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Original Article

Influence of Natural Polymers on Zolmitriptan Oral Fast Dissolving Film Formulations: A New Approach to Migraine Treatment

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ABSTRACT

Introduction: The main purpose of zolmitriptan fast-dissolving films aims to deliver zolmitriptan effectively alongside quick action for migraine therapy through a user-friendly dosage method. Fast dissolving films dissolve rapidly in the mouth through a waterless process to offer convenient treatment to people with swallowing problems along with patients enduring nausea or vomiting while experiencing migraine attacks. **Materials and Methods:** Zolmitriptan oral films with fast dissolution capability were formulated through a combination of Gum Karaya and Gum Olibanum as natural film-forming agents. Glycerin acted as a plasticizer together with the stabilizing agents which included citric acid and stevia powder. Production of these films occurred through the solvent casting technique. **Results and Discussion:** Researchers developed Zolmitriptan fast-dissolving films through oral administration which received evaluation regarding weight consistency and drug content along with film thickness and folding strength evaluation. The experimental findings matched the required values. The Franz diffusion cell apparatus served to conduct *in vitro* diffusion tests that utilized 6.8 pH phosphate buffer as the dissolution solution Zolmitriptan fast-dissolving films containing Gum Karaya and Gum Olibanum the drug release reached 98.99% in 5 min. The combination of Gum Karaya and Gum Olibanum improved film features by increasing solubility and dissolution rate and tensile strength beyond individual use of each gum. The pure drug and optimized formulation product Z7 showed transparent spectra through FTIR investigation which proved that the drug material did not interact with the optimized formulation. DSC analysis of pure drug with Gum Karaya and Gum Olibanum and optimized formulation (Z7) showed no physical changes or chemical degradation of drug substance or polymers or formulation components during testing. This proved overall stability of the optimized formulation.

Keywords: Zolmitriptan, Oral fast dissolving films, Solvent casting method, Polymers and plasticizers.

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INTRODUCTION

The oral dosage forms Fast-Dissolving Films (FDFs) dissolves swiftly in the mouth without requiring hydration and provides an advanced drug delivery solution that is convenient for use. Such films manufacturers create them to dissolve rapidly when put in the oral cavity since exposure to saliva triggers their decomposition. This process makes way for absorption of the active pharmaceutical ingredient through oral membrane tissue. Fast-dissolving films enable drug delivery to patients who need their medication to become rapidly effective because they have challenges with regular tablet or capsule swallowing especially when patients are elderly or pediatric or dysphagic (Vidyadhara *et al.*, 2013). The drug reaches the bloodstream quicker through oral mucosal absorption than standard oral formulations since it skips the gastrointestinal tract as well as liver first-pass metabolism (Vidyadhara *et al.*, 2015). FDFs demonstrate their strongest application in delivering drugs which need immediate therapeutic action through cases involving pain relief or treatment against nausea and acute diseases like migraines (Balakrishna *et al.*, 2016). HPMC together with PEG joins Gum Karaya and

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Gum Olibanum as prevalent film-forming components. Glycerin serves as a plasticizer to eliminate brittleness including citric acid which combines with flavoring elements like stevia to boost patient acceptance. This emerging technology increases in popularity for therapeutic uses which results in better patient behavior and enhanced medical outcomes. Fast-dissolving films containing zolmitripan (Juluru *et al.,* 2013). successfully produced results showing that more than 90% of the medication released through the film within 10 min. Zolmitriptan dissolves at a quick rate through skin membranes which leads to better therapeutic outcomes than standard oral tablets. The materials exhibited better tensile resistance that allowed them to endure physical contact but quickly disintegrated after application. Several additional excipients including stevia for sweetness and citric acid for stabilization both enhanced the taste of films and boosted their stability mechanism and patient usage acceptance. Zolmitriptan shows increased bioavailability when using natural gums such as Gum Karaya and Gum Olibanum due to elevated solubility and dissolution rate as film-forming agents according to research studies.

MATERIALS AND METHODS

Zolmitriptan originated at M/S Aurobindo Pharma Ltd., Hyderabad as a free product sample. The suppliers SD Fine Chem Ltd., located in Mumbai provided both Gum Karaya and Gum Olibanum. The supplier SD Fine Chem Ltd., Mumbai distributed both Glycerin and Citric acid.

