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(RESEARCH ARTICLE)

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Design, development, formulation and evaluation of hard gelatin aspirin capsule

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Abstract

Immediate-release Aspirin capsules are widely used for the treatment of pain, fever, and inflammation, and for the prevention of cardiovascular events. This study focuses on the formulation, development, and evaluation of immediate-release Aspirin capsules. The primary aim is to design a formulation that ensures rapid disintegration and dissolution, providing quick therapeutic effects. The capsules are prepared using a blend of active pharmaceutical ingredients (Aspirin) and excipients, including starch, lactose, and talc, utilizing a hand-filling method. The stability, dissolution, disintegration, and uniformity of drug content are assessed as per pharmacopeial standards, ensuring that the final product meets the required specifications for efficacy and quality. Stability studies conducted under ICH guidelines confirm that the capsules maintain their potency and integrity over time when stored under recommended conditions. The results of this study contribute to the development of a reliable, immediate-release Aspirin dosage form that provides rapid pain relief, fever reduction, and other therapeutic benefits.

Keywords: Aspirin; Hard Gelatin Capsule; Immediate Release; Disintegration; Dissolution

1. Introduction

Aspirin is used to reduce fever and relieve mild to moderate pain from conditions such as muscle aches, toothaches, common cold, and headaches. It may also be used to reduce pain and swelling in conditions such as Aspirin, also known as acetylsalicylic acid, is a nonsteroidal anti-inflammatory drug used to reduce pain, fever, and/or inflammation, and as an antithrombotic arthritis.[2]

Aspirin is classified as a *non-selective cyclooxygenase (COX) inhibitor* [5,6] and is available in many doses and forms, including chewable tablets, suppositories, extended-release formulations, and others.

Acetylsalicylic acid (ASA) or aspirin is one of the most researched medicines in the world and its history can be traced back 3500 years. It belongs to a group of drugs called salicylates which were first used in medicinal purposes in the form of willow bark that contained Salicin. It was used for treating inflammatory joint pains and other inflammatory conditions.[7]

1.1. Mechanism of action of asprin

The mechanism of action of ASA was not known for many years but it was later determined to be a cyclooxygenase (COX) inhibitor (Vane & Botting, 2003). The COX enzyme is required to convert arachidonic acid to prostaglandins. COX isoforms are responsible for different mechanisms in the body and therefore ASA has more than one mechanism of action. COX-1 is a housekeeping enzyme and has a role in platelet aggregation, renal water balance and gastric cytoprotecting. COX-2 has a big role in inflammation and is the main target for non-steroid anti inflammation drugs

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(Morita, 2002). By irreversible inhibiting COX-1 it blocks the formation of thromboxane which leads to antithrombotic affect and has effect on platelet aggregation (Micromedex, 2021). The inhibition of COX-2 leads to an antiinflammation effect, reduces fever and relieves pain (Vane & Botting, 2003). Different doses of ASA are taken based on what effect of the drug is desired. Lower doses are rather taken for antithrombotic affects than reduction of fever or pain, such as headaches or a migraine.

1.2. Medical uses of aspirin

ASA is widely used and has many different indications, both FDA and non-FDA. FDA uses include many kinds of cardio-vascular disorders such as angina and myocardial infraction. It is also used for fever, headache, migraine, general pain, and rheumatoid arthritis among other indications. ASA has many non-FDA uses including uses for Kawasaki disease, pregnancy induced hypertension and thromboembolic disorders to name a few. Further, taking low doses of ASA daily can reduce the risk of mortality in women, where it especially reduces the risk of death from cardiovascular disease.

1.3. Indications of the aspirin

- Analgesic (Headache, backache, myalgia, joint pain, tooth care)
- Antipyretics
- Anti-inflammatory
- Acute Rheumatic Fever
- Rheumatoid Arthritis
- Osteo Arthritis
- Post myocardial infraction & Post Stroke Patient
- Coronary Bypass
- Transluminal Angio plasty

1.4. Contra indications of the aspirin

- Gastric and duodenal ulcer
- Hepatic and renal diseases
- Bleeding diathesis
- Haemophilia
- Third trimester of pregnancy
- In Children below 12 years of age.

