ISSN: 2349-5448

Intercontinental Journal of Pharmaceutical Investigations and Research (ICJPIR)

ICJPIR | Vol.13 | Issue 1 | Jan - Mar -2026

www.icjpir.com

DOI: https://doi.org/10.61096/icjpir.v13.iss1.2026.34-46

Design and Evaluation of Ketoprofen-Loaded Oral Medicated Jellies Using Natural Polymers for Rapid Analgesic Relief

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Published by: 25.02.2026

Abstract Oral medicated jellies (OMJs) offer a patient-friendly dosage form with enhanced palatability, ease of administration, and rapid onset of action, particularly advantageous for populations with swallowing difficulties. This study aimed to formulate ketoprofen-loaded OMJs utilizing natural polymers pectin, guar gum, and carrageenan to achieve rapid analgesic effect, improved bioavailability, and patient compliance. Various jelly formulations were prepared via the heat-solvent dispersion method, varying polymer types and concentrations. Physicochemical parameters including appearance, pH, viscosity, spreadability, gel strength, drug content uniformity, and in vitro drug release were evaluated. Pectin-based jellies demonstrated faster drug release profiles suitable for immediate analgesia, whereas guar gum–carrageenan combinations provided a more controlled release. The optimized pectin formulation (F2) exhibited favorable organoleptic properties, consistent drug content (99.2%), rapid dissolution (~94% release at 60 minutes), and good short-term stability under accelerated conditions. Release kinetics indicated anomalous transport for pectin jellies and zero-order release for guar–carrageenan gels. These findings support the potential of natural polymer-based ketoprofen jellies as effective, patient-centric oral analgesic delivery systems.

Keywords: Ketoprofen, Oral Medicated Jellies, Natural Polymers, Pectin, Guar Gum, Carrageenan, Rapid Analgesic Delivery.

INTRODUCTION

Jelly is defined as semisolid formulations that lack greasy, transparent, or translucent properties, created for both internal and external use. Oral Medicated Jellies (OMJs) are semi-solid, non-flowable gel or jelly dosage forms intended for oral administration, formulated to dissolve or disintegrate in the mouth or pharynx to release the active pharmaceutical component either locally or systemically. They occupy a transitional state between solid and liquid dose forms, amalgamating certain benefits of both. They are frequently flavoured, sweetened, and contain a gel matrix that may be created through heating, congealing, or the gelation of polymers. OMJs may be designed for either immediate or modified release. The formulation components of medicated jelly comprise the active pharmaceutical ingredient. They also include gums, primarily naturally isolated gums or their synthetic equivalents. Due to their visually appealing appearance, palatable flavour, and ease of use, jellies are often favoured as a medicinal option over traditional oral preparations.[1, 2] According to Japanese regulatory information, once-weekly jelly formulations, such as those for osteoporosis, have received approval, indicating

that jelly forms are formally acknowledged in some regulatory frameworks.[3]

Oral medicated jellies address important limitations of conventional solid dosage forms, particularly for patients with dysphagia such as geriatric and paediatric populations, and individuals with neurological disorders or head and neck cancers. [4] Tablets and capsules may pose choking risks, require crushing or splitting, or lead to poor acceptance, whereas jellies with appropriate texture and viscosity offer safer and more comfortable swallowing. Their pleasant taste, palatability, and ease of administration—often without water—significantly enhance patient acceptability and adherence, especially among children and the elderly. [5]

By eliminating the need to alter solid dosage forms, jellies reduce risks associated with improper tablet manipulation, such as dose dumping. [6] Additionally, their well-controlled rheological properties improve swallowing safety and reduce aspiration risk, thereby enhancing quality of life. Advances in formulation also support incorporation of modified or sustained-release systems using safe, biocompatible natural polymers. [7] However, oral medicated jellies also present limitations, including moisture sensitivity, higher risk of microbial contamination requiring preservatives, restricted use for low-dose drugs, temperature sensitivity leading to softening or melting, increased packaging costs, potential syneresis affecting appearance and consistency, and a generally shorter shelf life compared to solid dosage forms. [8, 9]

Natural polymers are macromolecules originating from biological sources such as plants, animals, algae, or microorganisms that serve as excipients in pharmaceutical formulations. They are typically polysaccharides or proteins (e.g., gelatin, chitosan) and have been utilised for their gelling, thickening, stabilising, film-forming, and drug-release-modifying attributes. Natural polymers are preferred because to their intrinsic biocompatibility, biodegradability, low toxicity, and frequently GRAS ("Generally Recognised as Safe") designation. Their chemical structures frequently permit functionalisation, crosslinking, or blending, facilitating the manipulation of features such as viscosity, gel strength, mucoadhesiveness, and drug release kinetics.[10]

Ketoprofen is a propionic acid derivative of a nonsteroidal anti-inflammatory drug (NSAID), with significant analgesic and anti-inflammatory efficacy. It is efficacious in peripheral inflammatory pain models (e.g., carrageenan-induced paw edema) owing to robust COX inhibition.