Preparation of Zolmitriptan oral fast dissolving films

The preparation of fast-dissolving oral thin films of Zolmitriptan utilized the solvent casting method. Different 100 mL beakers contained individually dissolved film-forming polymers from Gum Karaya and Gum Olibanum using alcoholic solutions to produce see-through solutions. The chemical mixture started with weighing Zolmitriptan and citric acid and stevia powder together in the alcoholic solution followed by complete mixing to obtain an even mixture. The solution mixture received non-adhesive base plate treatment before exposure to infrared lamp curing for 24 hr (Balakrishna *et al.,* 2017). The researchers cut the dried films into their intended dimensions. Researchers performed several trials in order to develop the best formulation design for Zolmitriptan oral fast-dissolving films. The following is the final composition of Zolmitriptan fast-dissolving oral films. The film compositions appear in Table 1 along with their specifications.

Evaluation of physical parameters for Zolmitriptan oral fast dissolving films

The evaluation of Zolmitriptan oral fast dissolving films included physical measurements for weight uniformity, drug content, film thickness and folding endurance. The obtained findings are displayed in Table 2.

Weight Uniformity

Weighing the film uniformity happens manually through the use of digital electronic balance.

Uniformity of Drug Content

Drug content uniformity testing of the films used an UV spectrophotometric method by measuring their absorbance at 283 nm (Balakrishna *et al.,* 2018). The drug content percentage assessment of different films appears in Table 2.

Film Thickness

Researchers used a screw gauge with 0.01 mm least count measurement to measure the film thickness in different spots of the product. The average weight determination used measurements taken at three different points of the film to compute final values. The experimental findings appear in Table 2.

Folding Endurance

The researchers measured folding endurance by making multiple folds in the same film area at one spot using a tiny strip of film until it cracked. The recorded number became the folding endurance value. The research method involved folding the film from 1800° in the same spot until it broke either by excessive bending or after 100 repeated folds (Balakrishna *et al.,* 2018). The researchers finished the tests within a proper time frame while calculating the average mean.

Dispersion Test

Drug equivalent to 10 mg was placed into 200 mL of pH 6.8 phosphate buffer solution while stirring with a glass rod for 3 min before filtering the solution through a mesh with 22 mesh opening. The test was considered valid after determining that no residue remained on the mesh.

In vitro diffusion studies

The Franz diffusion cell apparatus evaluated all Zolmitriptan oral fast dissolving films through diffusion tests which used pH 6.8 phosphate buffer as the dissolution media. The dissolution tests covered a time period of 15 min for every formulation. The dissolution tests executed three times affirmed the sink conditions remained constant for all drug solutions. The experiments used spectrophotometry at 283 nm to analyze filtered aliquot samples obtained from regular time measurements (Balakrishna *et al.,* 2022). The *in vitro* drug release profiles of all film formulations appeared in Figure 1.

Evaluation of various *invitro* dissolution parameters

The researchers measured dissolution parameters T50, T90, DE5% and first order rate constant using obtained dissolution data which they reported in Table 3.

Characterization of Zolmitriptan oral fast dissolving films

Selection of optimized formulations relied on diffusion study results from all developed formulations. An investigation through characterization studies occurred after selection of the optimized formulation and its components including pure drugs and polymers.

Fourier-Transform Infra Red Spectroscopy (FTIR)

The drug-carrier bond investigation occurred through FTIR spectrum analysis of Z7 formulation and zolmitriptan samples using a Bruker FTIR spectrophotometer. A mixture of two milligram drug with 200 milligram KBr powder resulted in the formation of the sample discs for analysis. Measurement of spectra occurred under 400-4000 cm^{-1} range and with 4 cm^{-1} resolution. The FTIR spectra present information throughout Figures 2 and 3.

Differential Scanning Calorimetry (DSC)

The DSC 60 (Shimadzu) obtained heat uptake rates through DSC curves for Zolmitriptan samples. Ten milligrams of the sample received weight measurement in standard open aluminum pans before which the device scanned temperatures between 20 and 300°C at a rate of 10°C/min while running under dry nitrogen purging. The DSC analysis included pure drug zolmitriptan as well as Gum Karaya and Gum Olibanam and the optimized formulation Z7. The obtained DSC thermograms appeared in Figures 4-7.

