

Formulation and Quality Control Test for Fast-Dispersible Aspirin Tablets

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The goal of this study was to create and evaluate dispersible aspirin tablets in order to increase patient compliance, especially for those who have difficulty swallowing regular pills. Aspirin, a widely used analgesic and anti-inflammatory medicine, frequently causes stomach discomfort in its standard form. Dispersible pills have the potential to improve stomach tolerance and have a quicker onset of action. To achieve rapid dispersion in water, relevant excipients such as Disintegrants, binders, and diluents were added to the direct compression method utilised in the tablet and wet granulation procedures. The physicochemical characteristics of the produced tablets, such as weight variation, hardness, friability, disintegration time, and homogeneous drug content, were assessed. After optimization, the tablet characteristics exhibited promising results, releasing more than 85% of the drug after 30 minutes and dispersing in less than 3 minutes. There may be quicker absorption and therapeutic benefits as a result of this rapid disintegration and dissolving profile. Expedited stability testing found no noticeable modifications in the tablet's chemical and physical features throughout a three-month period. Dispersible aspirin tablets are a potential dose form that provide a practical and efficient substitute for conventional aspirin tablets, according to the study's findings. This formulation strategy may help increase patient compliance, especially in the case of elderly and paediatric patients, as well as those who have swallowing issues.

Keywords: Aspirin; Disintegration time; Fast dissolving; Oral dispersible tablet; Pre-formulation; Swallowing.

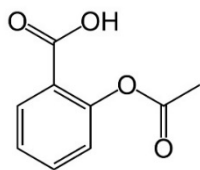
Capsules and tablets are the most used solid dosage forms. Yet, many individuals have serious swallowing problems. Drinking water helps facilitate the swallowing of oral dosage forms. Traditional dosage forms, tablets are often difficult for people to swallow when they are dehydrated, experiencing motion sickness, or suddenly developing a cold, allergies, or bronchitis. Due to these characteristics, tablets that dissolve or disintegrate rapidly in the oral cavity have attracted a lot of interest.¹⁻³ A solid dosage form

that dissolves fast on the tongue usually in a few seconds is called an oral dispersible tablet. The term "oral dispersible tablet" was introduced by the European pharmacopoeia to describe these dosage forms and highlight their significance. The term describes a tablet that can be taken orally and quickly dissolves before being swallowed.⁴

A highly specialised method called drug delivery system (DDS) is used to deliver pharmaceutical chemicals throughout the body in order to provide specific therapeutic effects. In

order to ensure that the right amount of medication is delivered in the appropriate location and time within the body, these systems are essential to modern medicine. This approach is crucial for minimizing side effects, maximizing drug efficacy, and improving patient outcomes.⁵ DDS is essential for improving a medication's therapeutic index. By regulating the medication release's rate, time, and place, these systems can significantly improve both pharmacokinetics (the movement of drugs within the body) and pharmacodynamics (the effects of drugs on the body). For instance, traditional oral or injectable formulations may lead to fluctuating drug levels in the bloodstream, which can reduce efficacy and increase side effects. However, advanced DDS can provide sustained and controlled release of the drug, maintaining optimal therapeutic levels over extended periods and minimizing the need for frequent dosing.⁶

Drug and excipients profile



Aspirin

Non-proprietary name

Ph Eur, BP, USP/NF: Acetylsalicylic acid (ASA)

Synonyms: Acetylsalicylic acid (ASA), Acetyl salicylate, 2-Acetoxybenzoic acid, O-Acetylsalicylic acid, Salicylic acid acetate
Chemical name and CAS registry number
Acetylsalicylic acid and 50-78-2

Molecular weight of aspirin: 180.15 g/mol

Function categories: Analgesic, Anti-inflammatory, Antipyretic, Antiplatelet.

Applications in Pharmaceutical Formulation and Technology

- Aspirin is commonly formulated as tablets for oral administration, often combined with other ingredients like buffers, fillers, and binders. There can be filled into capsules, providing a convenient and easy-to-swallow dosage form.
- Patients who struggle to swallow tablets or capsules, whether young or old, can utilize the aspirin liquids.
- This is used in injectable formulations for acute pain management or anti-inflammatory treatment and it is incorporated into creams, gels, or patches for localized pain relief and anti-inflammatory effects and formulated as sustained-release or extended-release tablets to provide prolonged pain relief.⁷⁻⁹

MATERIALS AND METHODS

For the formulation and assessment experiments, the following chemicals and tools were employed.

