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Formulation and Characterization of Oro Dispersible Films of Etoricoxib (ET-ODF)

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ABSTRACT

Drug delivery by oral route is the very convenient, safe and economical. The goal of the current study is to develop oro-dispersible films of etoricoxibe to improve patient compliance and convenience for older and younger patients, ultimately leading to improved therapeutic efficacy, in comparison to typical solid oral dosage forms. Using varying concentrations of PVA, HPMC and maltodextrinealong with glycerin, sodium starch glycolate, and purified water, different batches of oro-dispersible films of etoricoxibe were prepared by the solvent casting method. The films were then assessed for appearance, weight variation, thickness, folding endurance, drug content, disintegration time, in vitro drug release and Analgesic Activity. The optimized formulation F4 (PVA, HPMC and maltodextrine) exhibited acceptable folding endurance (more than 25), least disintegration time (51±1.00 seconds), highest drug content (59±0.89) and highest drug release (98.84±0.12%) in 10 minutes. It can be concluded from the study that the Oro Dispersible Films of etrocoxibe, formulation F4 for sublingual administration can be an optimized formulation.

Keywords: *Oro Dispersible Films, Arthritis, Etrocoxibe, PVA and maltodextrine.*

1. INTRODUCTION

Oral drug delivery is the most practical, secure, and cost-effective method. For many patients, including youngsters, the elderly, and individuals with mental illnesses who have trouble swallowing tablets, there is an increasing need to improve medication compliance. For these patients, creating a rapid-disintegrating or orally-disintegrating dosage form that dissolves in the oral cavity without the need for water or chewing is a better alternative to conventional oral medication.Because the oral mucosa is more vascular (permeability of the oral mucosa is 4-1000 times more than that of the skin), it has a more permeability to many medications and serves as a best site for drug absorption[1, 2]. As per FDA definition, an oral disintegrating tablet (ODT) was defined as a solid-dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds, when placed on the tongue.[3, 4]

A thin, flexible, non-friable polymeric film containing an active medication that is intended to be placed on the tongue for quick dissolve in saliva and subsequent administration into the gastrointestinal tract is also referred to as an oro- dispersible film (ODF). Fas Oro-dispersible film has been shown in numerous clinical studies to increase bioavailability, improve patient compliance, and has an instant onset of action. Additionally, medicinal compounds with first-pass metabolism and lower oral bioavailability benefit greatly from such a delivery approach.[5-8]

Musculoskeletal disorders frequently worsen over time and are linked to significant pain and impairment. Due to missed productivity and medical expenses, these illnesses have a significant negative impact on society. The most prevalent musculoskeletal ailments in society are rheumatoid arthritis (RA), osteoarthritis (OA), and spinal disorders, particularly chronic low back pain [LBP]. Approximately 14% of all primary care visits are for musculoskeletal pain.[9-11]

In the pharmacologic treatment of pain and arthritis, nonsteroidal anti-inflammatory medications (NSAIDs), such as selective cyclooxygenase (COX)-2 inhibitors, have become crucial. With the potential benefits of simple once-daily dosing and better gastrointestinal tolerability when compared to conventional NSAIDs, Etoricoxib is an effective substitute for managing pain and arthritis[7].Various batches of Oro Dispersible Films of Etoricoxibe(ET) were prepared by using different concentration of PVA, HPMC and Maltodextrine with sodium starch glycolate, PEG 400, sodium saccharine, vanillin and purified water[6].

2. MATERIALS AND METHODS

2.1 Materials:

Etoricoxibe I.P. obtained from Yarrow chem, PVA, HPMC and Maltodextrine, Sodium Starch Glycolate (SSG), Glycerin, Disodium hydrogen phosphate and Potassium dihydrogen phosphate purchased from KIPM GIDA Gorakhpur.

2.2 Methods:

Formulation of Mouth Dissolving Films:

The solvent casting method was used to make the Oro dispersible film. In this approach, distilled water was used to prepare two aqueous solutions: one for polymers and glycerine, and the other for drug, SSG and tartrazines in specified amounts. To ensure that there were no air bubbles left, solutions I and II were combined, stirred, and left for an hour. Following the pouring of the combination solution into the petridish and allowed to dry at room temperature, the film was withdrawn from the petridish and trimmed to size (square film: 1 cm length, 1 cm width).The composition of ODFs is shown in table-1.