RESULTS

Preparation of Zolmitriptan oral fast dissolving films

This research aimed to develop Zolmitriptan oral fast disintegrating films through solvent casting techniques to obtain better dissolution and disintegration behavior together with enhanced bioavailability for poorly soluble Zolmitriptan drug. The research selected Gum Karaya and Gum Olibanum as film forming agents together with Glycerin as plasticizer and stevia powder and Citric acid for stabilizing the composition (Juluru *et al.*, 2013). The production of Zolmitriptan Oral fast dissolving films involved maintaining drug concentration steady and incrementing film forming agent concentration through solvent casting method. The Table 1 demonstrates the composition information about Zolmitriptan Oral fast dissolving films.

Evaluation of physical parameters for Zolmitriptan Oral fast dissolving films

Testing of weight uniformity together with drug content and film thickness and folding endurance occurred for every Zolmitriptan oral fast dissolving film. All Zolmitriptan oral fast dissolving films made with Gum Karaya and Gum Olibanum showed weight consistency between 105 to 202 mg. Each Zolmitriptan oral fast dissolving film checked for drug content showed values ranging from 3.4 to 5.2 mg. This result proves that the drug distribution

Table 1: Composition of Zolmitriptan oral fast dissolving films.

Ingredients (w/w)	Z1	Z2	Z3	Z4	Z5	Z6	Z7
Zolmitriptan (mg)	5	5	5	5	5	5	5
Gum Karaya (mg)	100	150	200	-	-	-	100
Gum Olibanum (mg)	-	-	-	100	150	200	100
Glycerin (mL)	2	2	2	2	2	2	2
Citric acid (mg)	2	2	2	2	2	2	2
Stevia Powder (mg)	1	1	1	1	1	1	1
Ethanol (mL)	QS	QS	QS	QS	QS	QS	QS

Table 2: Evaluation of physical parameters for Zolmitriptan oral fast dissolving films.

Formulation	Weight Uniformity (mg)	Drug Content (mg/film)	Film Thickness (mm)	Folding Endurance (no)	Dispersion Test
Z1	105	3.4	0.031	95	Passed
Z2	150	4.0	0.031	98	Passed
Z3	201	4.7	0.030	99	Passed
Z4	106	3.7	0.032	97	Passed
Z5	151	4.8	0.031	98	Passed
Z6	201	4.9	0.032	99	Passed
Z7	202	5.2	0.033	102	Passed