Preparation of standard stock solution

A 50 ml volumetric flask was taken with 50 mg of aspirin. Distilled water was used to dissolve up to the required level. This yields a stock solution with a concentration of 100 mg/ml; 5 ml was taken out and diluted to obtain 50ml of concentration (10 mg/ml).^{10,11}

Standard curve preparation of Aspirin

A Concentration of 1 to 10 mg/ml was obtained by withdrawing aliquots ranging from 1 to 10 ml from the standard solution stock solution and

Table 1. List of Materials

Materials used	Category	Manufacture/supplier
Aspirin	Active pharmaceutical ingredient	Zhenjiang Gaopeng Pharmaceutical
Sodium Starch Glycolate, Croscarmellose sodium, Crospovidone	Super disintegrant	JRS Pharma
Mannitol	Sweetener	Tate & Lyle
Microcrystalline cellulose	Diluents	Lactose India Limited
D. Sorbitol	Sweetener & stabilizer	Tate & Lyle
Talc	Glidant	Mondo Minerals
Magnesium Stearate	Lubricant	Perrigo

adding distilled water up to 10 ml. We measured the absorbance of these solutions at 275 nm.

Preformulation studies

Pre- formulation analysis refers to pharmaceutical and analytical study conducted with the intention of supporting efforts to improve the drug substance's dosage form through formula improvement. Pre- formulation produces the basic knowledge needed to expand on the right formula for toxicological use. In addition to providing body paints for the medication mixture with the pharmaceutical excipients inside the dosage form, it supplies the statistics required to characterise the medicinal ingredient. Therefore, using the drug sample that was collected, the following pre- formulation investigations were carried out.¹²

Organoleptic characters

This includes analysing the drug's colour, flavour, and odour. A record of the drug's colour is particularly helpful in choosing the right batches.

1. Bulk Density (Db)

It is ratio of the bulk quantity of powder to the total mass of powder. It was measured by adding the load powder, which had been passed through a general sieve #20- to a measuring cylinder and recording the starting weight. It is provided by and expressed as g/ml.

$$D_b = \frac{M}{V_b}$$

The results were mentioned in the table 09.

Tapped Density (Dt)

It represents the ratio of the powder's total mass to its tapped quantity. The volume of the powder was determined by tapping it 750 times, and if the volumes differed by less than 2%, the tapped quantity was recorded. If the proportion exceeds 2%, tapping is repeated 1250 times, and the volume tapped is recorded. Tapping was continued until there was less than 2% difference between each volume (in a bulk density apparatus).

$$D_t = \frac{M}{V_t}$$

The results were mentioned in the table 09.

Angle of Repose (θ)

The angle of repose can be used to determine the friction forces in a loose powder. It signifies the powder's waft residences. It is said to be the highest possible angle between the horizontal plane and the powder pile floor.

Tablet 2. List of formulation related Equipment

S. No	List of equipment	Manufacturer/ supplier
1	Tablet compression machine	Cadmach, Ahmedabad, India.
2	Digital weight Balance	Radwag
3	Hot air Oven	Thermo Scientific
4	Rapid Mixer Granulator	Medipharma
5	Disintegration tester	Electrolab
6	Friability test apparatus	Campbell electronics, Mumbai

Table 3. Angle of Repose of Powder of Flow Properties

Flow	Angle of repose
Excellent	25-30
Good	30-35
Fair	35-40
Poor	40-45
Very poor	45-50

Table 4. Relationship between % compressibility and flow ability

Flow	Carr's index
Excellent	5-15
Good	12-16
Fair	18-21
Poor	23-35
Very poor	35-38
Extremely poor	More than 40

$$\tan \theta = h / r$$

$$\tan \theta = h / r$$

$$\theta = \tan^{-1} (h / r)$$

The powder aggregate was able to consistently float through the funnel and drop at a precise height on a platform (h). The angle of repose was then established by estimating the radius and peak of the created powder heap.¹³

The results were mentioned in the table 9.