Conventional oral formulations often exhibit delayed therapeutic onset due to the time required for drug dissolution and absorption, the impact of first-pass hepatic metabolism, and potential gastric irritation that can slow gastric emptying or alter drug absorption. As a result, alternative drug-delivery routes such as buccal or mucoadhesive systems are being explored, as they can partially bypass gastrointestinal and hepatic barriers, enabling faster onset of analgesic action while potentially reducing systemic adverse effects..[11]

Numerous studies have demonstrated the versatility and effectiveness of advanced drug-delivery systems, particularly topical, transdermal, and oral jelly formulations, in improving drug performance and patient acceptability. Dhepe S. et al. explored ketoprofen microemulsions to enhance solubility and bioavailability of this BCS Class II drug, highlighting their stability, ease of preparation, and ability to improve drug dissolution. [12] Bukka R. et al. formulated ketoprofen nanoparticles for transdermal delivery, achieving enhanced permeation, particularly with oleic acid-based systems.

Several studies focused on oral jelly formulations to enhance patient compliance: Sabri L.A. et al. formulated flurbiprofen jellies with favorable viscosity and fast dissolution;[13] Chunda R. et al. highlighted oral jellies as attractive, easy-to-administer dosage forms;[14] Arifa Begum Sk. et al. developed salbutamol sulphate jellies with excellent drug content, stability, and immediate-release characteristics;[15] and Megha B. et al. designed cinnarizine jellies suitable for paediatric and geriatric patients.[16] Additionally, Hassen Elshafeey A. and Moataz El-Dahmy R. formulated optimized oral medicated jellies using natural polymers, achieving rapid drug release, improved bioavailability, and high palatability. Collectively, these studies emphasize the potential of novel formulations to enhance

solubility, bioavailability, therapeutic efficacy, and patient adherence.[17]

Although Ketoprofen is recognized for its analgesic and anti-inflammatory properties, there is a paucity of research dedicated to the formulation of natural polymer-based medicated jellies for expedited pain alleviation. A rapidly dissolving jelly system can markedly improve the beginning of action by facilitating swift dissolve in saliva, thereby providing immediate therapeutic advantages. Consequently, the formulation of Ketoprofen-loaded medicated jellies utilizing natural polymers fulfills existing therapeutic deficiencies by augmenting palatability, accelerating drug release, promoting adherence, and offering a rapid and easy dosing form for efficient pain control.

Therefore, the main goal of this study is to design, produce, and assess ketoprofen-loaded oral medicated jellies utilizing natural polymers to attain quick analgesic onset, increased bioavailability, and greater patient compliance via site-specific buccal drug administration.

MATERIALS & METHODS

Ketoprofen hydrochloride was obtained as a gift sample from UniChem Laboratories Ltd., Mumbai. Natural polymers including pectin and guar gum were sourced from Global Exports Private Ltd., Mumbai, while carrageenan was procured from Merck Life Science, India. Other excipients such as sucrose, citric acid, sodium benzoate, glycerol, natural flavor, and Ponceau 4R red color were obtained from reputable suppliers to ensure pharmaceutical grade quality.

Calibration of KTP

To a 100 mL volumetric flask, 100 milligrammes of carefully weighed KTP are introduced. The volume was raised to 100 ml using a stock solution of 1 mg/ml of 6.8 pH phosphate buffer. The stock solution was diluted to obtain solutions with concentrations of 2-10 µg/ml using 6.8 pH phosphate buffer. A UV-VIS spectrophotometer (EI 1372, Electronics India, Pune, India) phosphate buffer blank 6.8 pH was used to quantify these solution's absorbance using a standard graph at wavelenth 254 nm.

Formulation Design[18]

The oral medicinal jellies of Ketoprofen were developed utilizing natural polymers pectin, guar gum, and carrageenan at different ratios to attain optimal gel strength, consistency, and drug release properties. Each jelly included a standardized dosage of 25 mg Ketoprofen, however the polymer amount varied among formulations to examine their gelling capacity and influence on physicochemical characteristics. Formulations F1, F2, and F3 were developed with pectin concentrations of 300 mg, 350 mg, and 400 mg, respectively, to assess the impact of elevated pectin levels on jelly firmness and drug release. Conversely, F4, F5, and F6 utilized combinations of guar gum (150, 200, 250 mg) and carrageenan (250, 300, 350 mg) to evaluate synergistic gel formation and enhanced mechanical stability. Each formulation comprised 2000 mg of sucrose as a sweetening and bulking agent, 20 mg of citric acid to improve flavor and serve as a pH adjuster, 5 mg of sodium benzoate as a preservative, and 200 mg of glycerol as a plasticizer to ensure smoothness and mitigate brittleness. Natural flavor and allowable red color were added as needed to enhance taste and visual appeal. Purified water was added as needed to achieve a total volume of 10 mL for each batch. This methodical formulation design facilitated the assessment of natural polymers both individually and in combination to enhance jelly consistency, drug release, stability, and patient acceptance.

Table 1: Formulation table of Ketoprofen jellies.