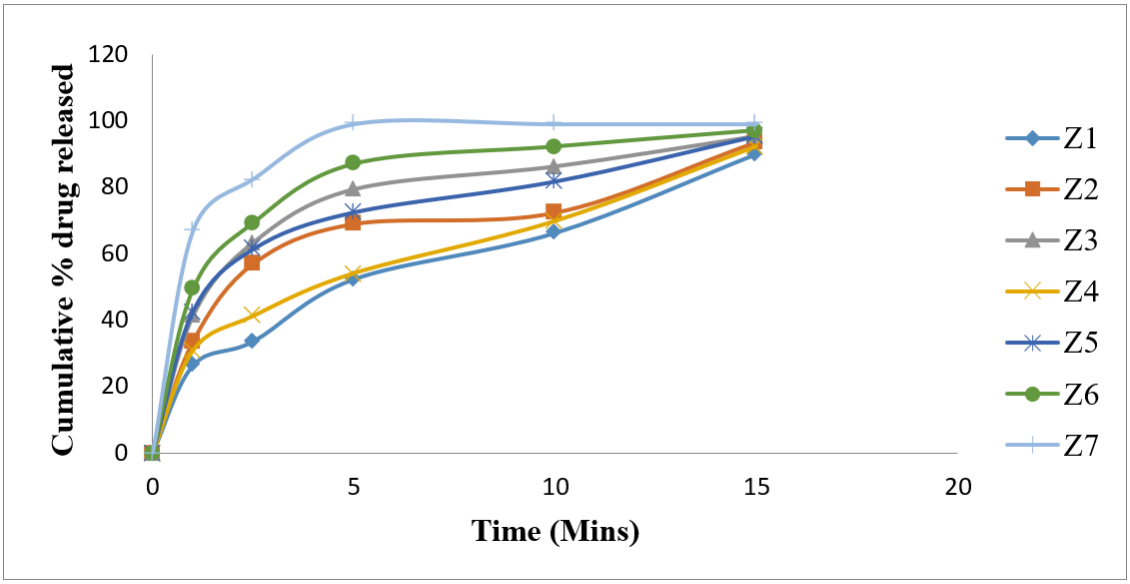

Figure 1: *Invitro* drug release profiles for Zolmitriptan oral fast dissolving films.

Table 3: Evaluation of *in vitro* Dissolution Parameters for Zolmitriptan oral fast dissolving films.

Sl. No.	Formulation	T_{50} (min)	T_{90} (min)	$DE_{5\%}$	First order	
					K (min^{-1})	R^2
1.	Z1	5.2	15	24.5	0.214	0.977
2.	Z2	3.2	14.2	23.1	0.210	0.952
3.	Z3	2	13.5	22.6	0.206	0.941
4.	Z4	4.8	14.0	23.6	0.210	0.980
5.	Z5	2.5	13.7	21.4	0.205	0.950
6.	Z6	1.5	9.6	20.8	0.201	0.933
7.	Z7	1.1	4.0	14.5	0.200	0.982

remains constant throughout all formulations. Each Oral fast dissolving film had a film thickness ranging between 0.030±0.034 mm (Banarjee *et al.*, 2015). All Oral fast dissolving films demonstrated suitable stability based on their folding endurance which ranged between 95 to 102 folds. This indicates the Oral fast dissolving films exhibit strong tensile capabilities. The dispersion examination for all prepared films delivered positive results. Table 2 displayed the test outcomes for the weight uniformity as well as drug content and film thickness and folding endurance parameters (Tomar *et al.*, 2012).

Invitro diffusion studies of Zolmitriptan oral fast dissolving films

Researchers performed diffusion studies with the Zolmitriptan Oral fast dissolving films through direct examination using Franz diffusion cell apparatus filled with pH 6.8 phosphate buffer as dissolution solution. The Z1-Z3 Zolmitriptan oral fast dissolving films containing Gum Karaya released 90.12% to 95.36% of drug within 15 min. The average drug release from Zolmitriptan oral fast dissolving films Z4-Z6 using Gum Olibanum reached 92.36 to 97.25% in exactly 15 min (Patel *et al.*, 2018). When preparing Z7 optimized formulation using Gum Karaya and Gum Olibanum together the drug release measured 98.99% during 5 mins. Only the all the prepared formulations were evaluated against each other. The *in vitro* drug release profiles appeared in the Figure 1.

Evaluation of various *invitro* dissolution parameters

The T_{50} and T_{90} for Zolmitriptan oral fast dissolving films Z1-Z3 containing Gum Karaya required a disintegration period of 5.2 to 2 mins and 15 to 13.5 mins. The T_{50} and T_{90} Zolmitriptan oral fast dissolving films Z4-Z6 that incorporated Gum Olibanum required between 4.8 to 1.5 min and 14 to 9.6 mins until 50% drug release was achieved. The T_{50} and T_{90} of Optimized formulation Z7 reached 1.1 mins and 4.0 mins when created from both Gum Karaya and Gum Olibanum. First-order release rates characterized all film formulations while the determination coefficient values ranged from 0.933 to 0.982. All drug release rates emerged directly from the film formulations while exhibiting first-order release rate constants K1 (Shendge *et al.*, 2020). The

