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FAST DISINTEGRATING IBUPROFEN TABLETS: A PATIENT-FRIENDLY APPROACH FOR RHEUMATOID ARTHRITIS TREATMENT

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ABSTRACT

Rheumatoid arthritis (RA) is a chronic autoimmune condition characterized by persistent joint inflammation, causing pain, stiffness, and a decline in quality of life. Although ibuprofen is commonly used to manage these symptoms, traditional oral tablets can be difficult to swallow especially for elderly patients or those with swallowing difficulties. This study focused on developing fast-disintegrating tablets (FDTs) of ibuprofen to improve ease of administration and speed up symptom relief. Formulations were prepared using the direct compression method and included super disintegrants like sodium starch glycolate, croscarmellose sodium, and Crospovidone. Among the tested formulations, the optimized batch (F4) showed good flow properties before compression, consistent quality after compression, a rapid disintegration time of just 25 seconds, and a drug release of 62.55% within 30 minutes during in vitro testing. These findings suggest that ibuprofen FDTs could serve as an effective and patient-friendly alternative to conventional tablets, offering faster relief and greater convenience for individuals with RA.

KEYWORDS: Rheumatoid arthritis, Fast-disintegrating tablets, Ibuprofen, Direct compression, COX enzymes.

INTRODUCTION

Rheumatoid arthritis (RA) is a chronic autoimmune disorder marked by joint inflammation, pain, stiffness, and fatigue, ultimately impairing physical function, quality of life, and work

productivity.[1] It is commonly associated with the presence of rheumatoid factor (RF) and anti- citrullinated protein antibodies (ACPA), and influenced by both genetic and environmental factors.[2] The condition typically manifests between the ages of 40 and 50, though it can occur at any age, with women being three times more susceptible than men.[3] Pain in RA primarily results from synovial inflammation triggered by cytokines and inflammatory mediators that sensitize nerve endings.[4] Pathophysiologic ally, RA involves immune system activation— often initiated by environmental triggers such as infections—which activates T and B lymphocytes and promotes the release of pro-inflammatory cytokines.[5] This immune response leads to the production of autoantibodies like RF and ACPAs, and the differentiation of CD4+ T cells into various subsets that amplify inflammation.[6] Activated macrophages and synovial fibroblasts contribute to joint damage by releasing enzymes and inflammatory substances, eventually resulting in cartilage and bone destruction through osteoclast activation.[7] Clinically, RA is characterized by symptoms such as joint swelling, periarticular erosions, and systemic bone loss.[8] Management often begins with nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen and naproxen, which inhibit COX enzymes to relieve pain and inflammation but carry risks such as gastrointestinal bleeding, kidney issues, and cardiovascular side effects.[9] Additionally, disease-modifying antirheumatic drugs (DMARDs) are used to suppress immune activity but may cause liver toxicity, bone marrow suppression, and gastrointestinal discomfort.[9]

Fast Disintegrating Tablets

Swallowing difficulties are common among the elderly due to hand tremors, dysphasia, and fear of choking; in children due to immature muscle and nerve control; and in patients with schizophrenia, leading to poor medication adherence.[10] As a result, fast-dissolving formulations have gained popularity. Oral disintegrating tablets (ODTs) are solid dosage forms that dissolve quickly in the mouth without water, forming a solution or suspension.[11] According to the US FDA's CDER, fast disintegrating tablets (FDDTs) are defined as solid dosage forms that rapidly disintegrate, usually within seconds, when placed on the tongue.[12]

Advantages of fast disintegrating tablet[13,17]

1. Enhanced bioavailability of drug, bio availability is enhanced due to absorption from mouth, pharynx and oesophagus.
2. Case compliance No need of water to swallow, Hence, it's accessible for cases Who are travelling and don't have immediate access to water.

3. Ease of administration Accessible to administer Especially for senior, paediatric, mentally impaired And bed ridden cases who have difficulty in Swallowing.
4. Enhanced delectability good mouth feel, especially for paediatric cases as taste masking agents is used to avoid the bitter taste of medicine.

Challenges in Formulating FDT[18,21]

Palatability

Rapid-disintegrating medicine systems often include drugs in a taste-masked form because most medicines don't taste good. Masking the taste is important for patient comfort and compliance, especially since these tablets break down in the mouth, releasing the medicine directly onto the taste buds.

Hygroscopicity

Oral disintegrating tablets often absorb moisture from the air, which can cause them to break down or lose their shape. Because of this, they need special packaging to protect them from humidity.

Amount of drug

The amount of drug that can be present into each FDT is limited. For freeze-dried (lyophilized) tablets, the dose should be under 60 mg for drugs that dissolve easily and under 400 mg for those that don't. This makes it especially challenging to develop fast-dissolving Tablet.