Carr's index (or) % compressibility

It displays the features of powder flow. It is given and stated as a percentage.

$$I = \frac{Dt - Db}{Dt} \times 100$$

The results were mentioned in the table 9.

Hausner ratio

The Hausner ratio is a crude measure of powder flow easiness. The following formula is used to calculate it.

$$\text{Hausner ratio} = Dt/Db$$

Where,

Dt is the tapped density.

Db is the bulk density.

Better flow characteristics are indicated by a lower Hausner ratio (<1.25) than by a higher one (>1.25).

The results were mentioned in the table 9.

Direct compression technique

• As specified in the table, precisely weigh the materials.

Table 5. Manufacturing method - formulation data for aspirin oral dispersible tablet with different Super Disintegrants

Ingredients	F1 (mg/tab)	F2 (mg/tab)	F3 (mg/tab)	F4 (mg/tab)	F5 (mg/tab)	F6 (mg/tab)
Aspirin(mg)	150	150	150	150	150	150
Micro crystalline cellulose(mg)	40	40	40	30	30	30
Sodium starch glycolate(mg)	30	-	-	40	-	-
Croscopovidone(mg)	-	30	-	-	40	-
Croscarmellose sodium(mg)	-	-	30	-	-	40
D-sorbitol(mg)	20	20	20	20	20	20
Mannitol(mg)	4	4	4	4	4	4
Talc(mg)	3	3	3	3	3	3
Magnesium stearate(mg)	3	3	3	3	3	3
Total	250	250	250	250	250	250

* Mean \pm SD (n=6)

Table 6. Weight Variation Specification as per IP

S. No	% Deviation	Average weight of tablet
1	± 10	80 mg or less
2	± 7.5	More than 80 mg but less than 250mg
3	± 5	250 mg or more

Table 7. ICH guidelines for stability study

Time period	Study	Storage condition
12 month	Long term	25°C \pm 2°C/60% RH \pm 5RH OR 30°C \pm 2°C/65% RH \pm 5%RH
6 month	Intermediate	30°C \pm 2°C/65% RH \pm 5%RH
3 month	Accelerated	40°C \pm 2°C/75% RH \pm 5%RH

The stability investigation for the optimised formulation was conducted at 40°C \pm 20°C/75% RH \pm 5% RH for one month.

• Microcrystalline cellulose, sodium croscarmellose, crospovidone, mannitol, D-sorbitol, and sodium starch glycolate should be passed through sieve number 60 and combined for five minutes in a plastic bag.

• Talc and magnesium stearate are used to lubricate the powder mixture, which is mixed for 20 minutes. It's prepared for compression.

The mixture is compressed on a lab press machine using a multiple tolling twenty station

Table 8. Pre-formulation Study of Pure Drug (Aspirin)

Parameters	Result	Conclusion
Bulk Density (gm/cm ³)	0.255	—
Tapped Density (gm/cm ³)	0.334	—
Angle of Repose (è)	30° 40'	Excellent
Carr's Index (%)	23.6	Excellent Flow
Hausner Ratio	1.11	Better Flow
Melting Point	119-120°C	—
Solubility	Freely soluble in methanol, ethanol, chloroform, very slightly soluble in water.	

Table 9. Pre-formulation Study of the blend

BatchCode	F1	F2	F3	F4	F5	F6
Bulk Density (gm/cm ³)	0.252	0.223	0.232	0.233	0.242	0.241
Tapped Density (gm/cm ³)	0.335	0.344	0.333	0.333	0.354	0.334
Angle of repose (è)	31° 14'	30° 44'	29° 34'	29° 24'	32° 33'	31° 19'
%Compressibility	24.77	26.20	26.22	26.40	26.80	25.20
Hausner's Ratio	1.32	1.36	1.35	1.30	1.29	1.28

Mean ±SD (n=6)