For three reasons aspirin (acetyl salicylic acid or acetyl salicylate) is an immensely important drug. First it is important because millions of people throughout the world can take it. Without heavy expense or having to consult a physician, with no risk of addiction and little of serious toxicity. To comeback several of the minor ills that flesh is heir to.

Second, acetyl salicylate is important because, as a result these properties, it becomes for long the most widely uses medicinal drug in the world. As such, it established the fortunes not only for the Rhineland Firme of Bayer that introduce it to the world, but also of several others combines, which, for reasons of war, where able to take over part of is immense market.

Third, Aspirin has proud of great important to medical science, because an experimental analysis of its molecular mechanism of action has played a vital role in the discovery of a for reaching system of bodily defences, based on the product of enzyme acting on arachidonic and related unsaturated fatty acid and their metabolites .we may call this the arachidonate and closely related system of lipid local hormones that Sune Bergstrom Bengt Samuelsson and john vane were awarded the 1982 Nobel prize for physiology and medicine.

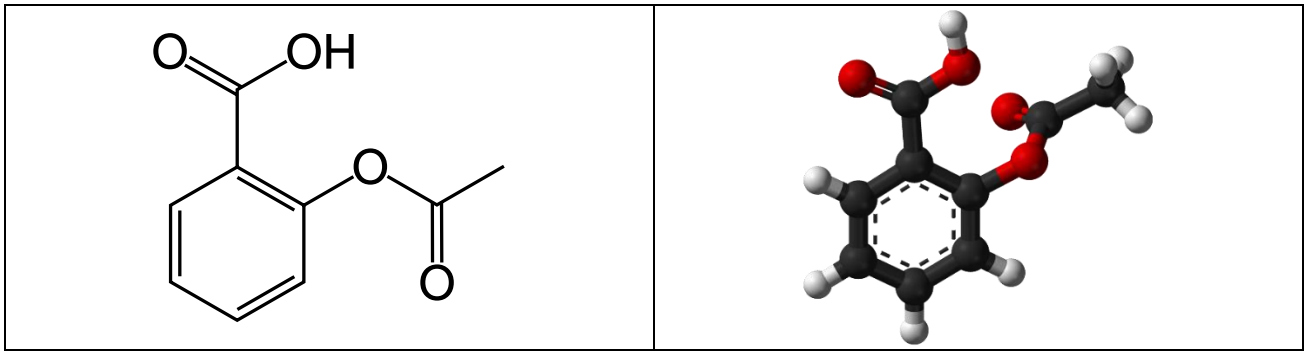

Figure 1 Structure Of ASPIRIN

Table 1 Physiochemical Property of Hard Gelatin Aspirin capsule

Formula	$C_9H_8O_4$
Molar mass	180.159 g·mol^{-1}
Density	1.40 g/cm^3
Melting point	135 °C (275 °F)
Boiling point	140 °C (284 °F) (decomposes)
Solubility in water	3 g/L
Other names	2-acetoxybenzoic acid 2-(acetyloxy)benzoic acid
Routes of administration	Oral, rectal
Drug Class	Non-Steroidal anti-inflammatory drug (NSAID)
Bio Availability	80-100%
Metabolism / Excretion	Liver / Urine, Sweat, Saliva, feces

2. Methodology

2.1. Formulation

The formulation of the immediate-release Aspirin capsule includes active pharmaceutical ingredients like Aspirin, along with excipients such as starch, lactose, and talc.

The formula for preparing a single 100 mg immediate-release Aspirin capsule per batch, utilizing the hand-filling method, is as follows:

Table 2 Ingredients for preparing a single 100 mg immediate-release Aspirin capsule.

S. No	**Ingredients**	**F1**	**F2**	**F3**	**F4**	**F5**
1	Aspirin	100 mg	100 mg	100 mg	100 mg	100 mg
2	Starch	50 mg	40 mg	30 mg	55 mg	40 mg
3	Lactose	80 mg	90 mg	100 mg	75 mg	85 mg
4	Talc	20 mg	20 mg	20 mg	20 mg	25 mg
Total Weight		250 mg	250 mg	250 mg	250 mg	250 mg

3. Result and discussion

3.1. Pre-evaluation study

3.1.1. Angle of repose

It is the maximum angle at which a pile of powder or granules remains stable without any material sliding off. It indicates the flowability of the powder.

