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Formulation and characterization of Oro Dispersible Films of Etoricoxib using PVA and HPMC

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ABSTRACT

Oral drug delivery is incredibly practical, secure, and cost-effective. In contrast to conventional solid oral dose forms, the current study aims to create oro-dispersible films of etoricoxibe to enhance patient compliance and convenience for both younger and older patients, ultimately leading to greater therapeutic efficacy. Using varying concentrations of PVA and HPMC along 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 and in vitro drug release. The optimized formulation C4 (PVA and HPMC) exhibited acceptable folding endurance (more than 25), least disintegration time (51±1.00 seconds), highest drug content (57±0.89) and highest drug release (100±0.12%) in 10minutes. It can be concluded from the study that the Oro Dispersible Films of etrocoxibe, formulation C5 for sublingual administration can be an optimized formulation.

Keywords: *Oro Dispersible Films, Arthritis, Etoricoxib, PVA and HPMC.*

1. INTRODUCTION

The most practical, safe, and economical way to give drugs is orally. Improving medication compliance is becoming more and more important for many patients, including children, the elderly, and people with mental conditions who have difficulty swallowing medications. A better option for these patients than traditional oral medication is to develop a rapid-disintegrating or orally-disintegrating dosage form that dissolves in the oral cavity without the need for water or chewing. 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]

An oro-dispersible film (ODF) is another name for a thin, flexible, non-friable polymeric film that contains an active ingredient and is meant to be applied to the tongue for rapid dissolution in saliva and subsequent delivery into the gastrointestinal tract. 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]

Nonsteroidal anti-inflammatory drugs (NSAIDs), such as selective cyclooxygenase (COX)-2 inhibitors, have become essential in the pharmacologic management of pain and arthritis. Etoricoxib is a good alternative to traditional NSAIDs for treating pain and arthritis7 because it has the potential advantages of easy once-daily dosing and improved gastrointestinal tolerability. Different batches of Oro Dispersible Films of Etoricoxibe (ET) were made utilising purified water, sodium starch

glycolate, PEG 400, sodium saccharine, vanillin, and varying concentrations of PVA and HPMC[6].

2. MATERIALS AND METHODS:

2.1Materials:

Etoricoxibe I.P. obtained from Yarrow chem, polyvinyl alcohol (PVA), and hydroxypropyl methyl cellulose (HPMC), 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:

Solvent casting method used to make the Oro dispersible film. In this method, distilled water was used to develop two aqueous solutions: first for polymers and glycerine, and the second 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.