Ingredients (mg)	F1	F2	F3	F4	F5	F6
Ketoprofen	25	25	25	25	25	25
Pectin	300	350	400	–	–	–
Guar Gum	–	–	–	150	200	250
Carrageenan	–	–	–	250	300	350
Sucrose	2000	2000	2000	2000	2000	2000

Citric Acid	20	20	20	20	20	20
Sodium Benzoate	5	5	5	5	5	5
Glycerol	200	200	200	200	200	200
Natural Flavor	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Red colour	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Purified Water (q.s. to 10 mL)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

Preparation of Jellies

Ketoprofen-loaded oral medicinal jellies were formulated via the heat-solvent dispersion method. The necessary quantity of natural polymer (pectin, guar gum, or carrageenan) was incrementally disseminated in purified water while continuously stirring and fully hydrated by heating to 60–70 °C. Ketoprofen was independently diluted in a minimal volume of warm water with citric acid to improve solubility. Sucrose, glycerol, sodium benzoate, colorant, and flavoring were incorporated into the polymer solution with gentle agitation until a homogeneous viscous mass was achieved. The Ketoprofen solution was subsequently integrated into the hydrated polymer matrix and stirred well to guarantee uniform drug distribution, while keeping the temperature below 50 °C to avert drug breakdown. The completed jelly mixture was transferred into pre-lubricated molds, permitted to cool at ambient temperature to solidify, and subsequently kept in airtight containers for further assessment.

Drug - Polymer Compatibility Studies

It is crucial that a drug material be compatible both chemically and physically before it is formulated into a dosage form. When a drug is combined with pharmaceutical excipients to create a dosage form, compatibility studies provide the framework for the combination and the information required to characterize the nature of the drug substance. Compatibility is one of the criteria for choosing appropriate excipients or carriers for pharmaceutical formulation. Consequently, an investigation was conducted in the current work utilizing an infrared spectrophotometer to determine whether KTP and excipients could potentially interact chemically.

Fourier Transform Infrared (FT-IR) Spectroscopy

Using the ATR FTIR spectrometer (Shimadzu FTIR-8400S, Japan) drug's FT-IR spectra were recorded. When using the diffuse reflectance technique, the mid-IR 4000-400 cm-1 spectral region was covered. The sample was placed in sample holder made from Zinc Selenide. The position and relative strength of the absorption maximums in the spectrum produced with the substance under examination match those in the reference spectrum. To create a transparent Jellies, the mixture was taken and compressed in a hydraulic press at a pressure of 10 tons. The particle was scanned in an infrared spectrophotometer between 4000-400 cm-1. Following the light route, the Jellies was placed, the spectrum was recorded twice, and the characteristic peaks associated with the functional groups were determined.

Evaluation parameters

Physical appearance:

All jelly formulations were visually assessed under appropriate lighting for color uniformity, transparency, clarity, presence of air bubbles, surface smoothness, stickiness, and structural integrity. Photographic documentation was conducted for comparative analysis.

Weight variation:[19]

Ten jelly units (n = 10) from each batch were weighed individually using an analytical balance. The average weight and standard deviation were computed.

$$\text{Mean Weight} = \frac{\sum W_i}{n}$$

$$\text{Standard Deviation (SD)} = \sqrt{\frac{\sum (W_i - \overline{W})^2}{n-1}}$$

Surface pH:

The pH of each formulation was assessed with a calibrated digital pH meter, calibrated with pH 4.0 and 7.0 buffers. A minor quantity of each jelly was distributed in 10 mL of distilled water, and the electrode was submerged in the dispersion. The pH was documented upon stabilization. An average of three measurements per formulation made[20].

Moisture Content:

Approximately 2 g of each jelly was measured (W_1) and subjected to drying in a hot air oven at 105°C until a stable weight was achieved (W_2). The moisture content (%) was determined as follows:

$$\text{Moisture Content (\%)} = \frac{W_1 - W_2}{W_1} \times 100$$

Water Activity (a_n):

Water activity was assessed utilizing a water activity meter. Each jelly specimen was positioned in a sealed sample cup, allowed to equilibrate, and the instrument measurement was documented. Stability is deemed adequate when: aw ≤ 0.60.

Texture (Firmness / Hardness Analysis):

A texture analyzer equipped with a cylindrical probe was utilized. The probe infiltrated the jelly at a steady velocity (1–2 mm/s), and the peak force (N) necessary to distort the jelly was documented.

Firmness (N) = Maximum force during probe insertion.

Spreadability:

A specified quantity of jelly (1 g) was positioned between two glass plates, with a 100 g weight applied to the upper plate. After one minute, the diameter of the spread (cm) was recorded. A larger diameter results in improved spreadability.

Investigation of Syneresis:

Jellies were preserved at 4°C, 25°C, and 40°C for durations of 24 and 48 hours. Samples were visually examined for surface liquid segregation.

Syneresis (%) was assessed utilizing:

$$\text{Syneresis (\%)} = \frac{\text{Weight of separated liquid}}{\text{Initial weight}} \times 100$$

Uniformity of drug content:

A jelly unit corresponding to 5 mg of Ketoprofen was precisely measured, dissolved in phosphate buffer at pH 6.8, subjected to sonication for 10 minutes, and subsequently filtered. Appropriate dilutions were prepared, and absorbance was measured at 254 nm[21]. The drug content (%) was determined utilizing the calibration curve:

$$\text{Drug Content (\%)} = \frac{\text{Amount of drug found}}{\text{Label claim}} \times 100$$

In vitro disintegration studies:

Each Jellies was immersed in 50 mL of simulated saliva (pH 6.8) at 37 ± 0.5 °C, and the duration necessary for total softening and dispersion was documented.

