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International Journal of Advanced Research in Science, Communication and Technology
onal Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429 Volume 5, Issue 1, July 2025 Impact Factor: 7.67

Formulation and Evaluation of Fast Dissolving Tablets

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Abstract: *The present study was aimed at the formulation and evaluation of fast dissolving tablets (FDTs) of Parecoxib to achieve rapid onset of analgesic and anti-inflammatory action, enhancing patient compliance. Fast dissolving tablets were prepared using sodium starch glycolate and crosscarmellose sodium as superdisintegrants, camphor as a subliming agent to impart porosity, and microcrystalline cellulose as a diluent, employing direct compression technique. Nine formulations (F1–F9) were developed by varying the concentration of superdisintegrants. Pre-compression parameters such as bulk density, tapped density, compressibility index, Hausner's ratio, and angle of repose confirmed good flow properties suitable for direct compression. The prepared tablets were evaluated for hardness, friability, weight variation, wetting time, water absorption ratio, drug content uniformity, in vitro disintegration time, and dissolution profile. Among all batches, formulations F3, F4, F8, and F9 exhibited rapid disintegration (less than 40 seconds) and acceptable mechanical strength. The optimized formulation F9 showed a disintegration time of 33.6 seconds, satisfactory drug content (94.8%), and friability below 1%, indicating good mechanical stability. Stability studies performed under ICH conditions confirmed the physical and chemical stability of the optimized formulation over three months. These findings suggest that the developed FDTs of Parecoxib can serve as a promising delivery system for immediate pain relief with enhanced patient acceptability.*

Keywords: Parecoxib; Fast dissolving tablets; Superdisintegrants; Subliming agent; Direct compression; Disintegration time

I. INTRODUCTION

Oral drug delivery remains the most preferred and convenient route of administration due to its simplicity, patient compliance, cost-effectiveness, and flexibility in dosage design. However, conventional oral dosage forms, such as tablets and capsules, often pose challenges for specific patient groups including pediatric, geriatric, bedridden, and mentally ill patients who may experience difficulties in swallowing (dysphagia). This has led to a growing interest in the development of novel oral dosage forms that disintegrate or dissolve rapidly in the oral cavity without the need for water. Among these, fast dissolving tablets (FDTs), also referred to as orally disintegrating tablets (ODTs), have gained substantial attention.[1,2]

Fast dissolving tablets are designed to disintegrate and dissolve quickly in the saliva, typically within a few seconds to minutes, releasing the drug which can then be absorbed through the oral mucosa or gastrointestinal tract. This rapid disintegration not only ensures faster onset of therapeutic action but also enhances patient compliance, particularly beneficial for acute conditions requiring immediate relief.[3,4]

Parecoxib is a water-insoluble prodrug of valdecoxib, a selective cyclooxygenase-2 (COX-2) inhibitor, widely employed in the management of acute pain and postoperative inflammation. Parecoxib offers advantages over non-selective NSAIDs by reducing the risk of gastrointestinal irritation and bleeding. However, its conventional formulations may exhibit delayed onset due to the need for dissolution and subsequent absorption. Thus, formulating Parecoxib as an FDT can provide rapid disintegration in the oral cavity, accelerating drug release and absorption, ultimately leading to a quicker onset of analgesic action.[5,6]

The formulation of effective FDTs relies heavily on the selection of suitable excipients. Superdisintegrants such as sodium starch glycolate (SSG) and crosscarmellose sodium (CCS) are incorporated to enhance the disintegration and

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dissolution rates of tablets by facilitating rapid water uptake and swelling. Additionally, the use of a subliming agent like camphor can create a porous structure within the tablet matrix upon sublimation, further improving water penetration and disintegration time. Incorporating sweetening agents like sodium saccharin enhances palatability, an important consideration for patient acceptability.[7,8]

In the present investigation, an attempt was made to develop fast dissolving tablets of Parecoxib employing direct compression method. Different formulations were prepared by varying concentrations of SSG and CCS along with camphor to achieve optimal porosity and rapid disintegration. The prepared tablets were subjected to comprehensive pre-compression and post-compression evaluations including flow properties, hardness, friability, weight variation, wetting time, disintegration time, drug content, and in vitro dissolution studies. Moreover, the stability of the optimized formulation was assessed under ICH prescribed conditions to ensure product robustness and shelf life.[9]

This study aims to establish a formulation strategy that could overcome the limitations associated with conventional dosage forms of Parecoxib, offering a patient-friendly, rapidly acting oral dosage form that enhances therapeutic efficacy and patient compliance.