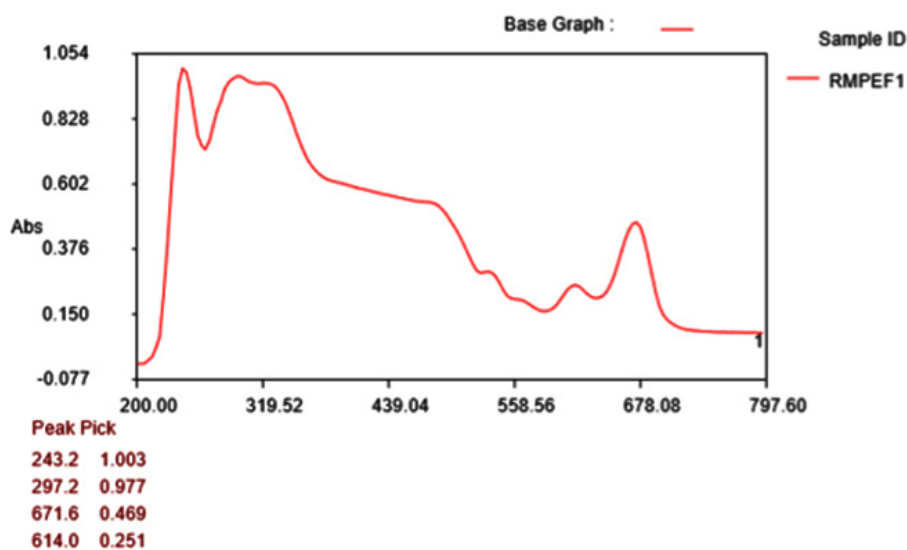


Fig. 1. Wavelength maxima for Aspirin

single rotary with a single pouch (8mm) to make round-shaped tablets. Every tablet has a weight of 250 mg. In order to obtain tablets with a hardness of 3-5 kg/cm², the compression force is adjusted.^{14,15}

Evaluation of oral dispersible tablets¹⁶

In process parameters evaluation

Weight variation test

20 tablets were chosen at random from the batch and each one was weighed separately to look for variations in weight. Specification for weight variation according to IP.

Hardness test

The hardness or tablet crushing strength (fc), or the force required to fracture a tablet in

a diametric compression, was measured with a Monsanto tablet hardness tester. It is stated as kg/cm².

The results were mentioned in the table 12.

Thickness

A Digimatic vernier calliper was utilised to ascertain the thickness of the tablets (Mitutoya, Japan). For every batch, three pills were utilised, and average results were determined.

The results were mentioned in the table 12.

Friability (F)

Using the Roche friabilator, the tablet's friability was assessed. In a plastic cylinder that rotates at 25 rpm and drops a tablet six inches in height with each rotation, this gadget combines the forces of shock and abrasion on the tablet. 100 revolutions were applied to a pre-weighted sample of tablets in the friabilator. After being reweighed, the tablets were dusted with a gentle muslin cloth. With this formula, we may find the friability (F).

$$F = \frac{W_{\text{Initial}} - W_{\text{Final}}}{W_{\text{Initial}}} \times 100$$

Percentage friability and weight loss must both meet acceptance standards of less than 1%.

The results were mentioned in the table 12.

Table 10. Standard calibration curve of Aspirin

Concentration (µg/ml)	Absorbance
1	0.0090
2	0.032
3	0.0545
4	0.0843
5	0.1052
6	0.1244
7	0.1486
8	0.1666
9	0.1836
10	0.1997