In vitro Dissolution test:[22]

A dissolution investigation of the formulated jellies was conducted in vitro utilising a USP type II (paddle) dissolution apparatus (EI-1916, Electronics India, Pune, India). The jellies were positioned in dissolving tubes containing 500 mL of pH 6.8 phosphate buffer, kept at 37 ± 0.5 °C and agitated at 50 rpm. At specified intervals (2, 4, 6, 8, 10, and up to 20 minutes), 5 mL samples were extracted and substituted with an equivalent volume of fresh medium to preserve sink conditions. The gathered samples were examined with a UV–Visible spectrophotometer (EI-1372, Electronics India, Pune, India) at 254 nm, and the drug concentration was determined from the standard calibration curve. The percentage of drug release was ascertained, and all dissolution studies were conducted in six repetitions, with mean results presented.

Release Kinetic:

Utilising the results of the in-vitro diffusion study, the order and mechanism of drug release kinetics of KTP jellies were examined. Plotting of the kinetic models included the zero order, first order, and Higuchi equations; the release was calculated using the Korsmeyer-Peppas equations. [23]

Stability Studies

Drug stability refers to the ability of a formulation to retain its physical, chemical, and therapeutic properties within specified limits throughout its shelf life. Stability studies were

conducted in accordance with ICH Q1A guidelines to ensure product quality and performance. Accelerated stability testing of the optimized formulations was carried out at 40 ± 2 °C / 75 ± 5% RH for three months**.** The samples were packed in self sealed pouches and stored under controlled conditions. At predetermined intervals, formulations were evaluated for appearance, drug content, and in-vitro drug release**,** confirming their stability over the study period.[24]

RESULTS & DISCUSSION

Calibration of KTP

A calibration curve for Ketoprofen was established in phosphate buffer at pH 6.8 utilizing standard solutions within a concentration range of 2–20 µg/mL. The absorbance of each solution was quantified at λmax 254 nm utilizing a UV–Visible spectrophotometer. A linear correlation between absorbance and concentration was noted, validating excellent analytical sensitivity within the specified range. The calibration curve demonstrated robust linearity, represented by the regression R^2=9979.

Drug – excipient Compatibility Studies

FTIR spectroscopy was used to determine the drug excipient compatibility, and the graphs were displayed figure 2-4. To find out if there is any interaction between the excipients and KTP, the physical mixture was put through FTIR analysis. The lack of a drug-carrier chemical interaction is confirmed by the absence of any drug-characteristic peak appearance or disappearance. Drug polymer and other excepient's physical mixtures all had their Fourier transform infrared spectra recorded and examined for chemical interactions. All samples, which were pure KTP, underwent FTIR analysis to determine the presence of the pure API in the mixtures and to describe it.

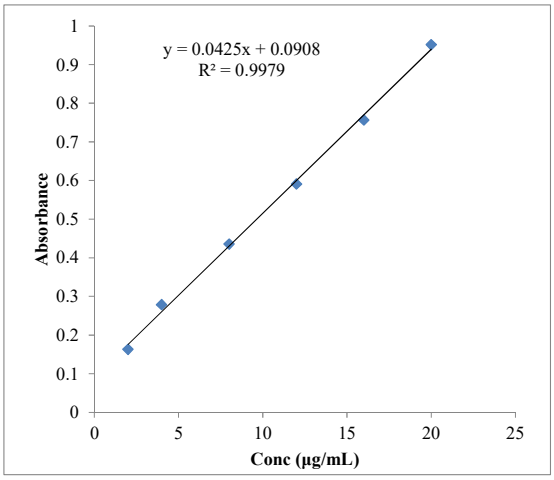

Fig 1: KTP standard calibration curve in phosphate buffer with a pH of 6.8

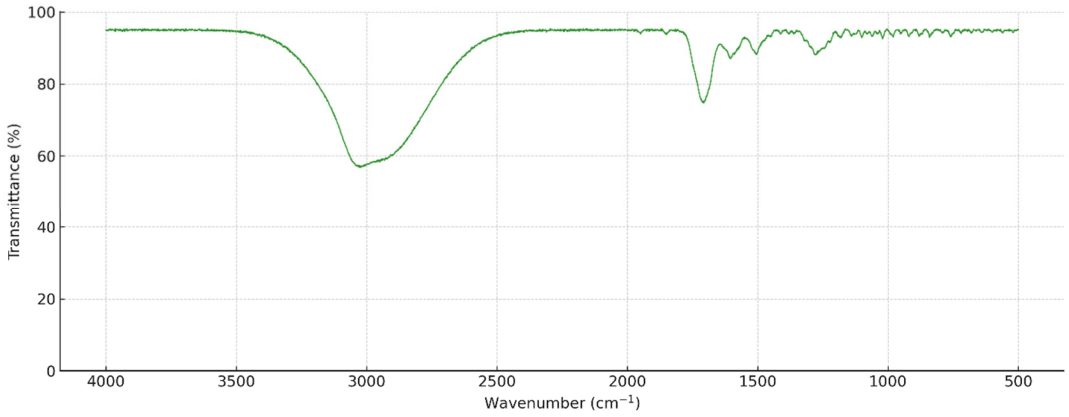

Fig 2: FTIR Spectral analysis of pure KTP.