θ = tan^-1(h/r)

Where,
- θ = Angle of repose
- h = Height of the powder pile
- r = Radius of the base of the pile

Table 3 Flow Property of Hard Gelatin Aspirin Capsule

Glidant	**Angle of Repose**				
	F1	**F2**	**F3**	**F4**	**F5**
Without Glidant	44° 21'± 0.42	39° 56'± 0.56	29° 14'± 0.68	29° 11'± 0.72	35° 36'± 0.85
With Glidant	35° 16'± 0.26	28° 06'± 1.35	25° 06'± 1.49	24° 17'± 1.62	26° 46'± 0.92

3.1.2. Bulk density

Bulk density is the mass of powder per unit volume, including void spaces between particles. It reflects the packing of the powder.

$$\rho_b = M/V_b$$

Where,
- ρ_b = Bulk density (g/cm^3)
- M = Mass of powder (g)
- V_b = Bulk volume (cm^3) (volume of powder including void spaces)

3.1.3. Tapped density

Tapped density is the density of the powder after being compacted by tapping or vibration, allowing the particles to settle more tightly.

$$\rho_t = M/V_t$$

Where,
- ρ_t = Tapped density (g/cm^3)
- M = Mass of powder (g)
- V_t = Tapped volume (cm^3) (volume after tapping)

3.1.4. Carr's index (compressibility index):

Carr's Index is a measure of the compressibility of a powder, which helps to assess the flowability and how much the powder can be compacted.

$$\rho_t - \rho_b/\rho_t \times 100$$

Where,
- ρ_t = Tapped density
- ρ_b = Bulk density

3.1.5. Hausner ratio

The Hausner Ratio is a ratio of tapped density to bulk density. It provides an estimate of the powder's flow properties.

$$\rho_t/\rho_b$$

Where,
- ρ_t = Tapped density
- ρ_b = Bulk density

3.2. Disintegration test

- Equipment: Use a disintegration apparatus fitted with a basket-rack assembly containing six tubes, each with a mesh screen at the bottom.
- Medium: Place the capsules in a 0.1 N HCl solution (simulating gastric fluid) maintained at 37 ± 0.5°C.
- Duration: Operate the apparatus for 15–30 minutes or as specified in the pharmacopeial guidelines for Aspirin capsules.

Table 4 Disintegration Rate of Hard Gelatin Capsule

Serial No. of Capsule	Disintegration Time (Mins)
1	10
2	10
3	10
4	10
5	10
6	10

3.3. Dissolution test

In this test, capsules are placed in a dissolution apparatus (usually a basket or paddle apparatus) containing a liquid medium (e.g., water, buffer solution). The capsules are rotated at a specified speed, and the concentration of the drug in the solution is measured at different time intervals to determine how quickly the active ingredient is released from the capsule.

- The capsule releases its drug over time, and the dissolution profile shows how much of the drug is dissolved in the medium.
- A rapid release within 5-10 minutes is generally preferred for immediate-release formulations.

The Immediate-release capsules should release the active ingredient quickly (within 5-10 minutes) so that the drug starts working fast in the body.

Table 5 Dissolution rate of hard gelatin capsule

Formulation Code						
S. No	**F1**	**F2**	**F3**	**F4**	**F5**	**Pure Drug ± SD**
10	8.91±1.307	10.69±0.758	14.2±0.634	17.82±0.667	16.1±0.707	14±0.22
20	15.57±0.908	18.36±0.357	21.24±0.627	28.26±0.707	24.03±0.384	22±0.68
30	25.33±1.980	26.6±0.786	30.6±0.818	40.1±1.842	34.6±1.403	41±0.85
40	31.95±0.895	37.8±0.820	38.43±0.485	51.12±0.632	48.6±0.489	53±1.25
50	68.46±1.474	72.1±0.693	75.9±0.456	87.13±0.934	79.6±1.964	62±1.54
60	85.5±0.482	86.1±0.487	88.56±0.432	98.1±0.930	95.94±0.894	71±1.79