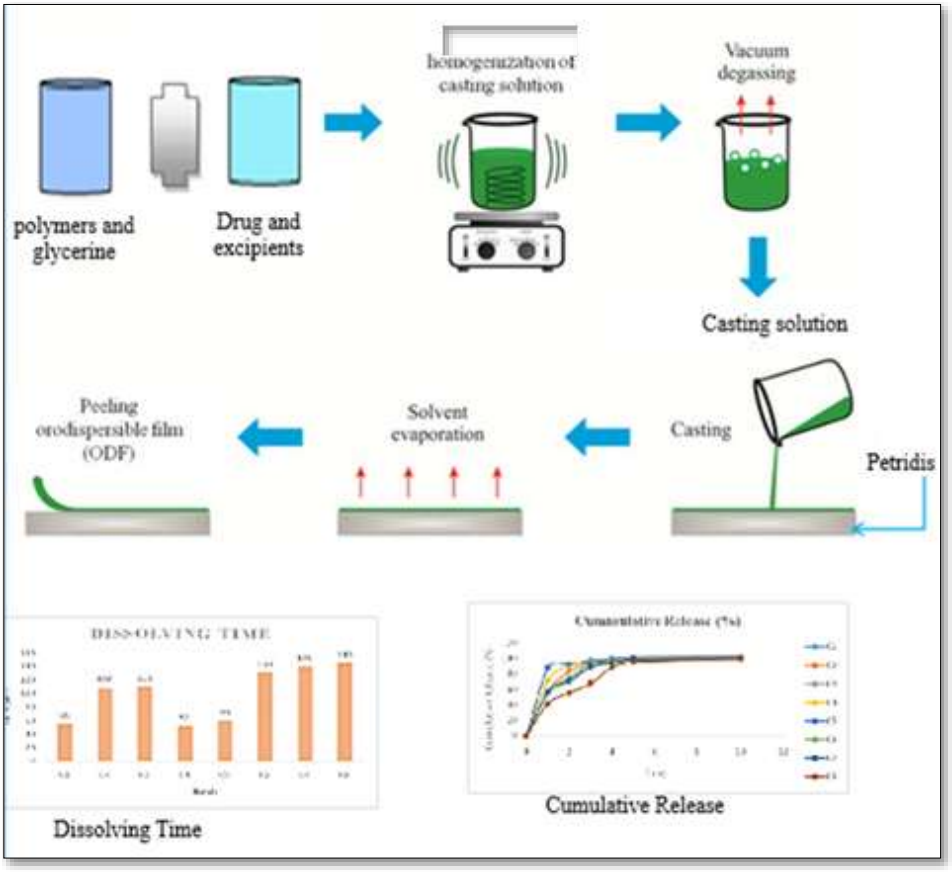

Fig-1 – Graphical Representation of Oro- Dispersible film

Table 1. Composition of ODFs using PVA and HPMC

Name of Ingredients	Quantity (in mg)							
	C1	C2	C3	C4	C5	C6	C7	C8
PVA	10	15	20	10	15	20	10	15
HPMC	10	10	10	15	15	15	20	20
Glycerin	6	6	6	6	6	6	6	6

SSG	5	10	15	10	5	10	5	10

3. EVALUATION OF MOUTH DISSOLVING FILMS: [12-25]

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

A weighing balance was used to weigh each of the ten films separately. The weight variation standard deviations were computed.

3.3. Thickness Uniformity

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

3.4. Folding endurance

In order to test the film's folding endurance, it was folded repeatedly in the same spot until it broke or a visible fracture appeared. The number of times the film could be folded without breaking was then determined.

3.5. Drug Content

A film of size 1x1 cm^2 was cut and put 10 ml of volumetric flask which containing solvent. This was then shaken in a mechanical shaker for 2 hr to get a homogeneous solution and filtered. The drug was determined spectroscopically at 233 nm.

3.7. Tensile Strength

Equipment made in a lab was used to measure the tensile strength of films. A thin strip of film (1 cm2) was cut and affixed to the assembly. A pointer installed on the assembly was used to measure the film's elongation while also noting the weight needed to break it.

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 300 mL of phosphate buffer pH 6.8 at 37^0C and rotating at 50 rpm. A five millilitre sample was taken every one to five and ten minutes, and the same volume was swapped out for fresh buffer solution that was maintained at 37 degrees Celsius. The 233 nm scanning double beam UV/visible spectrophotometer (Shimazdu 2008, Mumbai, India) was used to filter and analyse the samples. The drug content was determined using an equation derived from the standard Etrocoxibe calibration curve.

4. RESULT AND DISCUSSION

4.1 Formulation of Mouth Dissolving Films:

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

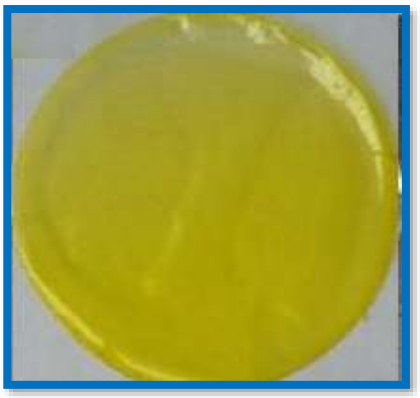

Fig 2. Formulated Oro Dispersible Films of Etoricoxib

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±0.671** 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 **1.21±0.005**

5.4. 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 59 seconds. The F5 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 F5 formulation shows highest amount of drug content was 94.89±0.982 % compared to other formulations.

5.8. 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 99.6419± 1.20 to 101.986.14±0.12%. The F5 formulation shows better drug release was 101.986±0.22 % at 10 minutes.

Table 2. Evaluation of ODFs using PVA and HPMC

Batches	Thickness ± SD*(mm)	Wt. Variation ±SD* (mg)	Tensile Strength ± SD*(Kg/mm^2)	Folding endurance (No. of folds)	Dissolving Time (Sec)	% Elongation ±SD*	Drug Content (mg)	
C1	1.1±0.010	115±1.25	1.71±0.117	>25	55	310 ±1.152	55.47	
C2	1.3±0.051	112±1.52	1.84±0.055	>25	108	370±1.124	55.7	

C3	**1.1±0.010**	**111±0.521**	**2.08±0. 034**	**>25**	**110**	**410.3±1.152**	**56.28**	
C4	**1.3±0.054**	**113±0.517**	**1.93±0.154**	> 25	**60**	**320±1.152**	**57.58**	
C5	**1.21±0.005**	**113.3±0.671**	**1.84±0.129**	**>25**	**59**	**370±1. 541**	**56.89**	
C6	**1.23±0.005**	**111±0.624**	**1.54±0.049**	**>25**	**130**	**340±2. 882**	**54.89**	
C7	**1.12±0.021**	**114±0. 641**	**2.31±0.031**	**>25**	**140**	**470±2.641**	**56.78**	
C8	**1.3±0.051**	**113±0.832**	**1.4±0.136**	> 25	**145**	**390±3.212**	**54.95**	