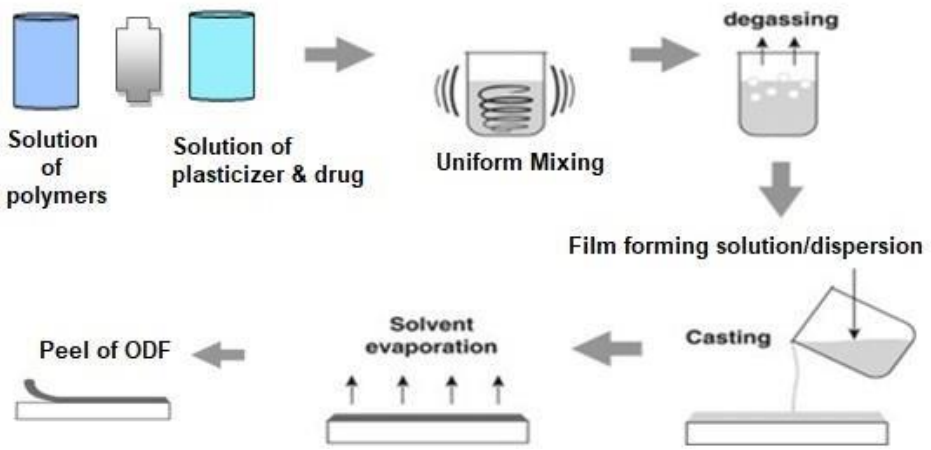


Fig-1 – Casting of Oro- Dispersible film

Table 1. Composition of ODFs using PVA, Maltodextrine and HPMC

Name of Ingredients	Quantity (in mg)								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
PVA	10	10	10	15	15	15	20	20	20
HPMC	10	10	10	10	10	10	10	10	10
Maltodextrine	10	15	20	10	15	20	10	15	20
Glycerine	6	6	6	6	6	6	6	6	6
SSG	8	8	8	8	8	8	8	8	8

3. EVALUATION OF MOUTH DISSOLVING FILMS: [12-24]

All the Oro Dispersible Films of Etoricoxibe were subjected to following quality control tests.

3.1. Physical appearance and Surface Texture

The films were subjected for determine the physical appearance and texture by visual inspection.

3.2. Weight Variation

Ten films were individually weighed using digital weighing balance. The standard deviations of weight variation were calculated.

3.3. Thickness Uniformity

The thicknesses of the films at three different points were measured by using digital caliper.

3.4. Folding endurance

The film was subjected to folding endurance by folding the film at the same place repeatedly several times until to break or visible crack was observed then calculating the number of times the film could be folded without breaking.

3.5. Drug Content

A film of size 1 cm^2 was cut and put 10 ml of volumetric flask which containing solvent. This was then shaken in a mechanical shaker for 2hrto get a homogeneous solution and filtered. The drug was determined spectroscopically at 233 nm.

3.7. Tensile Strength

Tensile strength of films was determined using an apparatus fabricated in laboratory. A small film strip (1cm^2) was cut and fixed to assembly. The weight required to break the film was noted and simultaneously film elongation was measured with the help of pointer mounted on the assembly.

Tensile strength =break force /ab (1+ $\Delta L/L$)

3.8. Percentage elongation

Determined by noting the distance travelled by pointer before break of the film on the graph paper.

% elongation = increase in length/original length X 100.

3.9. Disintegration Time

Determined manually by dipping the film in 10 ml of water in beaker with gently shaking when film was dissolved, time was noted.