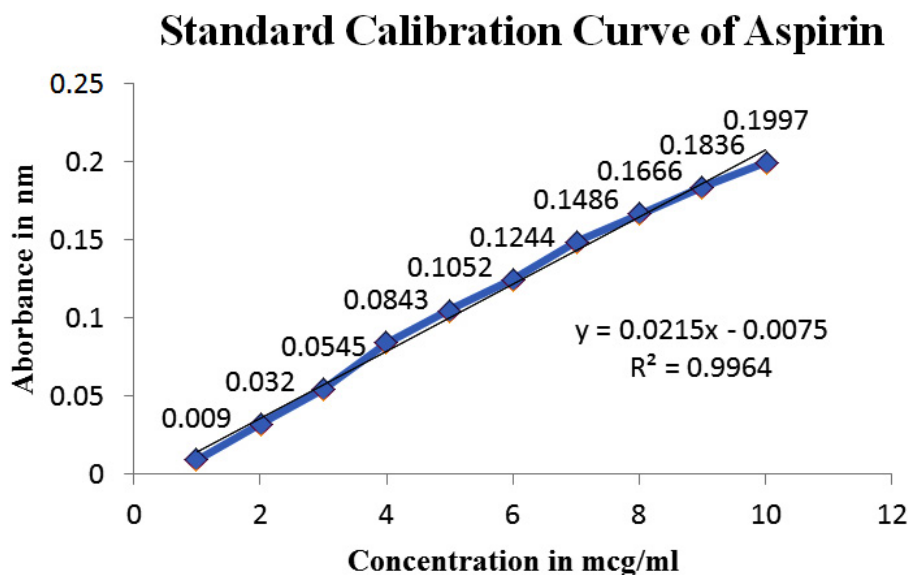


Fig. 2. Standard Calibration Curve of Aspirin

Finished product parameter**Disintegration time testing**

With 900ml of pure water without a disc at room temperature, the USP tablet disintegration test instrument was used to determine it. Six tablets were used for the test. The maximum disintegration time of 30 seconds is the limit specified.

Wetting time of tablet

The porosity, compressibility, and absorption capacity of the tablets are all determined by the wetting time test. Wetting times can be measured as an additional confirmatory test for tablet evaluation, Since the dissolution process of a tablet is dependent on tablet wetting followed by tablet disintegration.

The results were mentioned in the table 12.

Water absorption Ratio

A piece of tissue paper folded twice was placed in a tiny Petri dish containing 6 mL of water. After placing a tablet on the paper, the time it took

for it to get entirely wet was recorded. We then weighed the wetted pill. Equation (a) was used to get the water absorption ratio (R).

$$R = 100 \frac{W_b - W_a}{W_a}$$

The results were mentioned in the table 12.

Stability studies

A drug is deemed stable if its physical properties have not changed considerably or negatively, and its chemical or biological activity has not fallen below a predetermined level of marked potency during a time frame beginning with the date of production and formulation packaging. The stability of the active component must be a major factor in the design and evaluation of drug dosage forms before deciding whether to approve or reject them. A drug is deemed stable if its physical properties have not changed considerably or negatively, and its chemical or biological activity has not fallen below a predetermined level of marked potency during a time frame beginning with the date of production and formulation packaging. The stability of the active component must be a major factor in the design and evaluation of drug dosage forms before deciding whether to approve or reject them.

Table 11. Regression Analysis

Parameters	Value
R ²	0.996
Slope	0.021
Intercept	0.075

Table 12. Evaluation of Post compression parameters of Oral Dissolving tablets of Aspirin

Test	F1	F2	F3	F4	F5	F6
Weight Variation (mg)**	251±1.15	253±1.28	254±1.25	251±1.35	252±1.48	253 ± 1.45
Hardness (kg/cm ²)*	4.96 ±0.136	5.02 ±0.125	4.89 ±0.154	4.69 ± 0.226	4.78 ± 0.188	4.39 ± 0.12
Thickness (mm)*	4.51±0.0142	4.60±0.0112	4.50±0.0112	4.33±0.0132	4.41±0.0132	4.49±0.0133
Friability (%)*	0.542	0.547	0.545	0.49	0.44	0.42
Dis-integration Time(sec)*	13	17	12	15	14	10
Wetting Time (sec)*	53.2±1.527	54.5±1.577	51.1±0.577	51.1±1.527	45.6±1.577	15.3 ± 1.527
Water Absorption Ratio*	64.03±1.577	89.06±0.577	69.33±0.577	75.66±1.527	89.01 ± 1.01	57.2 ± 1.527
Drug-Content (%)*	95.84	95.76	96.57	97.30	98.76	99.89

*Mean±SD (n=6) **Mean±SD (n=20)

Objective of the study

Stability testing is done to forecast how a drug's ingredient or product will behave over time in response to various environmental factors like temperature, humidity, and light. This allows for suggested storage conditions, intervals between tests, and shelf lives. Generally speaking, it takes a while to observe how quickly a product deteriorates at room temperature. The expedited stability study principles are used in order to prevent this unfavourable delay.

The results were mentioned in the table 13.