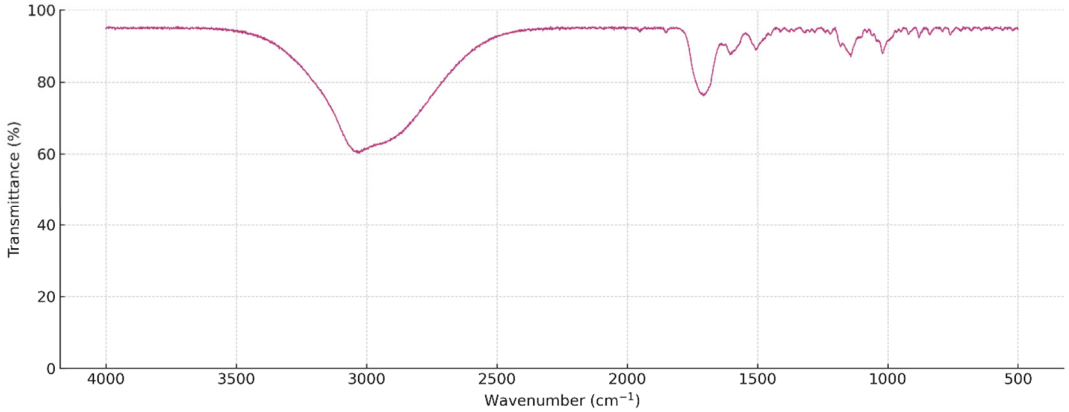

Fig 3: FTIR Spectral analysis of KTP+ Pectin

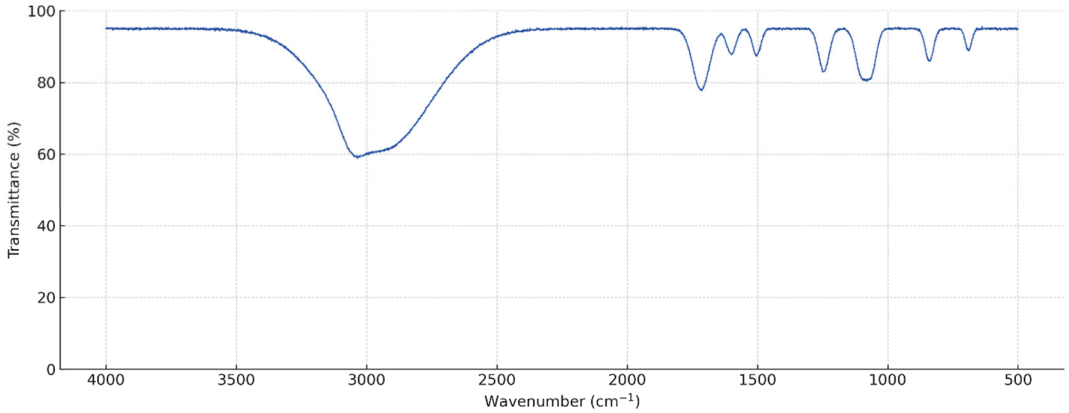

Fig 4: FTIR Spectral analysis of KTP + Guar gum + Carrageenan.

The acquired FTIR spectra are overlapped in the figure 2-4. The FTIR spectrum of pure ketoprofen displays characteristic functional group vibrations, including a broad O–H stretching band of carboxylic acid in the 3000–2500 cm^{-1} range, a prominent C=O stretching peak near 1708 cm^{-1}, distinct aromatic C=C absorptions around 1600–1500 cm^{-1}, and significant C–O and fingerprint-region peaks between 1300–800 cm^{-1}. The ketoprofen–pectin formulation exhibits significant spectral alterations, including a minor downward shift of the C=O band, broadening of the O–H region, and the emergence of pectin-related absorptions, such as the ester carbonyl band near ~1740 cm^{-1} and enhanced polysaccharide C–O–C peaks around 1150–1050 cm^{-1}, signifying hydrogen bonding and the integration of the drug within the polymer matrix. The ketoprofen–guar gum–carrageenan system exhibits additional spectrum variations, including an upward displacement of the C=O band, amplification of sulfate-associated carrageenan peaks in the ~1245 and ~840 cm^{-1} areas, and intensified saccharide-related C–O characteristics from guar gum. These modifications jointly facilitate physical interactions, hydrogen bonding, and molecular dispersion of ketoprofen inside the polysaccharide matrices, without indications of chemical incompatibility or the development of new bonds.