Objective of Study

The objective of present study was

1. To develop a fast-disintegrating tablet formulation of Ibuprofen for the treatment of Rheumatoid Arthritis, enhancing patient compliance and convenience.
2. To achieve rapid disintegration and dissolution of the tablet, ensuring quick release of Ibuprofen and faster onset of action.
3. To improve the therapeutic efficacy of Ibuprofen in managing symptoms of Rheumatoid Arthritis, such as pain and inflammation.
4. To enhance patient compliance by formulating a tablet that is easy to administer, particularly for patients with difficulty swallowing conventional tablets.

METHOD AND MATERIALS

List of Materials

The formulation included ibuprofen as the active ingredient, with super disintegrants like sodium starch glycolate, croscarmellose sodium, and Crospovidone. Mannitol and microcrystalline cellulose were used as diluents, while talc and magnesium stearate acted as glidant and lubricant, respectively. Aspartame was added as a sweetener. Most materials were sourced from Research Lab, except ibuprofen, which came from Dhamtec pharma and consultants.

Preparation of formulation[22]

Tablet constituents were directly weighed as mentioned in the formulation. These were passed through a 20-mesh sieve. Ibuprofen, microcrystalline cellulose, and Crospovidone were mixed in a large poly bag using a tumbling action. Eventually, magnesium stearate was added and mixed again for 5 minutes to ensure the particle surfaces were evenly coated with the lubricant. The mixture was compressed using a rotary tablet press equipped with caplet-shaped concave punches.[22]

Compression of tablets[23]

Fast disintegrating tablets were prepared by a direct compression method involving two steps. In the first step, the tablet powder blend (500 mg) was compressed using a flat-faced single punch (12 mm diameter) tablet press. In the second step, the upper punch was raised, and a backing layer of powder blend was placed on the pre-compressed layer. The two layers were then compressed together.[23]

Table No.1: Formulation of Fast Dissolving Tablet of Diclofenac Sodium.

Composition	F1	F2	F3	F4
Ibuprofen	200	200	200	200
Sodium starch glycolate	60	30	30	-
Crospovidone	-	-	10	-
Croscarmellose sodium	-	30	20	60
Mannitol	65	65	65	65
MCC	150	150	150	150
Talc	10	10	10	10
Magnesium Stearate	10	10	10	10
Aspartame	5	5	5	5

Post-compression parameters[24,30]

General Appearance[24]

The general appearance of a tablet, its visual identity and over all ―elegance‖ is essential for consumer acceptance and tablet's size, shape, colour, presence or absence of an Odour, taste, surface texture, physical flaws and Consistency and legibility of any identifying marking.

Size and Shaped[25]

The size and shape of the tablet can be dimensionally Described, monitored and controlled. A compressed tablet's shape and dimensions are determined by the tooling during the compression process. The thickness of a tablet is the only dimensional variable related to the process.

Tablet Thickness[26]

Tablet thickness is an important characteristic in Reproducing appearance and also in counting by using Filling equipment. Some filling equipment utilizes the Uniform thickness of the tablets as a counting Mechanism. Ten tablets were taken and their thickness Was recorded using micrometre. Tablet thickness should be controlled within a15% variation of a standard value.

Weight Variation[27]

20 tablets were selected randomly from the lot and weighted individually to check for weight variation. Weight variation specification as per I.P. is shown in following Table.

Weight Variation = $\frac{L^{-}A}{A} \times 100$

Where, L=Individual weight of tablet, A = Average weight of tablet.

Table No. 2: Weight variation (According to IP).

Average Weight of Tablet	o Deviation
80 mg or less	±10
80 mg to 250 mg	±7.5
250 mg or more	±5

Hardness[28]

Hardness of tablet is defined as the force applied across the diameter of the tablet in the order to break the tablet. The resistance of the tablet to chipping, abrasion or Breakage under condition of storage transformation and handling before usage depends on its hardness. Hardness Of the tablet of each formulation was determined using Monsanto Hardness tester.

Friability (F)[29]

Friability of the tablet determined using Roche Friabilator. This device subjects the tablet to the Combined effect of abrasion and shock in a plastic Chamber revolving at 25 rpm and dropping a tablet at Height of 6 inches in each revolution. Pre -weighted Sample of tablets was placed in the friabilator and were Subjected to the 100 revolutions. The friability (F) is Given by the formula.

$$\%\text{Friability} = \frac{Winitial - Wfinal}{W\ initial} \times 100$$

Disintegration Test[30]

The disintegration time for each formulation was measured using a standard tablet disintegration test apparatus. One tablet was placed in each of the six tubes, and the test was carried out in water maintained at 37 ± 2°C. The time it took for each tablet to fully break apart was carefully recorded.