RESULTS

Pre-formulation Studies of pure drug and excipients

Pre-formulation analysis refers to pharmaceutical and analytical study conducted with the intention of supporting efforts to improve the drug substance's dosage form system. It provides the documentation required to describe the nature of the drug ingredient and provides body paintings for the drug mixture with pharmaceutical users inside the dosage form. Therefore, using the drug sample that was collected, the following

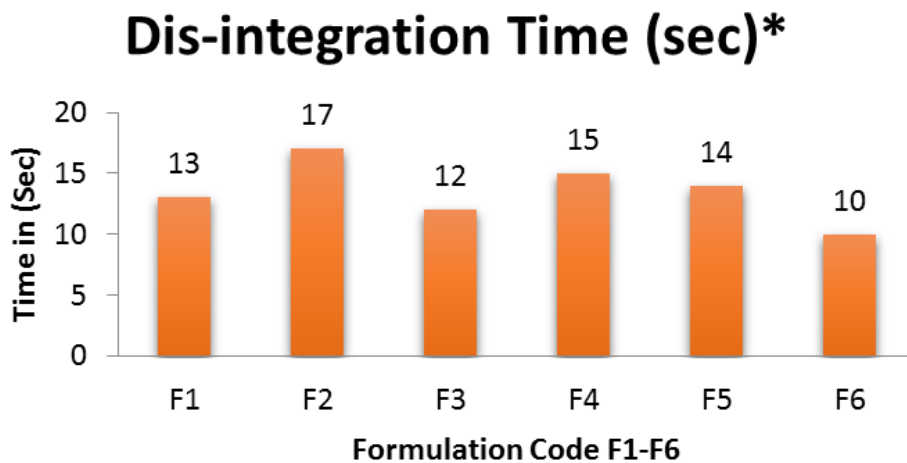


Fig. 3. Comparison of Disintegration Time of various formulations

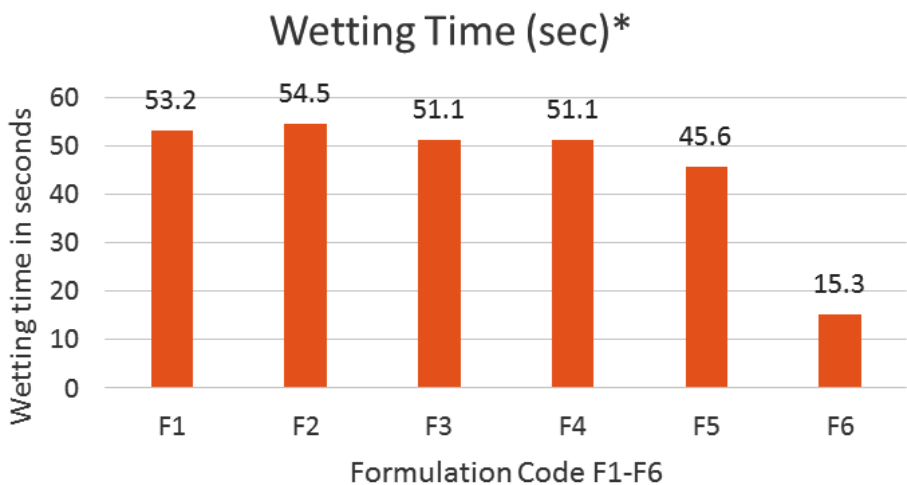


Fig. 4. Comparison of Wetting Time of various formulations

Table 13. Stability studies of optimized formulation F6 at room temperature 25°C

Parameters	Drug content (%) [*]	Disintegration Time (sec.) [*]	Wetting Time (sec.) [*]	Hardness (kg/cm ²) [*]	Friability % [*]
Controlled	99.89	10	15.3 ± 1.527	4.39 ± 0.12	0.42
After 15 days	99.09	11	15.2 ± 1.517	4.28 ± 0.11	0.41
After 1 month	98.79	11	15.01 ± 1.501	4.21 ± 0.01	0.37
Time	Cumulative % Drug Release				
	Controlled	After 15 days	After 1 month		
0	0	0	0		
1	50.31	50.01	49.81		
3	55.01	54.81	54.21		
5	77.92	77.02	76.82		
7	86.43	85.03	84.83		
10	100.05	100.00	99.70		
15	100.04	100.00	99.75		
20	100.04	100.00	99.75		

*Mean±SD (n=6)

pre-formulation investigations were carried out. Pre-formulation study parameters were computed using the method described in Section 5.5 of the experimental work.