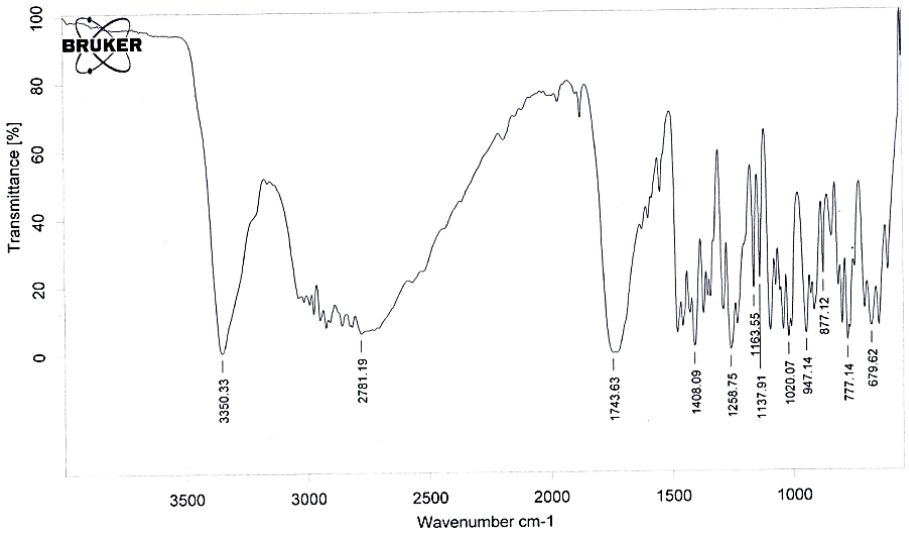

Figure 2: FTIR Spectrum of Zomitriptan Pure Drug.

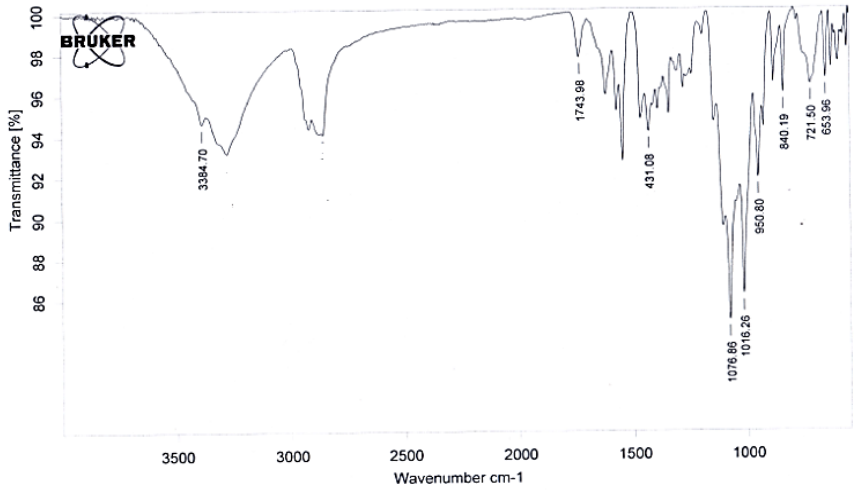

Figure 3: FTIR Spectrum of Optimized formulation (Z7).

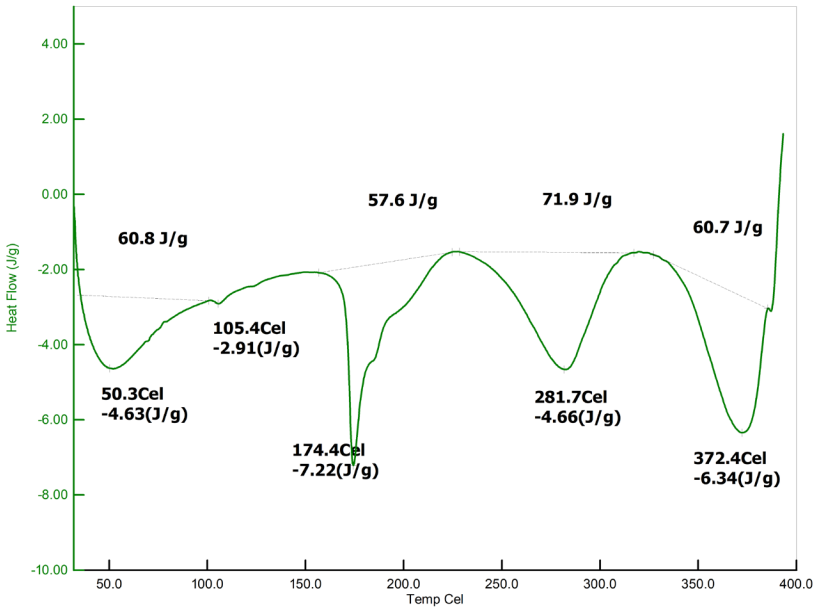

Figure 4: DSC Thermogram of Pure drug Zolmitriptan.