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

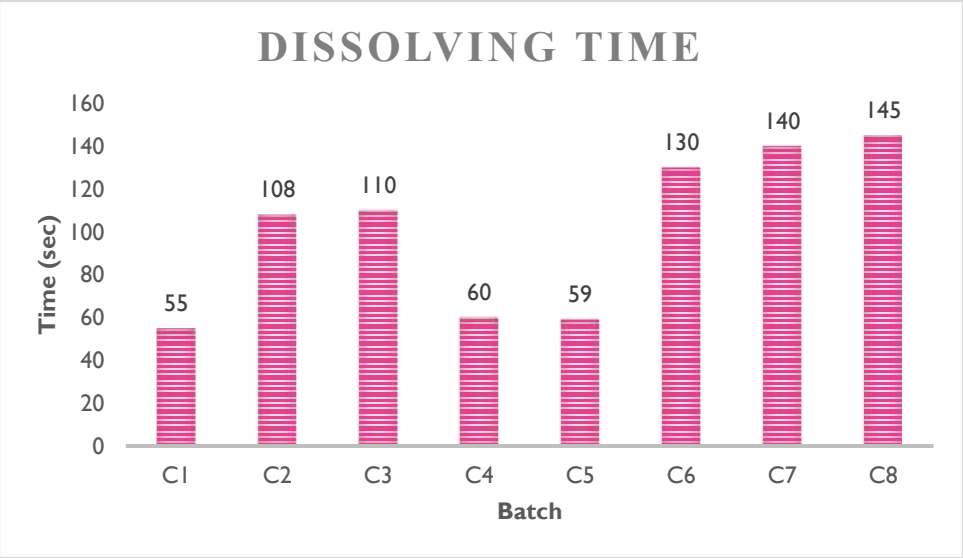

Fig-3- Dissolving Time of ODFs using PVA and HPMC

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

Time (min)	**Cumulative Release (%)**							
	C1	**C2**	**C3**	**C4**	**C5**	**C6**	**C7**	**C8**
0	0	0	0	0	0	0	0	0
1	87.7674	57.4884	55.6744	71.4419	87.4884	57.4884	55.3953	41.5814
2	92.3674	83.6837	69.6698	90.986	92.4977	75.0326	71.4744	55.386
3	96.7442	95.0605	87.5581	94.7767	96.7395	94.6326	89.9814	68.0698
4	98.3767	98.6326	94.107	98.8744	99.3488	96.4837	94.2372	88.7907
5	100.102	100.27	97.4326	100.219	101.107	97.5428	98.5395	95.3395
10	101.647	98.9302	98.6791	101.507	101.986	99.6126	99.5395	99.6419

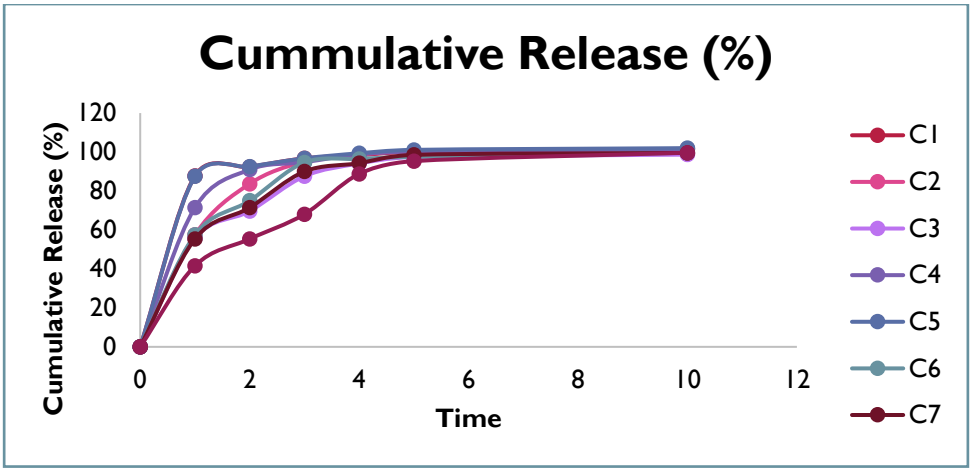

Fig 4 - In-vitro drug release of ODFs using PVA and HPMC

6. CONCLUSION

Total eight of the Oro Dispersible Films that were created in this investigation demonstrated acceptable film parameters. We may conclude that the solvent casting approach can be used to make Oro dissolving film that contains Etoricoxibe. Every formulation has the ideal thickness and weight variation, and it demonstrates the necessary folding endurance and disintegration time of 59 seconds. When comparing formulation containing polymer, the formulation F4 shows least disintegration time (59 seconds), highest drug content (98.33±0.89%) and highest drug release was about 101 % in 10 minutes. So, it concluded as the formulation F5, 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 for pain management.

7. ACKNOWLEDGEMENT

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8. CONFLICT OF INTEREST

Authors are declared no conflict of interest.

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