

FORMULATION AND EVALUATION OF FAST DISSOLVING FILM OF LORNOXICAM

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ABSTRACT

Objective: The aim of the present work was to formulate and evaluate fast dissolving film containing lornoxicam.

Materials and Methods: To prepare the film, hydroxypropyl methylcellulose E5 and polyvinyl alcohol (PVA) were used as film-forming polymers by solvent casting method. Glycerine was used as plasticizer, aspartame, and mannitol as sweetener. All prepared films were evaluated for its weight variation, disintegration time, thickness, drug content, pH, dissolution study, and folding endurance. The drug-excipients compatibility study was done using differential scanning calorimetry (DSC) and Fourier transform infrared (FTIR).

Results: Satisfactory results obtained when PVA was used as film-forming polymer, and the drug was dispersed in the polymer solution using poloxamer 407 as a solubilizing agent. Formulation F2 is considered as the optimized formulation as it showed good folding endurance (>300), faster disintegration rate (30 s), and maximum *in vitro* drug release (87%) within 5 min. DSC and FTIR studies showed no interaction between drug and the polymers.

Conclusion: It can be concluded from the study that the fast dissolving film can be prepared for poorly water-soluble drug lornoxicam using PVA as a suitable film-forming polymer.

Keywords: Lornoxicam, Fast dissolving film, Hydroxypropyl methylcellulose E5, Polyvinyl alcohol, Solvent casting method.

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INTRODUCTION

Despite so much of advancements in various delivery systems developed for the administration of various drugs through different routes such as oral, parenteral, transdermal, and nasal, the oral route is considered as the most convenient and the preferred route of administration [1]. The oral route of administration still continues to be widely used accepted route, contributing to 50–60% of total drug formulations due to ease of administration, self-medication, and pain avoidance as compared to parenteral [2]. Fast-dissolving drug delivery is rapidly gaining interest in the pharmaceutical industry. These systems either dissolve or disintegrate generally within a minute, without needing water or chewing [3]. Difficulty in swallowing (Dysphagia) is a common problem of all age groups, especially elderly and pediatrics, because of physiological changes associated with these groups of patients [4]. Fast dissolving films are very similar to ultra-thin strip of a postage stamp in their shape, size, and thickness. Fast dissolving film is simply placed on the patient's tongue or any oral mucosal tissue, instantly wet by saliva the film, and rapidly hydrates and adheres onto the site of application. It then rapidly disintegrates and dissolves to release the medication for oramucosal absorption or, with formula modifications, will maintain the quick-dissolving aspect but allow for gastrointestinal absorption to be achieved when swallowed [5].

Lornoxicam is a nonsteroidal anti-inflammatory drug (NSAID) of the oxamic class with analgesic (pain relieving), anti-inflammatory, and antipyretic (fever reducing) properties. It is available in oral and parenteral formulations. Lornoxicam inhibits the synthesis of prostaglandins through inhibition of cyclooxygenase enzyme [6]. Lornoxicam is classified as a low solubility and high permeability drug (Class II). Chemically, lornoxicam is (3E)-6-chloro-3-[hydroxy(pyridin-2-yl amino) methylene]-2-methyl-2,3-dihydro-4h-thieno [2,3-e] [1,2] thiazin-4-one 1,1-dioxide as shown in Fig. 1 [7].

The main objective of the study was to formulate and evaluate mouth-dissolving film containing lornoxicam using hydroxypropyl methylcellulose (HPMC E5) and polyvinyl alcohol (PVA) as film-forming polymers by solvent casting method.

MATERIALS AND METHODS

Materials

Lornoxicam and HPMC E5 were purchased from Wuhan Senwayer Century chemical Co., Ltd. PVA was obtained from Fine Indian chemicals. All other reagents and chemicals used were of analytical grade.

Methods

Determination of λ_{max}

The standard solution of 100 $\mu\text{g/ml}$ was scanned between 400 nm and 200 nm in ultraviolet (UV) spectrophotometer against phosphate buffer solution pH 6.8 as blank after baseline correction.