Distinct peak in the region 2982-2862 cm-1 for C-H aliphatic, 1350-1000 cm-1 for C-N amine and 3500-3100 cm-1 secondary amine, 3450-3300 cm-1 for N-H group, 3200-3000 cm-1 for = C-H group and 1900-1600 cm-1 for C=O group was identical to that off which confirm the compatibility of the drug and carrier. The spectra are shown in fig. 2 for pure TF, PEG 8000 and TF-PEG 8000 solid dispersion respectively. Distinct peak in the region 2982-2862 cm-1 for C-H aliphatic, 1350-1000 cm-1 for C-N amine and 3500-3100 cm-1 secondary amine, 3450-3300 cm-1 for N-H group, 3200-3000 cm-1 for = C-H group and 1900-1600 cm-1 for C=O group was identical to that off which confirm the compatibility of the drug and carrier. The spectra are shown in fig. 2

for pure TF, PEG 8000 and DM-PEG 8000 solid dispersion respectively. Distinct peak in the region 2982-2862 cm-1 for C-H aliphatic, 1350-1000 cm-1 for C-N amine and 3500-3100 cm-1 secondary amine, 3450-3300 cm-1 for N-H group, 3200-3000 cm-1 for = C-H group and 1900-1600 cm-1 for C=O group was identical to that off which confirm the compatibility of the drug and carrier. The spectra are shown in fig. 2 for pure DM, PEG 8000 and DM-PEG 8000 solid dispersion respectively.

Physical Appearance and Organoleptic Characteristics of Ketoprofen Jellies:

All formulations demonstrated satisfactory physical and organoleptic characteristics appropriate for oral medicated jelly dose forms. Pectin-based jellies (F1–F3) exhibited superior transparency and a softer texture, whereas guar gum–carrageenan combinations (F4–F6) yielded harder, more elastic gels. The intensity of color augmented with the concentration of polymer owing to enhanced dye adhesion. The surface appearance was consistently smooth and homogeneous across all batches, signifying adequate gelation without syneresis. The best flavor acceptability was seen in F3 and F6, due to their ideal texture and superior masking of Ketoprofen's bitterness. The formulations exhibited acceptable visual and sensory attributes crucial for patient adherence.

Table 2: Findings of physical appearance and organoleptic characteristics of Ketoprofen jellies.

Formulation	Color	Transparency	Surface Appearance	Texture	Flavor Acceptability
F1	Light red	Semi-transparent	Smooth, uniform	Soft, slightly gelled	Good
F2	Light red	Semi-transparent	Smooth	Firm, cohesive	Good
F3	Red	Slightly opaque	Smooth	Firm, elastic	Very good
F4	Light red	Semi-transparent	Slightly glossy	Soft, flexible	Moderate
F5	Red	Opaque	Smooth, uniform	Firm and springy	Good
F6	Dark red	Opaque	Smooth, glossy	Highly elastic, cohesive	Very good

Evaluation results of Jellies:

All six Ketoprofen jelly formulations (F1–F6) were assessed for weight uniformity, pH, moisture content, water activity, hardness, and drug concentration. The results exhibited satisfactory performance across all batches.

Table 3: Findings of weight variation, pH of the surface and moisture content, water activity, hardness (texture analysis) and drug content of all formulations.

F code	Weight (g)	Surface pH	Moisture Content (%)	Water activity (aw)	Hardness (N)	Drug content (%)
F1	9.85 ± 0.30	3.45 ± 0.10	66.2 ± 2.0	0.89 ± 0.03	9.8 ± 0.4	98.6 ± 2.5
F2	10.10 ± 0.35	3.60 ± 0.12	68.5 ± 2.6	0.91 ± 0.03	11.2 ± 0.5	99.2 ± 2.9
F3	10.25 ± 0.41	3.75 ± 0.14	71.0 ± 3.0	0.93 ± 0.04	13.6 ± 0.6	98.9 ± 3.2
F4	9.60 ± 0.29	3.30 ± 0.11	64.8 ± 2.3	0.88 ± 0.03	8.5 ± 0.3	97.8 ± 2.4
F5	9.95 ± 0.30	3.55 ± 0.13	67.5 ± 2.0	0.90 ± 0.03	10.6 ± 0.4	99.5 ± 3.8

F6	10.05 ± 0.40	3.65 ± 0.15	69.2 ± 3.1	0.92 ± 0.04	12.8 ± 0.6	100.2 ± 4.1

The weight variation results are shown in table 3. All formulations demonstrated satisfactory weight uniformity, varying from 9.85 ± 0.30 g to 10.25 ± 0.41 g, showing commendable consistency of the jelly mass. The minor discrepancies were ascribed to variances in polymer hydration and gel density. The results are shown in table 6. The surface pH of all jellies was maintained within the permissible oral range (3.30 ± 0.11 to 3.75 ± 0.14), indicating non-irritancy to buccal tissues. The moisture content ranged from 66.2 ± 2.0% to 71.0 ± 3.0%, with somewhat elevated values in carrageenan-based formulations attributed to enhanced water-binding capacity. The 3–5% standard deviation signifies consistent moisture retention among batches. Water activity values varied from 0.89 ± 0.03 to 0.93 ± 0.04. These results signify microbiological stability and sufficient preservation attributed to sucrose and sodium benzoate. The hardness escalated with polymer concentration, varying from 9.8 ± 0.4 N to 12.8 ± 0.6 N. Combinations of guar gum and carrageenan produced more robust gel networks, yielding firmer jellies. The drug content across all formulations was consistent, varying from 98.6 ± 2.5% to 100.2 ± 4.1%, indicating effective drug loading and negligible drug loss during processing.