3.10. In-vitro dissolution studies

The in vitro release was assessedusing USP Drug Dissolution Apparatus II (Paddle type). The oral strip (1 × 1 cm2) was fixed to rectangular glass plates to prevent it from floating throughout the test. It was then placed at the bottom of a dissolving vessel filled with 900 mL of phosphate buffer pH 6.8 at 37^0C and rotating at 50 rpm. Every one to twenty minutes, a five millilitre sample was obtained, and the same volume was replaced with brand-new buffer solution kept at 37 degrees Celsius. The samples were filtered and analyzed at 233 nmusing double beam UV/Visible spectrophotometer (Shimazdu 2008, Mumbai, India); the content of drug was calculatedusing equation generated from standard calibration curve of Etrocoxibe

3.11Evaluation of Analgesic Activity

The analgesic activity of the test solutions of Etoricoxib formulations was evaluated by tail flick test in Wistar albino rats. The experimental procedures and protocols followed in the animal studies were reviewed and approved (Proposal number KIPM/IAEC/2024/064) by the Institutional Animal Ethical Committee (IAEC) of Kailash of Pharmacy and Management, GIDA Gorakhpur, constituted in accordance with the guidelines of the CPCSEA, Government of India Registration number 1711/P0/RE/S/13/CPCSEA.

Experimental Animals

Healthy Wistar albino rats of either sex weighing 150–200 g were used for the determination of analgesic activity of etoricoxib ODF. The animals were housed comfortably in a group of five in a single clean polypropylene cage with a metal frame lid on its top. They were housed in an environmentally controlled room (temperature 24 ± 1°C; relative humidity 30–70%) under a 12-hour light/dark cycle. The animals were fed on standard pelletized laboratory animal diet and tap water ad libitum (free feeding). The animals were used after an acclimatization period of 7 days to the laboratory environment. Each rat was conditioned for 30 min in the restrainer before starting the experiment

Tail Flick Test

The ventral surface of the tail of the animal (approximately 5 cm from the caudal end of the tail) was placed on the heating coil (45° ± 2°C) of digital Analgesiometer (Rolex Pvt. Ltd., Ambala) and the basal reaction times were noted. About 3–5 basal reaction times were noted for each rat at a gap of 5 min to confirm the normal behavior of the animal.

Based on previously available literature, the dose of etoricoxib was fixed as 10 mg/kg body weight. Etoricoxib film was placed in the inner side wall of mouth cavity with the help of rodant mouth opener and commercial tablets were dissolved in purified water and calculated equivalent dose was given to albino rats orally, using syringe and feeding needle. Tail flicking response of albino rats was observed for every 05 minutes for 25 minute. As the reaction time reaches 10 sec, it was considered as maximum analgesia and the tail was removed from the source of heat to avoid tissue damage. Analgesic activity was quantified by finding out the relative increase in reaction time to the maximum response (10 sec, reaction time)

which was calculated at each time interval using the formula given below:

4. RESULT AND DISCUSSION

4.1 Formulation of Mouth Dissolving Films:

The formulated Oro Dispersible Films of Etoricoxibe are shown in figure 1.

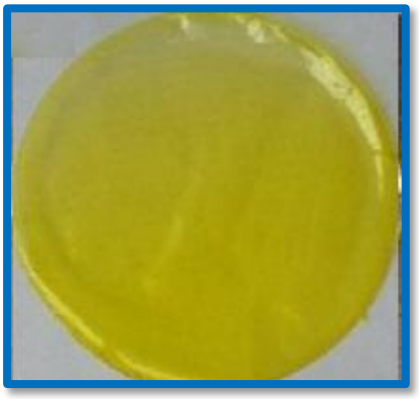


Fig 2. Formulated Oro Dispersible Films of Etoricoxib

5. EVALUATION OF MOUTH DISSOLVING FILMS:

5.1. Physical appearance and Surface Texture:

All films are clear, transparent, smooth and free from foreign materials and air bubbles with odor of vanilla.

5.2. Weight variation:

The percentage weight deviation of films between **113±0.517** was shown in table 2. The F4 formulation shows less weight variation.

5.3. Thickness uniformity:

Thickness of films was shown in table 2. The thickness of films is **1.1±0.01**

5.44. Folding Endurance:

The folding endurance of films between more than 25 times was shown in table 2. It was observed that increase the folding endurance of films when increase in concentration of the polymer.

5.6. Disintegration:

Disintegration of Oro Dispersible Films was shown in table 2. It was observed that increase the disintegration time of films, when increase in concentration of the polymer. All the formulation shows disintegration time less than 51 seconds. The F4 formulation shows least disintegration time was 45 seconds.