II. MATERIALS AND METHODS

A standard stock solution of Parecoxib was prepared by accurately weighing the required quantity of drug and dissolving it in methanol, followed by sonication to achieve complete dissolution, and subsequent dilution to the desired concentration for analysis. A calibration curve was constructed by preparing a series of standard solutions through serial dilution of the stock solution; the absorbance of each was measured at the selected wavelength using a UV-visible spectrophotometer and plotted against concentration. The FTIR spectrum of Parecoxib was recorded using an FTIR spectrophotometer to identify characteristic functional groups by preparing a KBr pellet of the sample. Pre-compression parameters were evaluated to assess flow properties and compressibility of the prepared granules. Bulk density was determined by gently pouring pre-sieved granules into a graduated cylinder and recording their volume and mass, while tapped density was measured using a mechanical tapper operated until a constant volume was achieved. Carr's index and Hausner's ratio were calculated from bulk and tapped densities to evaluate compressibility and flow characteristics. The angle of repose was determined by allowing the granules to flow through a funnel, forming a heap on a flat surface, and measuring the angle formed with the horizontal, thereby assessing the interparticle friction and flowability of the granules.[10]

Preparation of Parecoxib Fast Dissolving Tablets

All raw materials, including Parecoxib, selected excipients, and the subliming agent camphor, were passed through an 80-mesh sieve to ensure uniform particle size and then accurately weighed. The drug and excipients were physically blended in a mortar for 15 minutes to achieve a homogeneous mixture, with camphor incorporated at an optimized concentration to enhance tablet porosity, thereby facilitating faster disintegration. A sweetener was added to improve the palatability of the final formulation. The resulting powder blend was then lubricated with 1% w/w magnesium stearate to improve flow and reduce friction during compression. Finally, the lubricated mixture was compressed into tablets using a rotary tablet punching machine equipped with flat-faced punches of 9 mm diameter to produce uniform fast dissolving tablets of Parecoxib.[11]

Ingridients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Parecoxib	100 mg	100 mg	100 mg	100 mg	100 mg	100 mg	100 mg	100 mg	100 mg
Sodium starch glycolate	32	32	32	40	40	40	48	48	48
Crosscarmellose sodium	32	40	48	32	40	48	32	40	48
MCC	Q.s	Q.s	Q.s	Q.s	Q.s	Q.s	Q.s	Q.s	Q.s
Sodium sachhrine	12	12	12	12	12	12	12	12	12

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Magnesium stearate	12	12	12	12	12	12	12	12	12

EVALUATION OF TABLETS

The prepared Parecoxib fast dissolving tablets were evaluated for various physicochemical parameters to ensure formulation quality and performance. General appearance was examined visually for shape, color, texture, and odor. Tablet hardness was measured using a Monsanto hardness tester, which recorded the force required to fracture the tablet. Weight variation was assessed by weighing 20 tablets individually and comparing with the average weight to confirm compliance with pharmacopeial limits. Friability was determined by subjecting 20 pre-weighed tablets to 100 revolutions in a friabilator, with percent weight loss calculated to assess mechanical strength. Drug content was evaluated by crushing 20 tablets, dissolving powder equivalent to 100 mg of Parecoxib in methanol and phosphate buffer pH 6.8, filtering, diluting appropriately, and analyzing by UV spectrophotometry at 274 nm. Wetting time was determined by placing a tablet on tissue paper soaked with eosin-dyed water in a Petri dish and recording the time taken for water to reach the tablet's upper surface. In-vitro disintegration time was tested using a standard disintegration apparatus in water at 37 ± 2 °C, measuring the time required for complete disintegration, with compliance set within 3 minutes. In-vitro dissolution studies were conducted using the USP paddle method at 50 rpm in 900 ml phosphate buffer pH 6.8 at 37 ± 0.5 °C; aliquots were withdrawn at intervals, replaced with fresh medium, and analyzed at 274 nm to determine drug release profiles. Stability studies of the optimized batch (F9) were performed under ICH conditions at 40 °C and 75% RH for three months in a stability chamber, with periodic evaluation of hardness, weight variation, friability, drug content, and disintegration time to ensure formulation stability over time.[12-15]