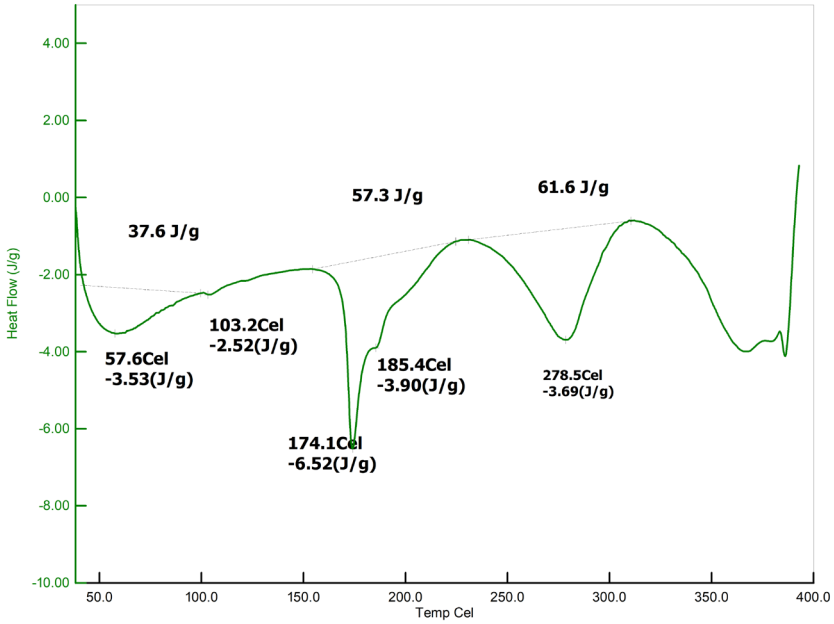

Figure 5: DSC thermogram of Gum Karaya.

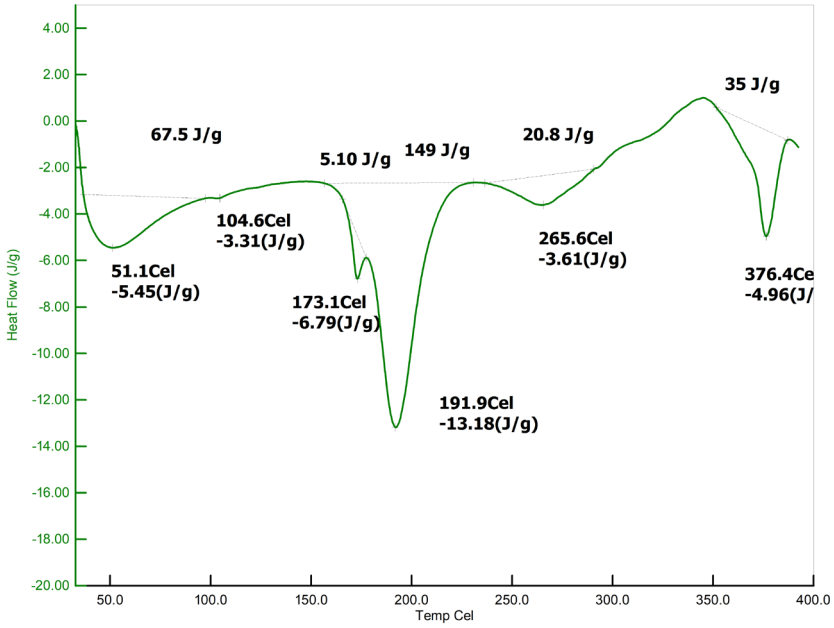

Figure 6: DSC thermogram of Gum Olibanam.

physical parameter evaluation results for Zolmitriptan Oral fast dissolving films appeared in Table 3.