Table 4: Spreadability and syneresis data.

Formulation	Spreadability (cm)	Syneresis (%) at 24 h	Syneresis (%) at 48 h
F1	5.7 ± 0.3	0.0	0.0
F2	5.5 ± 0.2	0.0	0.0
F3	5.3 ± 0.2	0.0	0.0
F4	7.2 ± 0.3	0.0	0.0
F5	6.9 ± 0.3	0.0	0.0
F6	6.5 ± 0.2	0.0	0.0

Spreadability and syneresis:

The spreadability values of the medicated jellies varied from 5.3 ± 0.2 cm to 7.2 ± 0.3 cm, demonstrating favorable deformability and ease of application, with pectin-based formulations (F1–F3) often exhibiting marginally superior spreadability owing to their softer gel matrix. All formulations exhibited 0% syneresis at both 24 and 48 hours, indicating superior water retention and gel stability.

In-vitro dissolution:

In-vitro dissolution investigations were conducted in 900 mL of phosphate buffer at pH 6.8 and a temperature of 37 ± 0.5°C utilizing the paddle method. Cumulative drug release statistics for 60 minutes are displayed in figure 5.

The dissolution profiles indicate a distinct, polymer-dependent hierarchy: F1 > F2 > F3 > F4 > F5 > F6, with pectin jellies (F1–F3) exhibiting a more rapid release of ketoprofen compared to guar–carrageenan jellies (F4–F6) at all time intervals. At 10–30 minutes, pectin batches demonstrate an increased percentage of release owing to the more permeable, acid–sugar–set pectin matrix that hydrates swiftly and presents reduced diffusional resistance. Conversely, guar (a very viscous galactomannan) in conjunction with carrageenan (a helical sulfated galactan) produces a denser, more elastic gel with increased tortuosity, consequently retarding drug diffusion. In each polymer set, an increase in polymer load (F1→F3 and F4→F6) further impedes release by elevating matrix viscosity and constricting the gel network. After 60 minutes, pectin jellies exhibit nearly whole release (F1–F3 =90–97%), whereas guar–carrageenan systems maintain a regulated release (F4–F6 =79–86%), indicating pectin's suitability for rapid analgesic onset and guar-carrageenan's effectiveness for prolonged delivery.

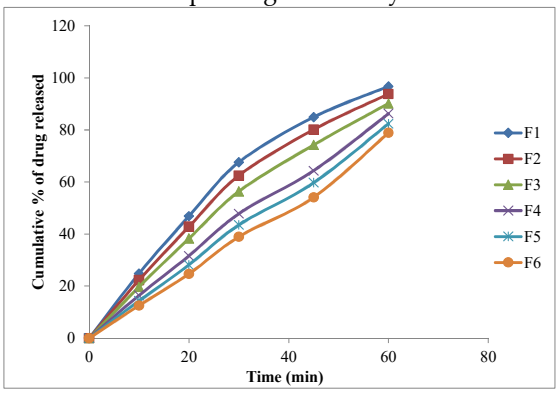

Fig 5: In-vitro dissolution studies of KTP formulations.

Application of Release Rate Kinetics to Dissolution Data:

The kinetics of drug release were investigated using a range of models. The drug release rate mechanism of the dose form kinetics was examined by fitting a variety of release models, such as first-order, zero-order, higuchi, and Korsmeyer-Peppas, to the collected data. The kinetics results were displayed in figures 6-9.

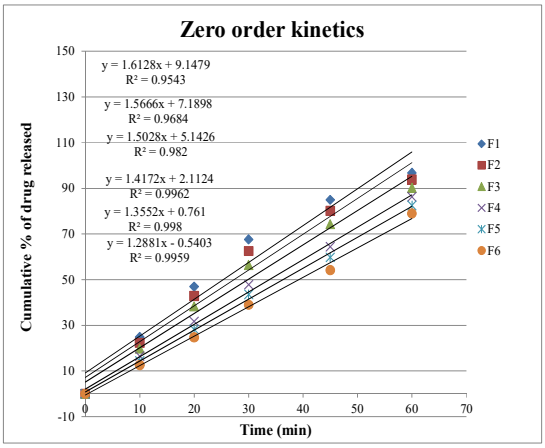

Fig 6: Zero order release kinetics graph of KTP formulations.

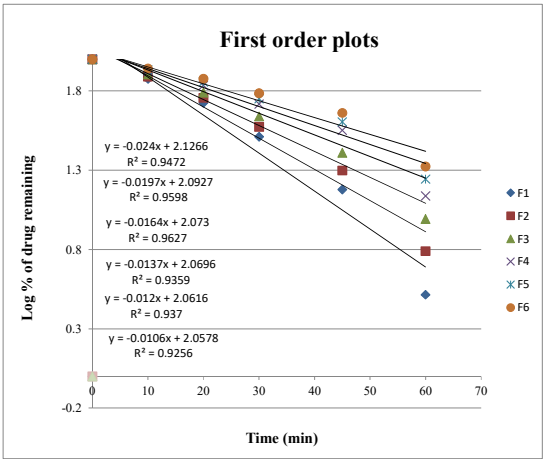

Fig 7: First order release kinetics graph of KTP formulations.