III. RESULTS AND DISCUSSION

The pre-compressional evaluation provided insight into the flow properties and compressibility of the powder blends. Bulk density ranged from 0.41 g/mL (F3) to 0.75 g/mL (F9), while tapped density values were slightly higher, indicating expected particle rearrangement upon tapping. Carr's index (compressibility index) is a critical parameter reflecting flowability and packing ability. Formulations F1–F4 and F7–F8 showed CI values between ~12–19%, indicating good to fair flow properties. Notably, F9 exhibited the lowest CI (6.25%), signifying excellent flowability, while F2 displayed the highest (19.7%), suggesting borderline acceptable flow. The Hausner's ratio data further supported these observations; values between 1.1 and 1.25 generally indicate good flow, with F9 again showing the best ratio (1.07), consistent with superior flow characteristics. Overall, these results confirm that most batches possessed adequate flow and compressibility, crucial for uniform die filling and consistent tablet weight during compression.

Weight variation tests demonstrated that all formulations except F7 and F9 complied with pharmacopoeial standards, indicating acceptable uniformity of tablet mass. Hardness ranged from 3.0 to 3.75 kg/cm², reflecting tablets with sufficient mechanical strength to withstand handling. F8 exhibited the highest hardness, whereas F7, with the lowest, may correlate with its failing the weight variation, potentially due to poor die fill uniformity.

The wetting time is critical for fast dissolving tablets, influencing patient acceptability. Values varied from 60.66 s (F7) to 80.33 s (F8). Water absorption ratios ranged from 7.98 to 9.25, showing that higher polymer or subliming agent content enhanced water uptake. Correspondingly, in vitro disintegration times ranged from 33.6 s (F9) to 57.4 s (F1). Formulations F3, F4, F8, and F9 demonstrated rapid disintegration (<40 s), likely due to optimal porosity from subliming agent (camphor) creating channels post-sublimation, coupled with adequate hydrophilicity.

All formulations showed drug content within 94.8–99.2%, indicating uniform drug distribution. Friability was below 1% for most formulations, ensuring mechanical integrity, though F9 approached the upper limit (0.75%). This might be linked to its slightly lower hardness. The rapid disintegration and wetting seen in F9 suggest that despite somewhat higher friability, it achieved superior disintegration, a desired characteristic for fast dissolving systems.

The study shows that careful modulation of excipients—especially superdisintegrants, subliming agents, and polymer content—can effectively tailor tablet properties. F3, F4, F8, and F9 emerged as promising batches due to their balanced mechanical strength, rapid disintegration, and acceptable wetting profiles. However, the slightly higher friability and weight variation issues in F7 and F9 point to the need for minor optimization, perhaps by adjusting lubricant or binder

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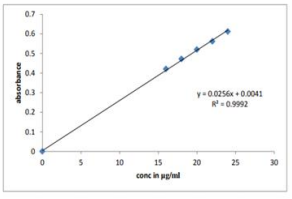
concentration. These findings collectively indicate the potential of these formulations to provide a fast onset of action, improving patient compliance and therapeutic effectiveness.