Dissolution Test[30]

In vitro dissolution testing was conducted using the USP dissolution apparatus with a phosphate buffer of pH 7.2 as the dissolution medium. The paddles were rotated at a constant speed of 100 rpm, while the medium was maintained at 37 ± 0.5 °C to simulate body temperature. Samples were collected at regular intervals of 5 minutes. To maintain a consistent volume of the dissolution medium, each withdrawn sample was immediately replaced with an equal volume of fresh buffer. The collected samples were then filtered, and their absorbance was measured at 221 nm using a UV-visible spectrophotometer to assess drug release.

Fig 1: Final Formulation at VPCP.

RESULT AND DISCUSSION

Calibration Curve of Ibuprofen

The calibration curve of Ibuprofen in Methanol is shown in the graph. Represents linear relationship Between absorbance and concentration in the range of 2-10 µg/ml as in table 3 Shows the data. The correlation coefficient was y =0.0715×0. 0357. The graph showed a linear Relationship between absorbance & concentration.

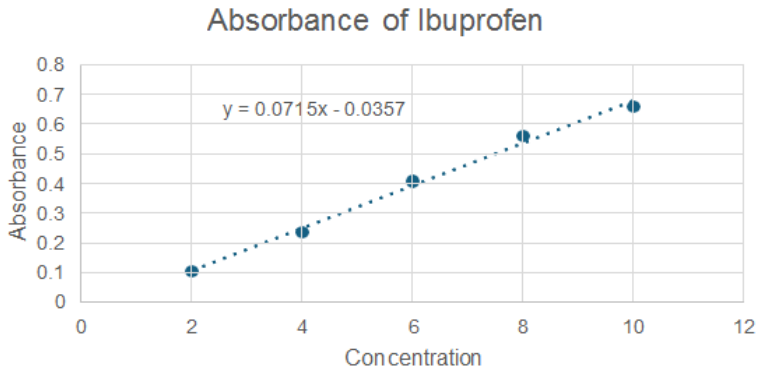


Fig 2: Calibration Curve of Ibuprofen FDT.

Table No 3: Calibration Curve of Ibuprofen FDT.

Sr. No.	Concentration µg/ml	Absorbance
1.	2	0.1056
2.	4	0.2363
3.	6	0.4062
4.	8	0.5604
5.	10	0.6589

Pre-Compression Study

The angle of repose of the formulation blend was in the range of 34.22º-34.99º, which indicates good flow properties of the different blends. The Carr's index, Hausner's ratios were found to be in the range of 15.25-19.67 and 1.18-1.24 indicating good compressibility.

Table no. 4: Evaluation of pre-compression parameters.

Formulation batches	Angle of repose (θ)	Hausner's ratio	Carr's index (%)	Tapped density (g/mol)	Bulk density (g/mol)
F1	34.61°	1.24	19.67	0.61	0.49
F2	34.61°	1.22	18.03	0.61	0.50
F3	34.99°	1.18	15.25	0.59	0.50
F4	34.22°	1.20	16.39	0.60	0.51

Post Compression Parameter of Tablet Uniformity of Thickness

The crown diameters of all the formulations were found to be uniform. Thickness Of all the formulations was in the 2.48 mm to 2.51 mm.

Weight Uniformity

As the percentage weight variation was within the pharmacopoeia limits of ± 5 %. It is Related to tooling of the compression machine, head pressure, machine speed and flow properties of the powder.

Hardness

In all the formulations, hardness test indicated good mechanical strength, as the hardness of the FDTs Was found in the range of 3 to 4.5 kg/cm2.

Friability

Friability was observed less than 1%, indicated that FDTs had a good mechanical resistance. It is Designed to evaluate the ability of the tablet to withstand abrasion in packaging, handling and shipping.

Table No. 5: Evaluation of post compression parameters.

Formulation batches	Appearance	Thickness	Average Weight	Hardness	Friability
F1	White	2.51 mm	501.6 mg	3.5 kg/cm2	0.50%
F2	White	2.48 mm	505.2 mg	4.5 kg/cm2	0.49%
F3	White	2.48 mm	501.55 mg	3 kg/cm2	0.41%
F4	White	2.49 mm	501.3 mg	3.5 kg/cm2	0.42%

In-vitro Disintegration Time

The in vitro disintegration time was found between 25s to 34s. The outcomes were tabulated and Data demonstrated in graph 2. The disintegration times of all the formulation were less than 180s. It was found that the Formulation F4 has least disintegration time 25s when compared to other formulations.

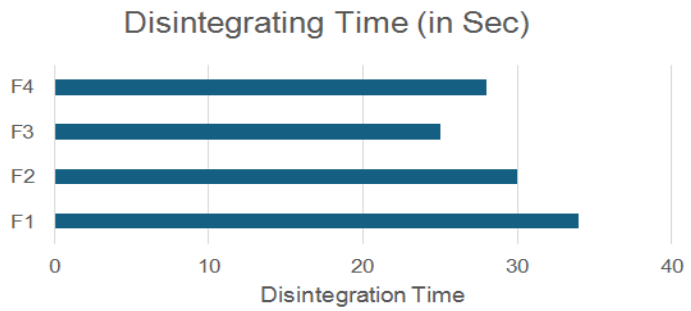
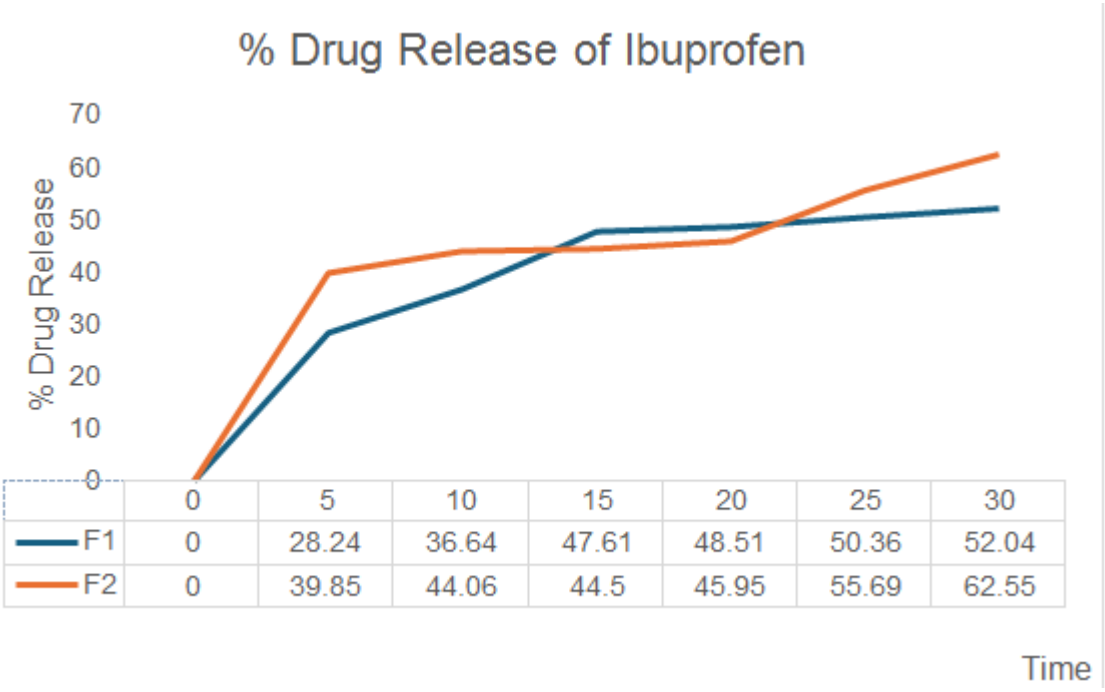


Fig 3: Evaluation of Disintegration Time of Ibuprofen FDT.

***In vitro* drug Release of fast disintegrating ibuprofen Tablet**

Formulation F4 which shows most satisfactory result is 62.55%, where drug Released maximum by 30 min. At the end of 30 min formulation F4 showed maximum drug release among Best 2 batches, and hence from the result it was concluded that the F4 formulation is the best batch Among best action.



	0	5	10	15	20	25	30
F1	0	28.24	36.64	47.61	48.51	50.36	52.04
F2	0	39.85	44.06	44.5	45.95	55.69	62.55

Fig 4: Evaluation of % Drug Release of Ibuprofen FDT.

CONCLUSION

This study successfully developed fast disintegrating tablets (FDTs) of ibuprofen to help improve both treatment effectiveness and ease of use for people with rheumatoid arthritis. Out of all the formulations tested, the F4 batch showed the best results, with a quick disintegration time of just 25 seconds and the highest drug release over 62% within 30 minutes. Using croscarmellose sodium as a super disintegrant and a simple direct

compression method led to tablets with good strength and fast-acting properties. Overall, these ibuprofen FDTs could be a more convenient and patient-friendly option than traditional tablets, especially for those who have trouble swallowing, offering faster relief and better treatment adherence.

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