Fourier-Transform Infra Red (FTIR) Spectroscopic Analysis

The main absorption peaks in Zolmitriptan FTIR spectra appeared at 3122 cm-1 (N-H Stretching) and 1799 cm-1 -C=O-Stretching. All principle peaks linked to Zolmitriptan pure drug appeared in the FTIR spectra of optimized formula Z7. Analysis through spectra peaks showed no changes indicating that the drug did not interact chemically with the employed polymer (Mahajan *et al.,* 2012). FTIR spectra provided information about the drug and optimized formulation Z7 were showed in Figures 2 and 3.

DISCUSSION

Zolmitriptan, a selective serotonin receptor agonist, is also known as the common drug used in the acute treatment of migraine. Rapid onset action required in therapy for migraine makes Oral Fast Dissolving Film (OFDFs) a perfect dosage form because of ease of administration, rapid disintegration and increased bioavailability levels. In this study, zolmitriptan OFDFs were prepared using individual natural polymers (Gum Karaya and

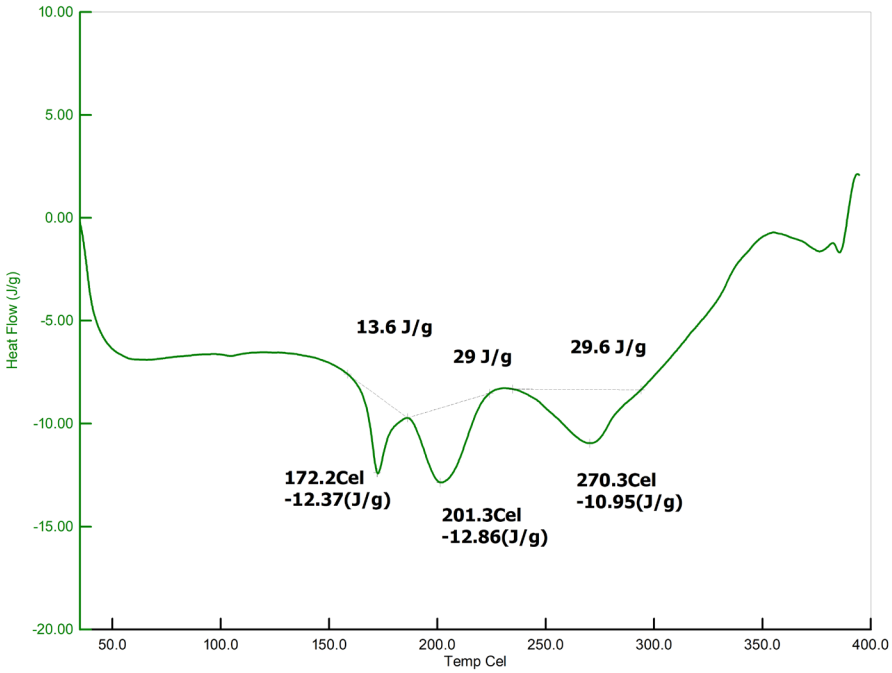

Figure 7: DSC thermogram of Optimized formulation Z7.

Gum Olibanum) to identify their effect on the release profiles of a drug.

Z1 to Z3 formulations were made using Gum Karaya as the major film-forming agent. The *in vitro* drug release results recorded that for these issued formulations, the zolmitriptan was released to 90.12% and 95.36% within 15 min. One of the known natural polysaccharide is Gum Karaya, known for its high quality of film form and also swelling, contributing to the immediate disintegration and efficient drug leakage. However, the release profile shows that though effective, its release percentage varies somewhat, probably because of the gum's natural viscosity and swelling index which could just impeded its release rate slightly.

Compared to this, formulation Z4 to Z6 formulated with Gum Olibanum demonstrated slightly enhanced and controlled release of drug to the level of 92.36% to 97.25% within 15 min. Gum Olibanum from the Boswellia serrata resin possesses desirable film-forming properties and its viscosity is lower than that of Gum Karaya; these might be the factors enhancing the drug penetration through the film matrix. It can be inferred from these results that Gum Olibanum has a more homogeneous release profile, possibly because of the ease of hydration and solubility.

The best result was achieved by the optimized formulation Z7, which co-authors Gum Karaya and Gum Olibanum. This formulation got a high release of drugs of up to 98.99% in a very minimal span of time (5 min). Both gums used synergistically appear to improve the film's disintegration and drug diffusion properties. Gum Karaya's high swelling ability might have hastened rupture of the films and Gum Olibanum's low viscosity might have increased drug diffusion. Its likely consequences were a balanced matrix that both optimizes the mechanical strength and fast drug release.