To guarantee efficient formulation, aspirin's physicochemical characteristics, stability, and compatibility with excipients and packaging materials are assessed in pre-formulation research. Solubility, melting point, polymorphism, particle size, and chemical stability are important factors.

DISCUSSION

Based on the flow ability scale, the medication has good flow characteristics. The excipients had no impact whatsoever on the blend's flow. It chose to use the direct compression method as a result.

Determination of UV absorption maxima of Aspirin

Using a double beam UV/VIS spectrophotometer, UV scanning was performed for a 10 mg/ml drug solution from 200–400 nm in methanol as a blank. The wavelength at which the maximum was discovered was 275 nm. (Figure 1).

Calibration curve

Aspirin at varying concentrations (1 to 10 µg/ml) was produced using distilled water and subjected to UV analysis at 275 nm, with matching

media serving as a blank. In the 1 to 10 µg/ml range, the absorbance complies with the Beers-Lamberts law. The data are shown in Table 10 and Figure 2.

Considering the concept of initial identity, it can be inferred that the substance adhered to the original identity. It was also determined by scanning the drug in methanol dissolving fluid that the drug's maximal wavelength was 275 nm.

Evaluation studies of OD Tablets

Disintegration Time of Formulations F1 to F6

When evaluating oral dissolving tablets, the primary metric to be considered is the disintegration time. The image below visually depicts the effect of four distinct super-Disintegrants and the variances in their functionalities. The combination of two super disintegrates at moderate concentration was found to have the shortest disintegration time among all tablet formulations. It is caused by the water being absorbed quickly—in less than a second—without forming lumps, which results in a burst effect. It was discovered that as the concentration of super-disintegrant increased, disintegration time decreased. According to the type of super-disintegrant, the disintegration time follows the order.

Wetting Time of Formulations F1 to F6

The most crucial factor in oral dissolving tablet formulations is the wetting time. The time it takes for water to reach the tablet's surface indicates

how long it will take for the tablet to become wet. This signifies both the drug's hydrophilicity and the impact of super-Disintegrants. According to the current study, crospovidone had the shortest wetting time among the several super-Disintegrants. Additionally, a graphic comparison of all the formulations from F1 through F6 is shown in the picture below. In the present investigation, wetting times are lowered for all batches as the super-disintegrant ratio rises. Each formulation has a different wetting time, which is listed in this sequence.

Stability Studies of Oral Dissolving Tablets

The manufacturing company bears the task of ensuring that products arrive to customers in an active state. Pharmaceutical stability is therefore a crucial factor. The capacity of a certain formulation in a given container to maintain its physical, chemical, microbiological, therapeutic, and toxicological specifications is known as drug stability; in other words, a medication's stability is its resistance to deterioration. The approved potency label requires a minimum potency of 90%. Stability testing is therefore required for pharmaceutical items. The table was below the Table 13.

CONCLUSION

The dispersible aspirin tablets were successfully formulated with the desired characteristics, including appropriate hardness, disintegration time, and dispersion quality. The use of suitable excipients, such as Disintegrants and binders, was crucial in achieving these properties. Stability studies indicated that the dispersible aspirin tablets maintained their efficacy and quality over the proposed shelf life. The formulation was stable under the tested storage conditions, which supports its potential for long-term use.

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Conflict of Interest

The author(s) do not have any conflict of interest.

Data Availability Statement

This statement does not apply to this article.

Ethics Statement

This research did not involve human participants, animal subjects, or any material that requires ethical approval.

Informed Consent Statement

This study did not involve human participants, and therefore, informed consent was not required.

Clinical Trial Registration

This research does not involve any clinical trials.

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Not Applicable.

Author's Contribution

• Umamaheswari D: wrote the protocol and first draft of the manuscript. • Kumar Mohan: The study's analyses. • Anand sanjay kamaraj and Sudharsan Jayasankar: The literature searches. • Thirumoorthy Poomalai and Vignesh Ezhilarasan: Data collection, writing – review and editing.

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