5.7. Drug content:

The drug content in various batches of film was shown in table 2. The B4 formulation shows highest amount of drug content was 98.33±0.982 % compared to other formulations.

5.88. In-vitro drug release:

The in-vitro dissolution in various batches of film shown in table 3. All the formulation shows drug release range from 99.02± 1.20 to 102.14±0.12%. The F4 formulation shows better drug release was 101.1±0.22 % at 10 minutes.

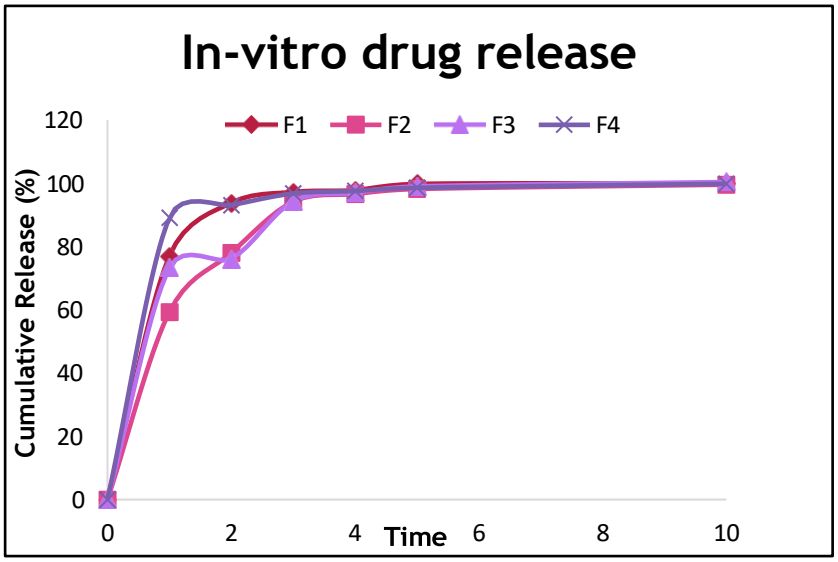
Table 2. Evaluation of ODFs using PVA, HPMC and Maltodextrine

Batches	Thickness ± SD*(mm)	Wt. Variation ±SD* (mg)	Tensile Strength ±SD*(Kg/mm²)	Folding endurance (No. of folds)	Disintegration Time (Sec)	% Elongation ±SD*	Drug Content (mg)
F1	0.91+0.0083	117±1.15	1.64±0.017	>25	55±0.531	270±1.152	54.99± 0.462
F2	0.81+0.0083	112±0.517	1.56±0.005	>25	51±0.651	280±1.124	55.0±0.842
F3	0.92+0.0070	119±1.52	1.455±0.034	>25	58±0.562	26+0±1.152	54.98±0.54
F4	1.1±0.010	113 ±0.517	2.29±0.154	> 25	51±0.556	340±1.152	59.0±0.982
F5	1.3±0.054	116±0.671	1.68±0.029	>25	55±0.861	350 ±1.541	58.1±0.541
F6	0.8±0.005	116±1.52	1.88±0.049	>25	75±0.571	370±2.882	54.95±1.154
F7	0.93±0.005	115 ±0.571	1.45±0.031	>25	80±1.05	290±2.641	54.97±2.882
F8	1.12±0.021	112±0.531	1.48±0.026	> 25	86±0.462	320±3.212	55.1±1052

Data are presented as mean ± SD (n = 3).