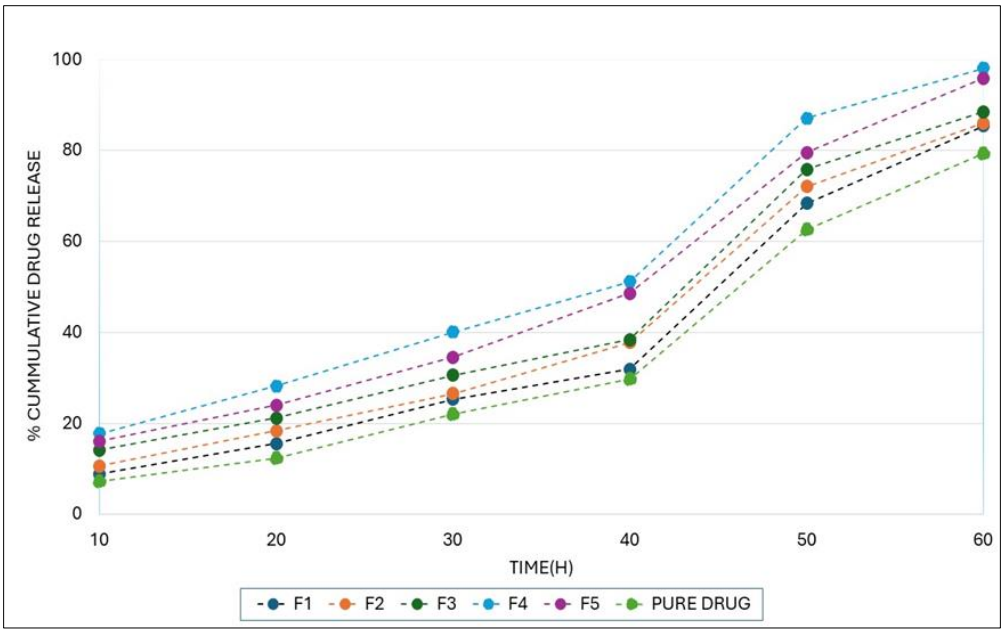

Figure 2 Effect of formulation (f1-f5) on absorption rate"

4. Conclusion

The results clearly show that the formulations exhibit a rapid release of the active ingredient, which is a characteristic feature of immediate-release formulations. The dissolution data indicates a quick and consistent release of Aspirin within the first 10 to 20 minutes of administration. This rapid release ensures that the drug reaches therapeutic concentrations in the bloodstream promptly, providing quick pain relief for conditions requiring fast action, like fever, headache, or mild to moderate pain. By observing the in-vitro drug release, F4 is best formulation, because it shows [98.1%± 0.930] drug release more than the other formulations. In the F4 formulation, Disintegration agent [starch] is added more and binding agent is added less.

The dissolution profiles of F1, F2, F3, F4, F5 show that the release of Aspirin is uniform and consistent, confirming the suitability of these capsules for immediate-release applications. The data suggests that these formulations are effective in achieving rapid therapeutic effects, ensuring that patients get timely relief.

This study highlights the importance of formulation design in optimizing the drug release characteristics. The Aspirin 100 mg capsules show promise as an immediate-release dosage form, offering fast and effective action. However, further studies on bioavailability and clinical trials are recommended to confirm these results in real-world applications.

Compliance with ethical standards

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Disclosure of conflict of interest

The Author declare that there is no conflict of interest to be disclosed.

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Authors short Biography

I'm Abarna P, currently in my final year of Bachelor of Pharmacy (B. Pharm). My academic journey in pharmacy has been enriching, and I'm excited to apply my knowledge in the healthcare field. Outside of studies, I enjoy reading historical books, which have broadened my understanding of different cultures and timelines. I'm passionate about personal growth and believe in continuous learning. As I approach the end of my degree, I'm focused on gaining practical experience and looking forward to contributing to the pharmaceutical industry.