CONCLUSION

Research by Zolmitriptan oral fast dissolving films prepared through solvent casting method confirmed excellent flexibility features and positive film performance. A fast drug release of 98.99% took place in Z7 since this formulation used Gum Karaya with Gum Olibanum to achieve rapid dissolution and absorption in only 5 min. The fast dissolving zolmitriptan films made through solvent casting achieved the goal of migraine prevention and treatment.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

FDS: Fast dissolving films; **FTIR:** Fourier transform infrared spectroscopy; **DSC:** Differential Scanning Calorimetry.

REFERENCES

Balakrishna, T., Vidyadhara, S., Abhigna, N., Akhila, N., Sravanth, S. L., Vardhan, G., & Anjal, L. (2022). Development and evaluation of valsartan fast disintegrating films. Asian Journal of Pharmaceutics, 16(1), 51-56. https://doi.org/10.22377/ajp.v10i03.770

Balakrishna, T., Vidyadhara, S., Murthy, T. E. G. K., Ramu, A., & Sasidhar, R. L. C. (2018). Formulation and evaluation of esomeprazole fast dissolving buccal films. Asian Journal of Pharmaceutics and Clinical Research, 11(10), 193-199. https://doi.org/10.22159/ajpcr.2018.v11i10.27321

Balakrishna, T., Vidyadhara, S., Murthy, T. E. G. K., & Sasidhar, R. L. C. (2018). Formulation and evaluation of lansoprazole fast dissolving buccal films. Asian Journal of Pharmaceutics, 12(2). https://doi.org/10.22377/ajp.v10i03.770

Balakrishna, T., Vidyadhara, S., Murthy, T. E. G. K., Sasidhar, R. L. C., & Venkateswarao, J. (2016). Formulation and evaluation of doxylamine succinate fast dissolving buccal films. Asian Journal of Pharmaceutics, 10(3).

Balakrishna, T., Vidyadhara, S., Murthy, T. E. G. K., Sasidhar, R. L. C., & Vikas, S. (2017). Formulation and evaluation of fast dissolving buccal films of sumatriptan succinate. International Journal of ChemTech Research, 10(6), 545-552.

Banarjee, T., Ansari, V. A., Singh, S., Mahmood, T., & Akhtar, J. (2015). A review on fast dissolving films for buccal delivery of low dose drugs. International Journal of Life Sciences, 117-123. https://doi.org/10.13040/IJPSR.0975-8232

Juluru, N. S. (2013). Fast dissolving oral films: A review. International Journal of Advances in Pharmacy, Biology and Chemistry, 2(1), 108-112.

Mahajan, A. (2012). Formulation and evaluation of fast dissolving buccal films of sertraline. International Journal of Drug Development and Research, 4(1), 220-226.

Patel, A. (2018). An overview of formulation and evaluation aspects of fast dissolving oral films. World Journal of Pharmaceutical Research, 7(9), 1610-1622. https://doi.org/10.20959/wjpr20254-35434

Shendge, R. S., Salunkhe, K. S., & Girish, K. (2020). Formulation and evaluation of fast dissolving sublingual film of antihistamine drug. European Journal of Molecular and Clinical Medicine, 7(4).

Tomar, A., Sharma, K., Chauhan, N. S., Mittal, A., & Bajaj, U. (2012). Formulation and evaluation of fast dissolving oral film of dicyclomine as potential route of buccal delivery. International Journal of Drug Development and Research, 4(2), 408.

Vidyadhara, S., Balakrishna, T., Sasidhar, R. L. C., Babu, C. S., & Harika, D. L. (2013). Formulation and evaluation of zolmitriptan fast dissolving buccal films. Scholar Research Library, 5(4), 145-152.

Vidyadhara, S., Sasidhar, R. L., Balakrishna, T., & Vardhan, M. S. (2015). Formulation of rizatriptan benzoate fast dissolving buccal films by emulsion evaporation technique. International Journal of Pharmaceutical Investigation, 5(2), 101-106. https://doi.org/10.4103/2230-973X.153387.

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