Table 3. In-vitro drug release of ODFs using PVA, HPMC and Maltodextrine

Time (min)	Drug Release (%)							
	F1	F2	F3	F4	F5	F6	F7	F8
0	0	0	0	0	0	0	0	0
1	77.023	59.302	73.2558	89.163	55.535	57.488	69.488	47.721
2	93.823	78.023	76.1163	93.112	65.758	78.381	89.526	78.056
3	97.284	94.233	94.3395	96.814	86.586	91.116	93.828	89.535
4	97.828	96.665	97.0419	97.609	92.13	93.307	94.828	93.637
5	99.823	98.242	99.0372	98.609	96.233	96.87	97.437	95.688
10	99.972	99.61	100.442	99.88	98.842	99.479	99.619	98.13



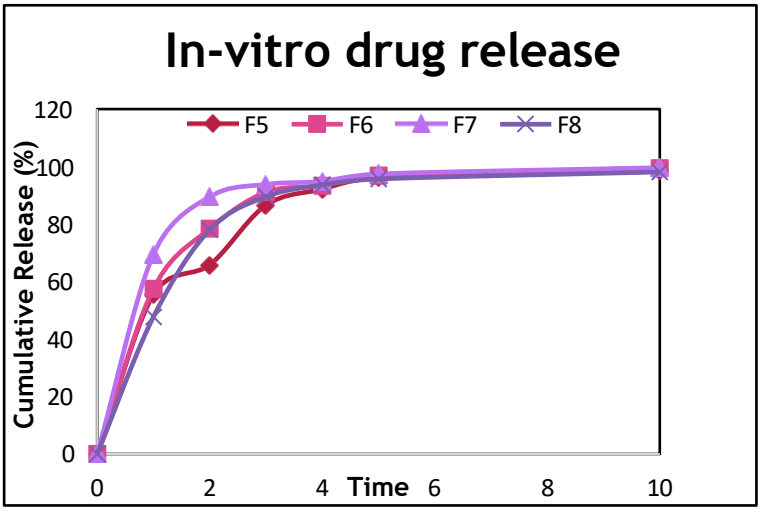


Fig 3 - In-vitro drug release of ODFs using PVA, HPMC and Maltodextrine

5.89 Evaluation of Analgesic Activity

Analgesic activity of Etoricoxib ODF was studied by tail flick test in Wistar rats. Results of tail flick test are presented in Table 4.

Table-4- Evaluation of analgesic activity by tail flick test (reaction time).

Treatment	Basal reaction time (Sec)	Reaction time (sec)				
		5 min	10 min	15 min	20 min	25 min
Control	1.26 ± 0.06	1.27 ± 0.11	1.22 ± 0.05	1.25 ± 0.09	1.27 ± 0.08	1.19 ± 0.04
Marketed IR tablet	1.44 ± 0.31	1.44 ± 0.25^{ns}	3.16 ± 0.36^{a} (20%)	8.83 ± 0.35^{b} (86%)	10.17 ± 0.04^{b} (102%)	>10 sec (>100%)

Treatment	Basal reaction time (Sec)	Reaction time (sec)				
		5 min	10 min	15 min	20 min	25 min
Etoricoxib ODF	1.26 ± 0.14	1.58 ± 0.28^{ns}	3.53 ± 0.26^{a} (26%)	8.85 ± 0.50^{b} (87%)	10.18 ± 0.16^{b} (102%)	>10 sec (>100%

The data showed that there is no significant analgesic activity for both etoricoxib ODF and commercially available immediate release tablets at 10 minutes when compared to control ($P > 0.05$). But both formulations showed significant activity at 20 min when compared to the control ($P < 0.01$). The results demonstrate the presence of drug in the dissolved state leading to immediate absorption followed by fast analgesia greater than/comparable to that of IR tablets of etoricoxib. Thus, better management of pain will be possible with the developed etoricoxib ODF.

6. CONCLUSION

In this present study reveals that all the nine formulated Oro Dispersible Films showed satisfactory film parameters. It can be concluded that, Oro dissolving film containing Etoricoxibe can be prepared by solvent casting method. All the formulations have optimum weight variation and thickness and exhibit required folding endurance and disintegration time within 51 seconds. When comparing formulation containing polymer, the formulation F4 shows least disintegration time (51±1.00 seconds), highest drug content (98.33±0.89%) and highest drug release was about 99.88±0.12 % in 10 minutes. So, it concluded as the formulation F4, is optimized formulation. Finally, it can be concluded that the optimized ODF can be a promising, easy, and cost-effective approach to improve the Etoricoxib bioavailability.

7. ACKNOWLEDGEMENT

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8. CONFLICT OF INTEREST

Authors are declared no conflict of interest.

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