Calibration curve of lornoxicam

Accurately weighed 10 mg of drug was dissolved in 10 ml of triethanolamine 5% v/v and diluted to 100 ml with phosphate buffer solution pH 6.8 to prepare 100 $\mu\text{g/ml}$ stock solution. The prepared stock solution was further diluted to get standard solutions of 5, 7.5, 10, 12.5, 15, and 17.5 $\mu\text{g/ml}$, and the absorbance was measured at λ_{max} at 376 nm, against phosphate buffer solution pH 6.8 as blank. The standard graph was plotted by taking a concentration of drug on X-axis and absorbance on Y-axis in the concentration range of 5–17.5 $\mu\text{g/ml}$.

Calculation of dose

The dose of lornoxicam is 4 mg. Therefore, the amount of lornoxicam in a film of 4 cm^2 is 4 mg. Area of the Petri dish of 9 cm diameter is 63.64 cm^2 so that the amount of drug present to be added to the 63.64 cm^2 area of Petri dish is 64 mg.

Preparation of HPMC E5 mouth dissolving film

Five formulas were prepared using HPMC E5 by casting method as shown in Table 1. The specified amount HPMC polymer was weighed and dissolved in sufficient quantity of water. The solution was kept aside for overnight for swelling of polymer. Further required quantities of aspartame and mannitol (as sweetening agents since lornoxicam has bitter taste) were dissolved in 2 ml of hot water and added to the polymer solution under continuous stirring using magnetic stirrer. Isopropyl alcohol was used as a solvent for the drug; polyethylene glycol (PEG) 400 was added to the solution as plasticizer at a concentration 20% of dry polymer. The resulting bubble-free solution was poured onto Petri dish and kept in oven at 40°C for 24 h for drying [8].

Preparation of PVA film

Films were prepared using polyvinyl alcohol by casting method as shown in Table 2. The specified amount PVA was dissolved in sufficient quantity of water at 80°C at hot plate. Glycerin was added to the polymer solution as a plasticizer at concentration 20% of dry polymer, and the solution was sonicated for 15 min. Poloxamer 407 (act as a surfactant) was added to the polymeric solution with sonication. Further required aspartame and mannitol were added to the hot polymeric solution as sweetening agents. 64 mg of lornoxicam was dispersed in the polymer solution and sonicated for 30 min. Finally, vanilla was added as flavoring agent to the solution with sonication for 5 min. The resulting bubble-free solution was poured onto Petri dish and kept in an oven at 40°C for 24 h for drying. The film was removed from the mold and preserved in a aluminum paper and in a desiccator.

Evaluation of lornoxicam film using PVA as a film-forming agent

Appearance of films

Appearance of strip was evaluated by visual observation such as transparent and semitransparent nature of strip [9].

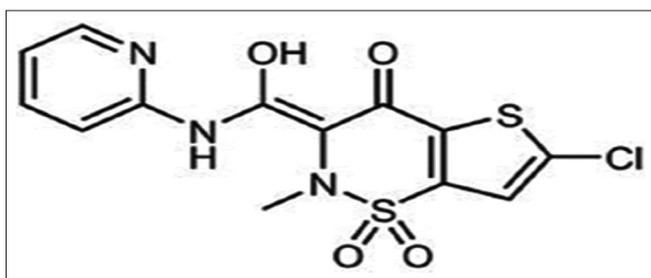


Fig. 1: Chemical structure of lornoxicam

Weight variation

10 films were randomly selected from each formulation, and the average weight variations were determined. The weight of each film was taken using digital weighing balance. The standard deviation (SD) of weight was computed from the mean value [10].

Thickness of films

The thickness of the film was measured by micrometer screw gauge (digital Vernier caliper) at five different places, at the corners, and at the center, and an average of three values and the SD were calculated. This is essential to ascertain uniformity in the thickness of the film which is directly related to the accuracy of dose in the film [11].

Folding endurance

The folding endurance was determined by repeatedly folding one film at the same place until it broke. The number of times the film folded at the same place without breaking or cracking gives the value of folding endurance and folded up to 300 times that is satisfactory to reveal good film properties [12].

Surface pH

The film to be tested was placed in a Petri dish and was moistened with 0.5 ml of distilled water and kept for 30 s. The pH was noted after bringing the electrode of the pH meter in contact with the surface of the formulation and allowing equilibration for 1 min. The average of three determinations for each formulation was taken and the SD was calculated [13].

In vitro disintegration test

Disintegration test was performed by placing the film of size 2×2 cm² in the glass Petri dish containing 10 ml of water. It was stirred at every 10s time interval. The time required for the film to disintegrate was recorded, and the results are expressed as the mean of three determinations ± SD [14].

Content uniformity

Drug content of lornoxicam films was determined by UV-spectrophotometric method. For this, one strip of 4 cm² was dissolved in 100 ml of pH 6.8 buffer; then the solution was suitably diluted, and the absorbance was recorded at 376 nm [15].

In vitro dissolution studies

In vitro dissolution of fast dissolving film was studied in USP paddle dissolution test apparatus using phosphate buffer pH 6.8 as the dissolution medium. The temperature was maintained at 37±0.5°C throughout the experiment. 5 ml sample was withdrawn at 1, 2, 3, 4, 5, 10, 15, 20, and 30 min intervals, and the same quantity was replaced with phosphate buffer of pH 6.8. The percentage of drug

Table 1: Formulation of lornoxicam films using HPMC E5

Formula	Lornoxicam (mg)	HPMC (mg)	PEG 400 (ml)	Aspartame (mg)	Mannitol (mg)	Water (ml)	Isopropyl alcohol (ml)
F1	64	750	0.15	100	100	q.s	20
F2	64	1000	0.2	100	100	q.s	20
F3	64	1250	0.25	100	100	q.s	20
F4	64	1500	0.3	100	100	q.s	20
F5	64	2000	0.4	100	100	q.s	20

HPMC: Hydroxypropyl methylcellulose, PEG: Polyethylene glycol

Table 2: Formulation of lornoxicam films using PVA

Formula	Lornoxicam (mg)	PVA (mg)	Glycerin (mg)	Poloxamer 407 (mg)	Aspartame (mg)	Mannitol (mg)	Vanilla (ml)	Water (ml)
F1	64	400	80	120	45	45	q.s	q.s
F2	64	500	100	120	45	45	q.s	q.s
F3	64	600	120	120	45	45	q.s	q.s
F4	64	700	140	120	45	45	q.s	q.s

PVA: Polyvinyl alcohol

released was determined using UV visible spectrophotometer at 376 nm [16,17].

Fourier-transformed infrared (FTIR) spectroscopic analysis

FTIR spectra of pure lornoxicam, PVA, and the physical mixture of lornoxicam and PVA at ratio (1:1) were analyzed using FTIR lambda 7600-Australia spectroscopy. FTIR spectrum was recorded between 400 and 4000 cm^{-1} by KBr disc method.

Differential scanning calorimetry (DSC)

DSC thermograms were recorded using a differential scanning calorimeter (DSC-60 plus, Shimadzu). An accurately weighed sample (2–4 mg) of pure drug, PVA, and the physical mixture of lornoxicam and PVA at ratio (1:1) was heated in hermetically sealed aluminum pans under nitrogen purge (100 ml/min) over a temperature range of 25°C–300°C at a constant rate of 10°C/min [18].

Statistical analysis

ANOVA test (one-way analysis of the variance) and student t-test were employed for statistical analysis. When $p < 0.05$, then there would be a significant statistical differences [19].

RESULTS AND DISCUSSION

λ_{max} for pure lornoxicam in phosphate buffer solution pH 6.8

100 $\mu\text{g}/\text{ml}$ sample was prepared and scanned between 200 and 400 nm. The drug showed maximum absorption at 376 nm. Hence, the λ_{max} of lornoxicam was found to be 376 nm as shown in Fig. 2.

Calibration curve of lornoxicam

Lornoxicam showed maximum absorption at wavelength 376 nm in phosphate buffer (pH 6.8) as shown in Fig. 2. Standard curve was plotted by taking absorbance of diluted stock solutions at wavelength 376 nm. A linear relationship was obtained in Beer-Lambert's plot of lornoxicam which is shown in Fig. 3.

Effect of the type of polymer as film-forming agent

HPMC is a film-forming polymer, having excellent film-forming ability, but it had not give a satisfactory results to give a good film since the drug is water insoluble and isopropyl alcohol was not efficient to solubilize the drug and the dispersion of the drug was not achieved throughout the film, while the use of PVA gave a good film that can peel from the Petri dish and the drug was dispersed homogeneously throughout the film, so PVA was used as selected film-forming polymer.

Effect of plasticizer type

Plasticizers were used to maintain the flexibility of the films, and PEG 400 was used as plasticizer in the preparation of fast dissolving film, but it noticed that it had bitter taste affecting on the palatability of the film. Glycerin was found to be better when compared to PEG 400 since it acts as plasticizer and sweetening agent.

To improve the palatability of the mouth dissolving films, the natural sweeteners and artificial sweeteners are used in combination. Lornoxicam is being bitter in taste, and taste masking was achieved by the use of sweeteners (mannitol and aspartame) and flavors such as vanilla. Mannitol was used as natural sweetener; it was expected to give good mouthfeel and cooling sensation when incorporated with other sweeteners.

Appearance of lornoxicam film using PVA as a film-forming agent

The prepared films were found to be good without any major film manufacturing defects; the film was semitransparent with yellow color since the drug has yellow to dark-yellow color as shown in Fig. 4. The surface of the film was found to be smooth; there is no sign of picking, and cracking except F1 containing 30% of PVA was sticky and excluded from the evaluation. The other prepared films F2, F3, and F4 were evaluated for post-evaluation parameters.

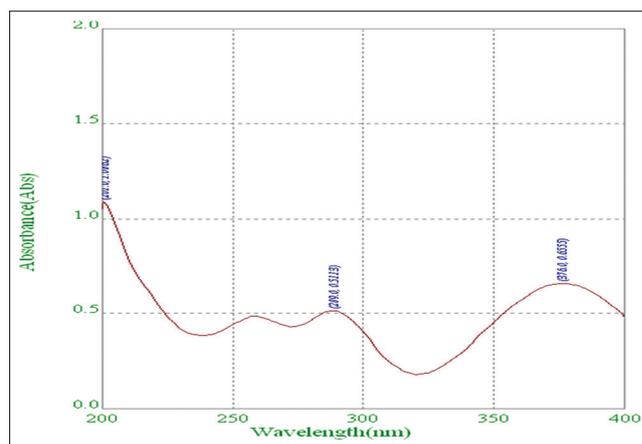


Fig. 2: Ultraviolet scan of lornoxicam in phosphate buffer solution pH 6.8

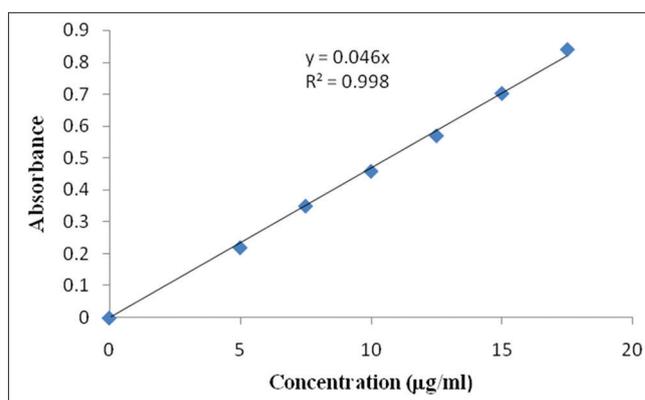


Fig. 3: Calibration curve of lornoxicam in phosphate buffer solution pH 6.8

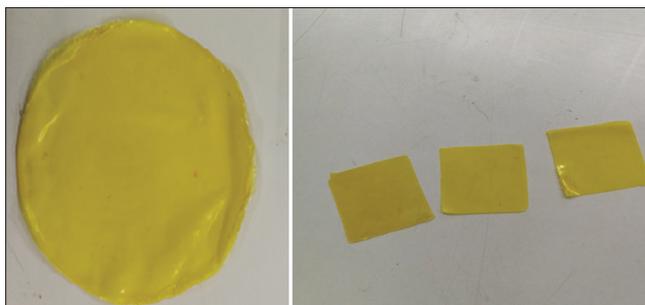


Fig. 4: Fast dissolving film of lornoxicam

Weight variations

Ten films each of 4 cm^2 were cut from the casted film, and weight variation was determined. Weight variation varies from 80.46 ± 2 to 91.44 ± 3 mg. The result of weight variation is shown in Table 3.

Thickness

As all the formulations contain different amount of polymers, the thickness was gradually increased with the amount of polymers. The thicknesses of formulated films were found to be in range of 0.071–0.114 mm. The results are given in Table 3 which shows a gradual increase in the thickness.

Folding endurance

Brittleness of the film was determined through the folding endurance. It measures the ability of the film to withstand rupture. Any formulated

Table 3: Evaluation of physicochemical parameters of fast dissolving film of lornoxicam

Formula	Weight variation (mg)	Thickness (mm)	Folding endurance	pH	Disintegration time (s)	Drug content (%)
F2	82.9±1	0.081±0.02	>300	6.76±0.12	30.3±3	95±1
F3	80.46±2	0.071±0.013	>300	6.7±0.1	41±3	112±0.43
F4	85.1±3	0.114±0.016	>300	6.57±0.21	52±3.6	96±0.1

The values represent mean ± standard deviation, n=3

Table 4: *In vitro* dissolution studies of lornoxicam from F2 to F4

Time (min)	F2	F3	F4
0	0	0	0
1	7.16±0.08	11.8±0.7	9±0.03
2	25±0.09	13.5±0.3	9±0.06
3	51.5±0.02	20.3±0.06	22±0.4
4	77±0.04	29±0.07	36±0.1
5	87±0.1	40±0.5	50±0.03
10	95±0.045	66±0.021	76±0.05
15	98±0.2	77.5±0.05	82±0.06
20	99±0.3	80±0.04	87±0.063
30	100±0.4	87±0.2	93±0.09

All values expressed as mean ± SD (n=3), F: Formula, SD: Standard deviation

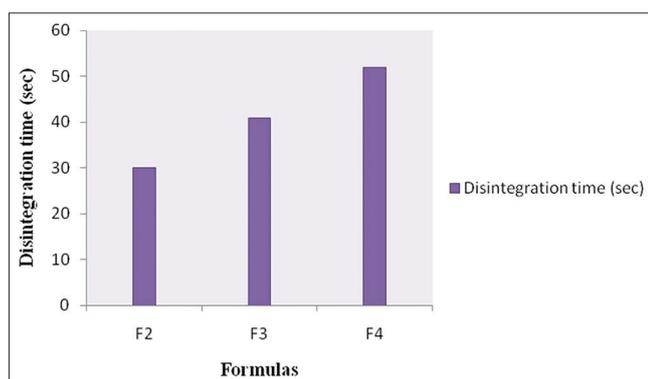


Fig. 5: Disintegration time of lornoxicam film

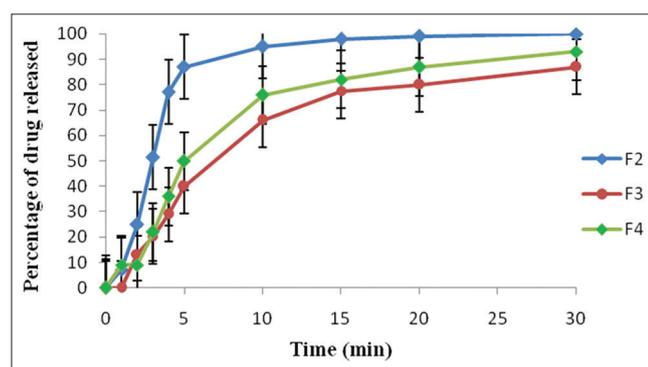


Fig. 6: Dissolution profile of lornoxicam film F2, F3, and F4. All values expressed as mean ± standard deviation (n=3), F = formula

film has a folding endurance value; a value more than 300 indicates acceptable results [19]. Glycerin acts as a plasticizer because it is capable to decrease the glass transition temperature. Lowering the glass transition temperature increases chain mobility and this, in turns, increases in folding endurance [1]. The folding endurance of all the formulations was >300, and the results are given in Table 3.

pH surface evaluation

Test the pH of the surface of oral film needs to be done to investigate the risk of side effects. Acidic or basic pH may cause disturbance in

the oral mucosa and impact the rate of hydration of the polymers, so it is important to maintain the pH remains close to neutral pH. From Table 3, it can be seen that the film has a near neutral pH which is in the range of 6.57–6.76. Hence, the dosage has a very small probability to irritate the oral mucosa [20].

In vitro disintegration time

It was observed that *in vitro* disintegration time varies from 30.3±3 to 52±3.6 s for the three formulations as demonstrated in Table 3 and Fig. 5. *In vitro* disintegration time of lornoxicam film containing PVA as polymer was affected by the thickness of the film, and as the amount of polymer increases [21], the disintegration time was increased significantly ($p < 0.05$) by increasing the concentration of the polymer as in F3 and F4 that contain 50% w/w and 55% w/w of PVA, respectively, while the disintegration time for F2 (40% of PVA) was the lowest. This can be explained as the higher concentration of the polymer, the thicker gel will produce on contact with the media, which require a longer time to disintegrate [19].

Content uniformity evaluation

Content uniformity test performed to ensure that all films contain a uniform weight of drug as desired. Content uniformity is determined by estimating the active ingredient contained in each film. Limit of content uniformity is 85–115% with a SD which must be ≤6% [22]. From Table 3, it can be seen that the levels of drug in the film range between 95% and 112%. It showed that levels of drug in oral film fulfill the limit of content uniformity.

In vitro dissolution study

The *in vitro* drug release from film of the three formulations was performed in triplicate using USP apparatus II (paddle method). Dissolution study was performed in pH 6.8 phosphate buffer; the release profile was demonstrated in Fig. 6 and and Table 4 shows the percentage of drug being dissolved in 30 min. In case of F2 that contains 40% of PVA formulation, about 87% of drug was released in 5 min and was considered as the best formulation. While in case of F3 and F4, containing 50% and 55% w/w of PVA, respectively, formulations about 40% and 50% of drug released, respectively, in 5 min. This drug release pattern indicates that the increased concentration of polymer decreases the drug release.

FTIR study

The FTIR spectrum of lornoxicam (Fig. 7) has a characteristic peak at 3066 cm^{-1} corresponding to -CH stretching of heteroaromatic ring, and sharp peak obtained at 1646 cm^{-1} represents the stretching vibration of C=O in structure of primary amide. Other peaks were observed at 1595 and 1549 cm^{-1} and were assigned to bending vibrations of the N-H group in the secondary amide. The stretching vibrations of the O=S=O and C-S groups appeared at 1326 cm^{-1} and 1425.46 cm^{-1} , respectively. Other prominent peaks was appeared at 869.74 cm^{-1} corresponding to -CH aromatic ring bending and heteroaromatics and at 790.67 cm^{-1} due to the C-Cl bending vibration. C-N stretching was observed at 1084.51 cm^{-1} . The presence of all these groups shows similarity with actual drug structure which indicates the purity of drug substance [23].

The most characteristic band of PVA (Fig. 8) and its respective assignments is observed at 3423 cm^{-1} and is ascribed to the O-H stretching from the intermolecular and intramolecular hydrogen bonds. The characteristic peaks of lornoxicam were still present in the physical mixture of drug and PVA (Fig. 9) at a ratio of 1:1, indicating no chemical interaction between the drug and polymer.

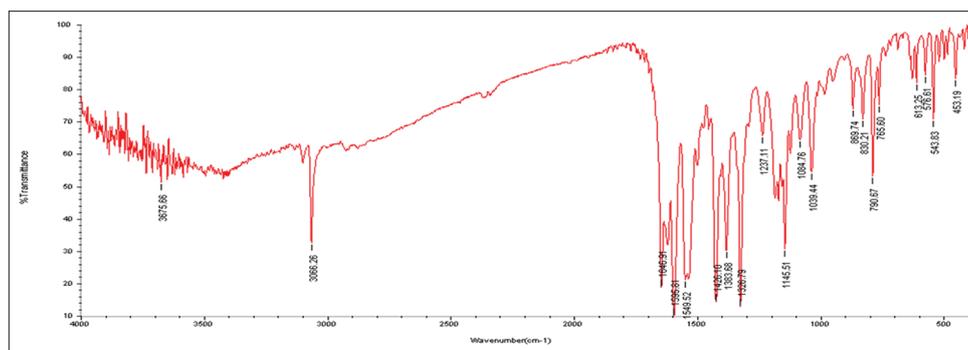


Fig. 7: Fourier transformed infrared spectrum of lornoxicam

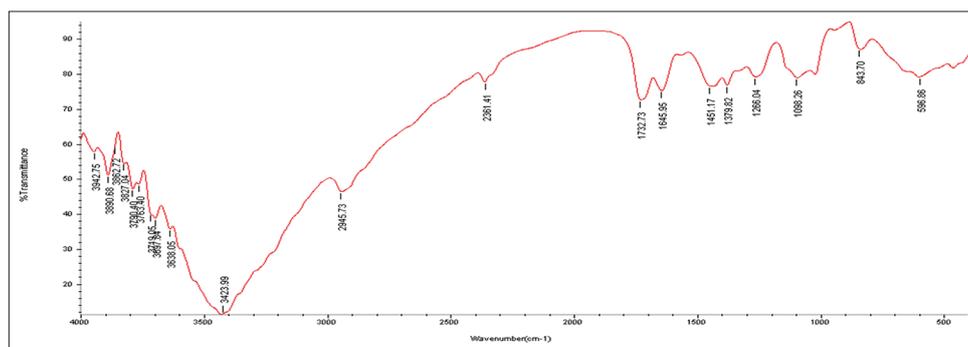


Fig. 8: Fourier transformed infrared spectrum of polyvinyl alcohol

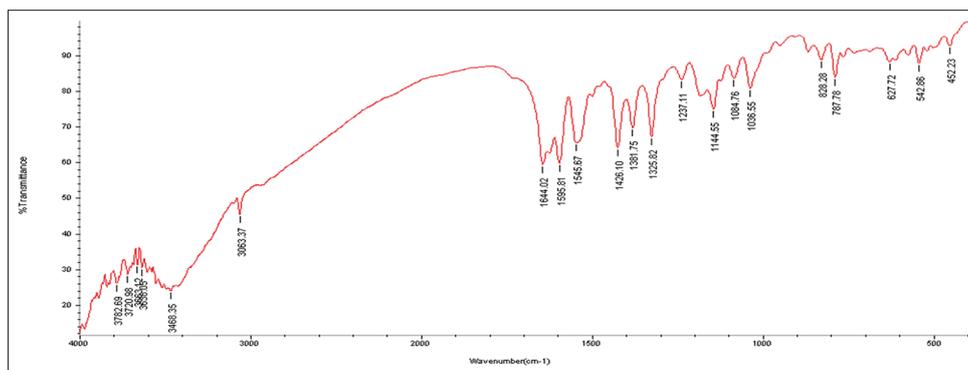


Fig. 9: Fourier transformed infrared of physical mixture of lornoxicam and polyvinyl alcohol at ratio (1:1)

DSC

DSC curves of lornoxicam, PVA, and physical mixture of lornoxicam and PVA at ratio (1:1) were obtained and shown in Figs. 10-12, respectively. Pure lornoxicam showed a sharp exothermic peak at 220°C which corresponds with the range of melting point of lornoxicam (220–230°C), and the sharp intense exothermic peak indicates the crystalline nature of drug [24,25].

The DSC curve of physical mixture showed a sharp endothermic peak at 224°C corresponding to melting point of lornoxicam and the exothermic peak of PVA at 191°C indicating that there is no interaction between lornoxicam and PVA.

CONCLUSION

In the present research work, an attempt has been made to prepare mouth dissolving films of lornoxicam which is NSAID, water-insoluble with bitter taste. The fast dissolving films of lornoxicam were prepared by solvent casting method using film-forming polymer PVA and glycerol

as plasticizer. Based on the *in vitro* disintegration time and dissolution profile, formulation F2 was found to be promising and showed a disintegration time of 30 s and 87% of drug released in 5 min.

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AUTHORS' CONTRIBUTION

The three authors contributed equally to this work.

CONFLICTS OF INTEREST

The authors report no conflict of interests and are responsible for the content and writing of this article.

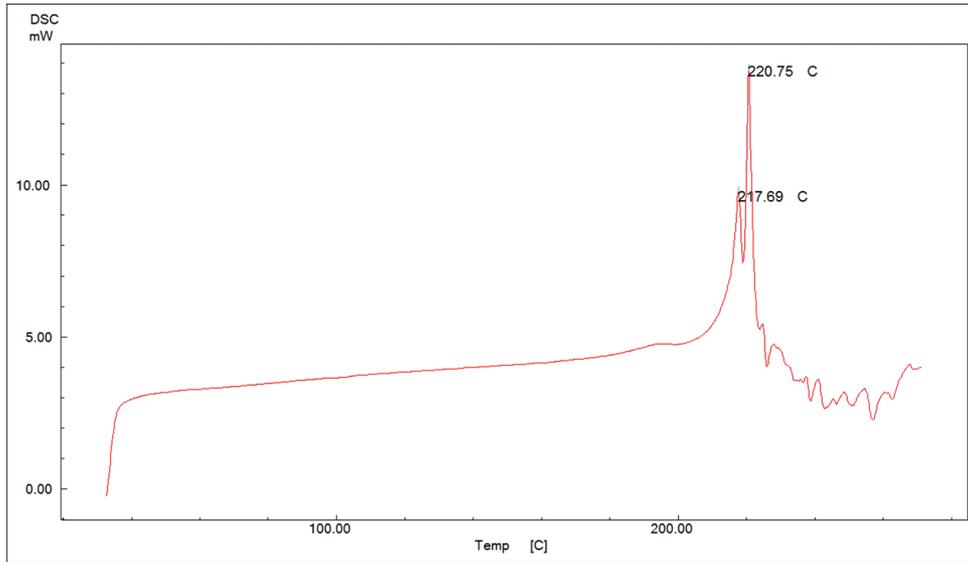


Fig. 10: Differential scanning calorimetry of lornoxicam

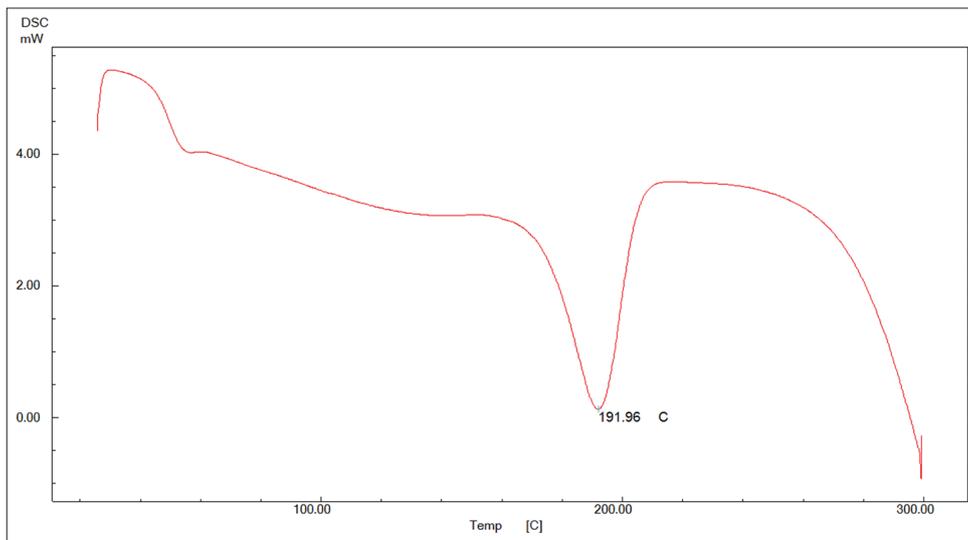


Fig. 11: Differential scanning calorimetry of polyvinyl alcohol

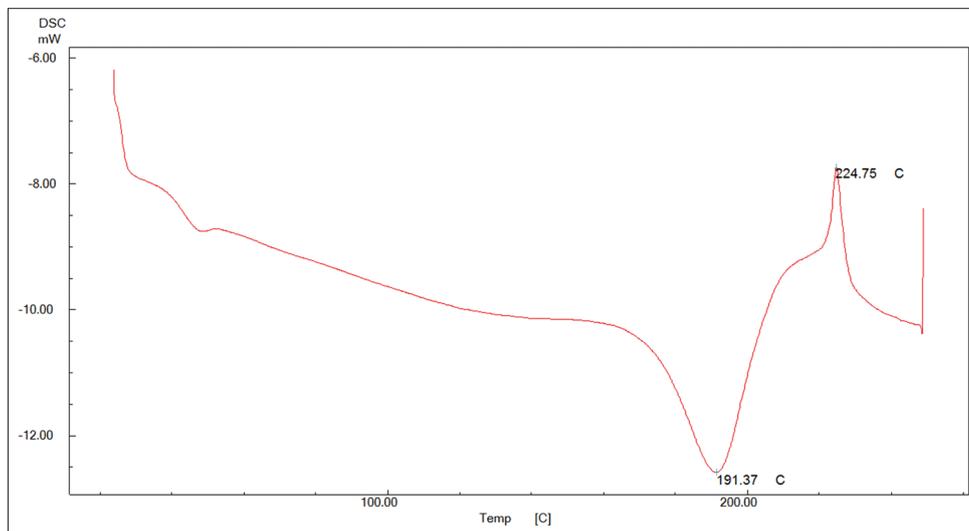


Fig. 12: Differential scanning calorimetry of physical mixture lornoxicam and polyvinyl alcohol

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