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Original Research Article

Development And Evaluation of Natural Polymer-Based Sustained-Release Matrix Tablets of Aceclofenac

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Abstract:

The development of sustained-release drug delivery systems is a promising approach to improve patient compliance and therapeutic efficacy by maintaining consistent drug levels over extended periods. