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Formulation and Evaluation of Fast Dissolving Tablet of Aspirin

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Abstract: *The purpose of this study was to develop and assess aspirin fast-dissolving tablets (FDT) in order to improve patient adherence, particularly for those who have trouble swallowing. Although aspirin is frequently used as an analgesic, antipyretic, and anti-inflammatory medication, some patient groups may not benefit from its standard dosage form. Several excipients, including binders (like hydroxypropyl methylcellulose) and super disintegrants (such sodium starch glycolate and croscarmellose sodium), were used in the formulation of the fast-dissolving tablets. The tablets were made using the direct compression method and evaluated for a number of characteristics, including as in-vitro dissolution, hardness, friability, and disintegration time. With a rapid release profile, the fast dissolving formulation's dissolution rate was noticeably higher than that of conventional tablets. Excellent tablet hardness, a quick disintegration period, and acceptable patient acceptability were all displayed by the enhanced formulation. According to the study's findings, aspirin tablets that dissolve quickly may be a viable dosage form for enhancing patient compliance and the medication's beginning of effect, especially in older and younger populations*

Keywords: Aspirin, Fast dissolving tablet, hyperlipidaemia

I. INTRODUCTION

Today's fundamental necessity and requirement is the formulation of medications into a presentable form. The drug is applied to a living body using a dosage form, which is a type of drug delivery mechanism.

There are numerous dosage forms with distinct drug delivery mechanisms, including tablets, syrups, suspensions, suppositories, injections, transdermal, and patches. There are certain benefits and drawbacks to these traditional and contemporary dose formulations. Thus, in the current situation, the pharmacist faces a significant problem in creating the optimal drug delivery system. The medicine should be administered to its site of action at a rate and concentration that maximizes therapeutic efficacy and minimizes adverse effect in order to provide the intended outcome. A comprehensive analysis of the physicochemical principles governing a particular formulation of a drug is necessary for the development of an appropriate dosage form. The medicine ought to be administered.[(1)]

Up to 50–60% of all dosage forms are administered orally. This indicates widespread acceptability of this method. Solid dosage forms are widely used because they are simple to administer, precisely dose, allow for self-medication, reduce pain, and—above all—ensure patient compliance. The most widely used solid dosage forms are pills and capsules; nonetheless, swallowing difficulties are a major problem for many individuals. Water consumption is crucial for the ingestion of oral dose forms. [(2)]

But some patients, especially young ones and elderly ones, find it difficult to chew or swallow solid dosage forms (traditional dosage forms) out of unwillingness or fear of choking. Several methods, including sublimation, tablet moulding , freeze drying or lyophilization, and direct compression, can be used to manufacture FDTs. [(3)]

Great efforts have been made to produce fast-disintegrating tablets (FDTs) in the oral cavity employing jelly, water-absorbing, swelling-related materials, or water-soluble polymers in an effort to increase treatment compliance and quality of life. [(6)]

Numerous businesses have been investigating and creating different kinds of fast-disintegrating dosage forms lately. Zaydis is a fast-disintegrating, freeze-dried porous wafer that was created and marketed by Cardinal Health. [(4)]

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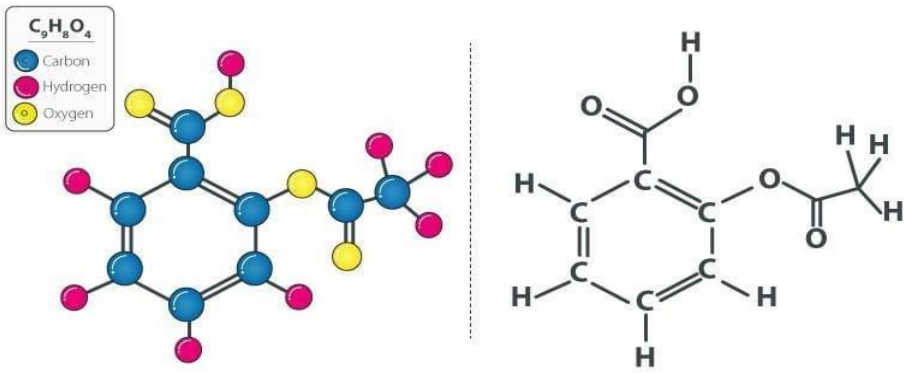
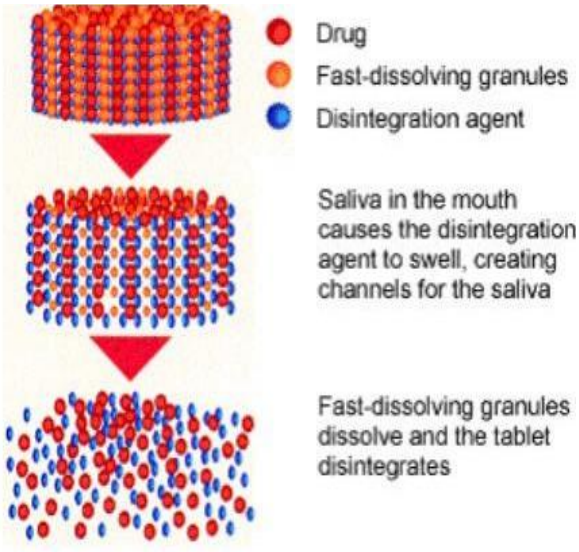


Structure of aspirin

How the Fast -dissolving pill works



Super disintegrants are essential to the breakdown and dissolve of tablets. They must meet the following requirements:

1. They must not be poisonous.
2. Need to work with APIs.
3. The pace of disintegration should be quick. [1]

Advantages[10]

Rapid Onset of Action

FDTs dissolve quickly in the mouth, allowing aspirin to be absorbed faster, leading to quicker therapeutic effects.

Ease of Administration

Suitable for patients with dysphagia (difficulty swallowing), including the elderly and pediatric populations.

No Need for Water

Can be administered without water, providing convenience for patients in emergency or on-the-go situations.

Improved Patient Compliance

The pleasant taste and ease of administration encourage better adherence to treatment, especially in children and older adults.

Reduced Gastrointestinal Irritation

Pre-gastric absorption minimizes direct contact of aspirin with the stomach lining, potentially reducing irritation.

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Enhanced Bioavailability
By dissolving and absorbing quickly, FDTs may improve the drug's bioavailability

Disadvantages[11]
Taste Masking Challenges
Aspirin's bitter taste requires effective masking to make FDTs palatable.
Moisture Sensitivity
FDTs are highly sensitive to moisture, requiring specialized packaging to prevent degradation.
Limited Dosage Strength
High doses of aspirin may not be feasible in FDT form due to tablet size constraints.
Cost of Production
Manufacturing FDTs requires advanced technology, making them more expensive than conventional tablets.
Potential for Oral Cavity Irritation
Direct contact with aspirin in the oral cavity may cause irritation in some individuals
Short Shelf Life
The hygroscopic nature of FDTs can result in a shorter shelf life compared to traditional tablets.
Reference: Chauhan, M. et al., "Recent Advances in Oral Fast Dissolving Drug Delivery," Journal of Drug Delivery Research, 2021.

Hyperlipidaemia
Depending on their etiology, the complex collection of disorders known as hyperlipidaemias can be classified as primary or secondary. Primary hyperlipidaemias can be brought on by a single genetic flaw or, more frequently, by a confluence of environmental and genetic variables. A more widespread metabolic condition like diabetes mellitus, heavy alcohol consumption, hypothyroidism, or primary biliary cirrhosis might cause secondary hyperlipidaemias. Other synonyms for hyperlipidaemia include acquired hyperlipoproteinemia, hyperlipidaemia, high blood triglycerides, high blood cholesterol, and high blood triglycerides. (4)

Mechanism of action of aspirin
Aspirin is a weak organic acid that is unique among the NSAIDs in that it irreversibly acetylates (and, thus, inactivates) cyclooxygenase.
The other NSAIDs, including salicylate, are all reversible inhibitors of cyclooxygenase. Aspirin is rapidly deacetylated by esterases in the body, thereby producing salicylate, which has anti- inflammatory, antipyretic, and analgesic effects

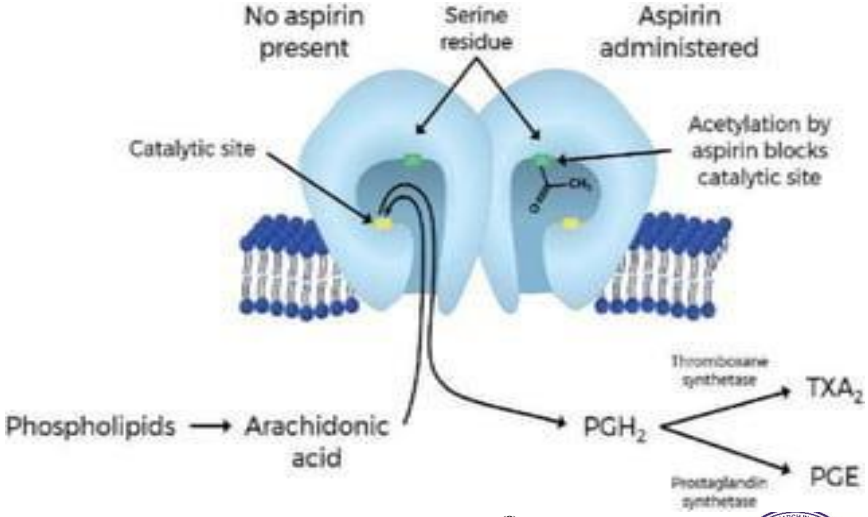

FIG. NO. 1.3 (8)

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II. MATERIALS AND METHODS

Chemicals

Aspirin, Sodium starch glycolate, Lactose, Talc, Magnesium stearate, Microcrystalline cellulose

Methods

Aspirin fast-dissolving tablets (FDT) were made using the direct compression technique. [5] The direct compression method was used to create three separate batches of tablets. Similar to how sodium starch glycolate and aspirin FDT were made by utilizing a physical mixing of super-disintegrants, the fast-dissolving tablets were made by directly compressing. Sodium starch glycolate, lactose, magnesium stearate, talc for gliding, and MCC were combined with the medication in this approach. After all components were put through a #60 mesh screen, a single punching machine was used to compress tablets with 20 mg of aspirin at a weight of 200 mg on average per tablet. [2]

Formulation of fast dissolving tablet of aspirin

SR NO.	DRUGS	BATCH – 1	BATCH – 2	BATCH – 3
1.	Aspirin	25mg	20 mg	20 mg
2.	Sodium starch glycolate	65mg	50 mg	40 mg
3.	Lactose	15mg	20 mg	30 mg
4.	Talc	2.5mg	10 mg	10 mg
5.	Magnesium stearate	2.5 mg	10 mg	10 mg
6.	Microcrystalline cellulose	90 mg	90 mg	90 mg
	Total	200 mg	200 mg	200

PRE EVALUATION PARAMETERS

Tablets physical characteristics

Three distinct formulation batches (F1 to F3) had their pre-compression parameters assessed for bulk density, tapped density, Hausner's ratio. This defines the formulation's physical characteristics.

Bulk Density [7]

The blend was poured into a graduated cylinder to calculate the bulk density. The powder's weight (M) and bulk volume (V) were calculated.

The following formula was used to get the bulk density:

$$\text{Bulk density} = \frac{\text{Mass of granules}}{\text{Volume of granules}}$$

Sr no.	Mass (g)	Volume (ml)	Bulk density (g/ml)
1.	10.01	14.48	0.691
2.	10.05	14.50	0.693
3.	10.03	14.52	0.693

Tapped density[7]

For a predetermined amount of time, the measuring cylinder with a known mass of mix was tapped. The blend's weight (M) and minimum volume (Vt) in the cylinder were measured. The following formula was used to determine the tapped density:

$$\text{Tapped density} = \frac{\text{Weight of the blend}}{\text{Volume occupied in the cylinder (Vt)}}$$

Sr no.	Mass (g)	Volume (ml)	Tapped density (g/ml)
1.	10.02	12.30	0.815
2.	10.05	12.50	0.804
3.	10.01	12.53	0.799

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Hausner's ratio[9]

Hausner's ratio is computed by applying the next equation Hausner's ratio= Tapped density/Bulk density

Tapped density \ Bulk density	Hausner's ratio
0.815/ 0.691	1.179
0.804 / 0.693	1.160
0.799 / 0.693	1.152

POST EVALUATION PARAMETERS

Thickness uniformity (2)

Verifying the tablet's uniform thickness was the current study's goal. Using a digital calliper, the thickness of the tablet was measured three times, and the average thickness of the three readings was computed.

No. of tablets	BATCH - 1	BATCH - 2	BATCH - 3
1.	4.92 mm	2.76 mm	5.33 mm
2.	2.9 mm	2.75 mm	3.7 mm
3.	5.1 mm	2.78 mm	4.13 mm
4.	3.72 mm	3.96 mm	4.7 mm
5.	4.9 mm	3.89 mm	2.37 mm

Interpretation: In the formulation of aspirin tablet BATCH 2 is more optimise than other two batches.

Hardness test (2)

A tablet's hardness level reveals how well it can tolerate handling-related mechanical shocks. Using a Monsanto hardness tester, the tablet's hardness was measured and reported in kg/cm².

No. of tablets	BATCH - 1	BATCH - 2	BATCH - 3
1.	8.77 kg	6.73 kg	5.23 kg
2.	9.53 kg	7.38 kg	6.10 kg
3.	7.40 kg	9.68 kg	7.26 kg
4.	9.67 kg	6.99 kg	5.30 kg
5.	8.50 kg	7.70 kg	6.47 kg

Interpretation: In the formulation of aspirin tablet BATCH 2 is more optimise than other two batches.

Friability test (2)

A friability test is carried out to evaluate the impact of shocks and friction, which frequently result in the tablet breaking, chipping, or capping. For this, Roche Friabilator was employed. Ten pre-weight pills were put in the friabilator, and it was turned on for one hundred revolutions. The tablets came out of the friabilator after one hundred revolutions. were weighed and dusted.

Friability was calculated by following formula.

Friability (%) = (Initial weight–Final weight/Initial weight) ×100.

Wt. of tablet before test (Batch - 2)	Wt. of tablet after test (Batch - 2)	Weight lost % (Batch - 2)
1.785	1.778	0.392

Studies on disintegration (2)

USP disintegration apparatus was used to measure the in vitro disintegration time at 50 rpm. Salicylic acid of (pH 1.5 – 3.5) was utilized as disintegration medium, with a constant temperature of 37±2°C. as well as one tablet being inserted into each of the six basket tubes of the equipment, and each tube received one disk. The duration of time required for the tablet's total breakdown (at which point, when no mass staying inside the device) was seen.

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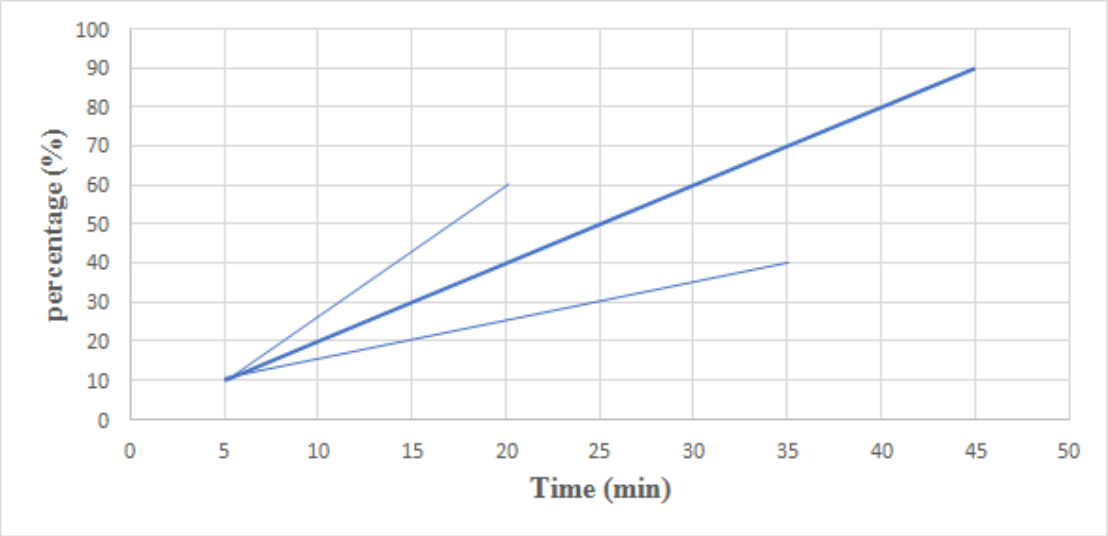
Dissolution [2]

The disintegrant's wetting time determines the dissolution rate; of all the formulations, batch 2 has the lowest wetting time and the highest dissolution rate; this is the other conformance test for choosing the right one. All of the formulations underwent in vitro dissolution tests, which are shown in fig. 7.1. Batch 2 was chosen as the most promising formulation out of all of the formulations. It demonstrated enhanced in vitro drug release due to the presence of sodium starch glycolate as a super-disintegrant. The improved dissolving rate of the Batch 2 formulation in comparison to the other formulation.

Three batches of pills that dissolve quickly were assessed. Assayed UV- spectrophotometrically at 210 nm, Batch 2 was chosen as a promising formulation that provides drug release of approximately 89.99% in 5 minutes, whereas Batch 1 and Batch 3 were formulation codes for fast dissolving tablets



Interpretation: In the formulation of aspirin tablet this graph is from BATCH 2 is more optimise batch.

III. CONCLUSION

The evaluation tests showed that the fast-dissolving aspirin tablets performed satisfactorily in every category, including disintegration time, dissolution profile, hardness, friability, and stability. The tablets' quick dissolving enhanced the overall therapeutic efficacy and is crucial for the prompt alleviation of pain or inflammation. Furthermore, the tablet's quick dissolution improves patient compliance, especially for people who have trouble swallowing regular tablets. Fast-dissolving aspirin tablets can therefore be seen as an effective strategy for improving aspirin administration, particularly in groups like young or elderly patients or those with dysphagia who might benefit from more convenient and quicker-acting treatment. The therapeutic effectiveness and long-term stability of these tablets in diverse patient populations may be the subject of future research.

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