.50±2.16	95.25±2.68	94.27±2.08	93.68 ±1.29	94.96±1.30

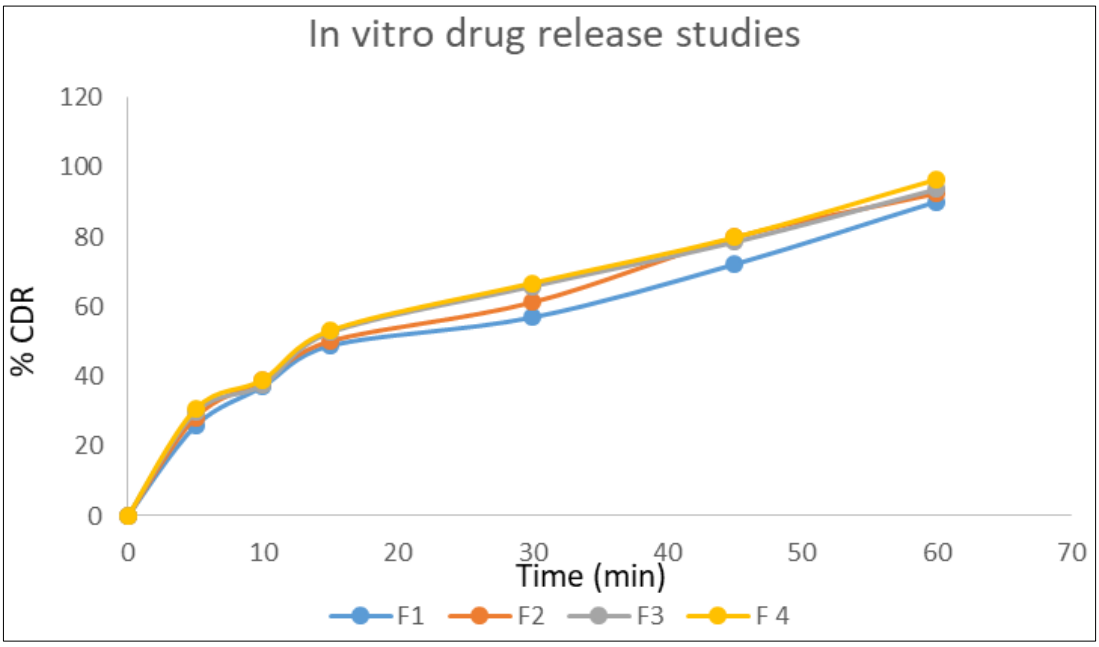

Fig 3: *In vitro* drug release studies for (F1-F4) formulation

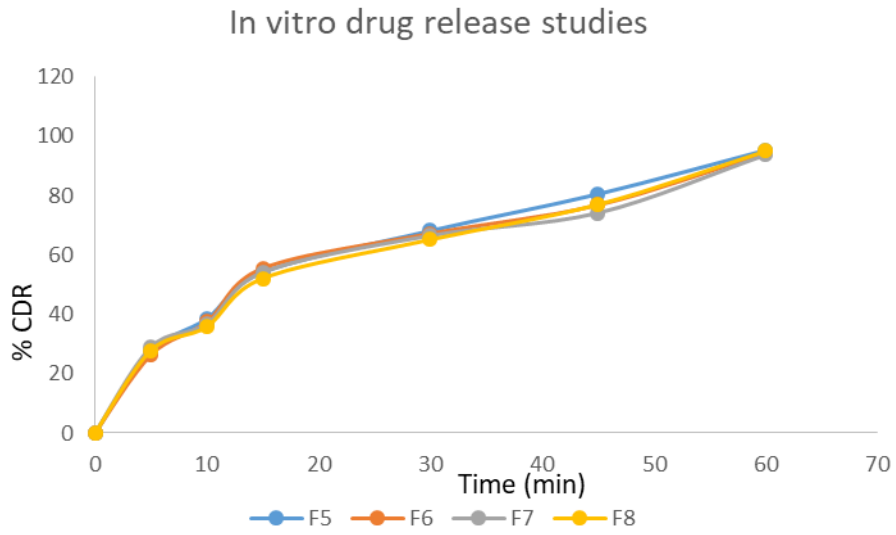

Fig 4: *In vitro* drug release studies for (F5-F8) formulation

Among all formulations, F4 shows better drug release when compared with all other formulations. So formulation F4 selected as optimized formula.

Stability studies

Table 4: Stability Studies of Optimized Formulation

S.NO	Time in days	Physical changes	Mean % drug release		
			Mouth dissolving tablet		
			25^0C/60%	30^0C/75%	40^0C/75%
1.	01	No Change	96.50±2.16	96.50±2.16	96.50±2.16
2.	30	No Change	95.50±1.84	95.46±1.58	95.51±1.79
3.	60	No Change	94.56±1.56	94.18±1.62	94.27±1.58
4.	90	No Change	93.50±1.09	93.18±1.56	93.16±1.94

There was no significant change in physical and chemical properties of the tablets of formulation F4 after 90 days, parameters like % drug release and assay values at various conditions(at 40^0C/ 75% RH) as per ICH guidelines quantified at various time intervals were shown in Table and dissolution profile.

Conclusion

The aim of the present study was to formulate and evaluate for mouth dissolving tablets containing Meloxicam. After pre-formulation studies it was decided to prepare mouth dissolving tablets prepared by direct compression method. Prior to compression the powders 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 *in vitro* drug release. In the above studies F4 formulation showed promising results. It was further supported by FTIR analysis which showed that F4 had no interaction with excipients. The stability studies were carried out for the optimized formulation for 3 months and it showed acceptable results. The kinetic studies of the formulations revealed that dissolution is the predominant mechanism of drug release. So F4 formulation was considered as the optimized formulation.

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