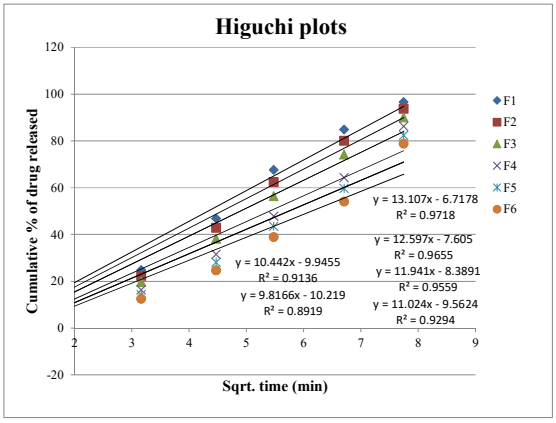

Fig 8: Higuchi release kinetics graph of KTP formulations.

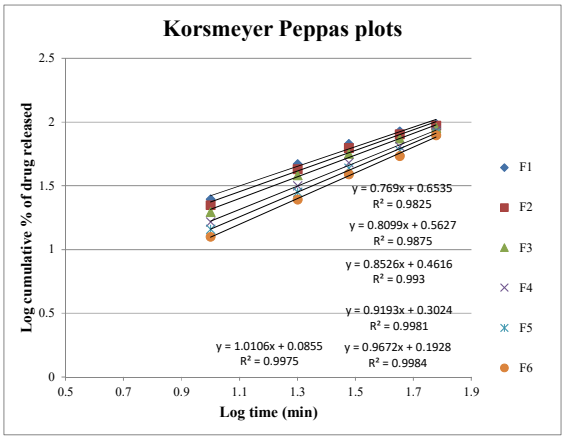

Fig 9: Korsmeyer-Peppas graph of KTP formulations.

Kinetic modeling demonstrates a distinct polymer-dependent variation: pectin jellies (F1–F3) conform to zero-order/Higuchi models adequately with Korsmeyer–Peppas n = 0.77→0.85, signifying primarily anomalous, diffusion-controlled transport accompanied by some polymer relaxation. In contrast, guar–carrageenan jellies (F4–F6) demonstrate nearly ideal zero-order release and exceptionally high Peppas fits with n values ranging from 0.92 to 1.01, indicative of a relaxation/erosion-controlled mechanism nearing Case-II. Consequently, pectin formulations promote rapid, diffusion-driven release, while guar-carrageenan matrices provide consistent, zero-order-like regulated release.

Selection of best formulation

Upon evaluating all datasets organoleptics, physical quality, and dissolution F2 provides the optimal overall balance for ketoprofen jellies designed for swift, dependable analgesic onset without an excessive burst effect. It demonstrates favorable acceptance (light-red,

semi-transparent, smooth surface; "Good" flavor), a powerful yet chewable texture (hardness 11.2 N, stiffer than F1 but less elastic than F3/F6), and uniformity (weight 10.10 g, drug content 99.2%). Moisture parameters are characteristic of jellies with no syneresis seen at 24/48 hours, signifying a robust gel matrix. Significantly, its breakdown is rapid yet regulated about 62% at 30 minutes and approximately 94% at 60 minutes surpassing the slower guar-carrageenan jellies (F4–F6) while evading the pronounced first surge of F1. F3 possesses the highest pectin content, resulting in a slightly firmer gel (13.6 N) and a "Very good" flavor; nevertheless, its release rate is slower, approximately 90% over 60 minutes. Consequently, F2 most effectively fulfills the required product profile: a patient-acceptable jelly characterized by consistent handling, absence of syneresis, and quick, nearly complete release within one hour.

Stability Studies

The optimized pectin jelly (F2) remained physically and chemically stable over 90 days at both RT (25 °C/60% RH) and accelerated (40 °C/75% RH) conditions: appearance stayed light-red and semi-transparent with no syneresis and surface pH were essentially unchanged, and only a slight humidity-related rise in moisture content was seen under accelerated storage. Textural firmness decreased modestly yet remained within the target chewable range. Drug content stayed within compendial limits, and 60-min dissolution showed only a minor decline, indicating preservation of the rapid-but-controlled release profile. Overall, the data support good short-term stability of F2 in moisture-barrier packs, with no clinically meaningful impact on quality or performance.

CONCLUSION

In conclusion, ketoprofen medicated jellies can be rationally tuned by polymer selection and concentration to meet distinct therapeutic intents from rapid onset (pectin) to more controlled profiles (guar–carrageenan). The optimized pectin (F2) formulation best satisfies the target product profile for fast, well-tolerated oral analgesic delivery, with reliable quality and short-term stability. The platform is readily scalable using standard confectionery/pharmaceutical unit operations and is adaptable to dose adjustments, pediatric-friendly flavors, and potential combination therapy. Future work may evaluate in-vitro–in-vivo correlations, sensory preference studies, and extended stability, while exploring sweetener/texture modulation and bioadhesive enhancers to further fine-tune onset and duration.

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