Table 2: Pre-compressional study

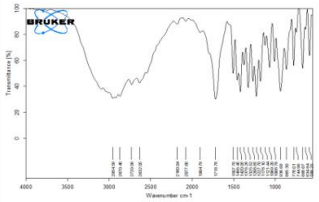
Formulation Code	Bulk Density (g/mL)	Tapped Density (g/mL)	Compressibility Index (%)	Hausner's Ratio
F1	0.721 ± 0.045	0.87 ± 0.01	17.126 ± 0.6	1.206 ± 0.06
F2	0.710 ± 0.043	0.873 ± 0.04	19.714 ± 0.7	1.251 ± 0.04
F3	0.41 ± 0.045	0.483 ± 0.5	15.113 ± 0.8	1.178 ± 0.08
F4	0.45 ± 0.045	0.52 ± 0.09	15.60 ± 0.2	1.15 ± 0.02
F5	0.45 ± 0.045	0.50 ± 0.07	12.23 ± 0.6	1.11 ± 0.04
F6	0.44 ± 0.044	0.50 ± 0.09	12.58 ± 0.8	1.13 ± 0.08
F7	0.60 ± 0.045	0.70 ± 0.05	14.50 ± 0.5	1.17 ± 0.05
F8	0.65 ± 0.050	0.75 ± 0.06	13.33 ± 0.4	1.15 ± 0.03
F9	0.75 ± 0.055	0.80 ± 0.07	6.25 ± 0.3	1.07 ± 0.02

Table 3: Evaluation of tablets

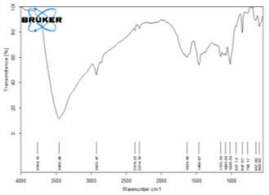
Formulation Code	Weight Variation Test	Hardness (kg/cm² ± SD)	Thickness (mm) ± SD	Wetting Time (Sec) ± SD	Water Absorption Ratio	Drug Content (%)	Friability (%)	In vitro Disintegration Time (Sec)
F1	Passes	3.2±0.015	2.73±0.07	73.66±3.51	8.508±0.05	97.31	0.537	57.4±1.54
F2	Passes	3.25±0.11	2.73±0.02	74.33±4.72	8.59±0.15	96.25	0.403	51.6±2.43
F3	Passes	3.4±0.65	2.70±0.15	73.33±4.16	8.315±0.23	98.91	0.438	34.68±1.43
F4	Passes	3.5±0.45	2.76±0.07	71.66±3.05	8.08±0.52	97.89	0.502	35.6±2.45
F5	Passes	3.3±0.22	2.73±0.04	64.33±3.51	8.09±0.45	98.72	0.468	49.1±2.14
F6	Passes	3.65±0.56	2.7±0.03	70.33±8.02	8.99±0.56	99.17	0.367	49.30±1.65
F7	Fails	3.0±0.10	2.72±0.05	60.66±2.77	7.98±0.25	95.25	0.625	45.2±2.34
F8	Passes	3.75±0.40	2.78±0.08	80.33±5.22	9.25±0.35	98.55	0.305	39.8±1.82
F9	Fails	3.1±0.20	2.75±0.06	65.00±3.82	8.75±0.28	94.80	0.750	33.6±3.42



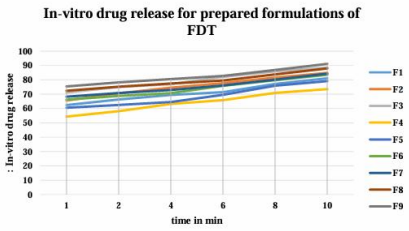
standard calibration curve of Parecoxib



FTIR Spectra of Parecoxib



FTIR Spectra of Parecoxib with Crosscarmellose sodium



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IV. CONCLUSION

The study successfully demonstrated the feasibility of formulating Parecoxib fast dissolving tablets using a combination of sodium starch glycolate and crosscarmellose sodium as superdisintegrants along with camphor to enhance tablet porosity. The pre-compressional evaluations confirmed satisfactory flow characteristics essential for consistent tablet formation. Post-compression studies revealed that most formulations complied with pharmacopoeial specifications for weight variation, hardness, friability, and drug content. Particularly, formulations F3, F4, F8, and F9 displayed rapid disintegration times of less than 40 seconds coupled with adequate mechanical strength, which is critical for handling and packaging. Among these, F9 was identified as the optimized batch due to its shortest disintegration time (33.6 seconds) and overall balanced profile. Stability studies confirmed the robustness of this formulation under accelerated conditions, supporting its potential for commercial development. Thus, the formulated FDTs of Parecoxib hold promise as an effective dosage form offering rapid onset of therapeutic action and improved patient compliance, especially beneficial in acute pain management scenarios.

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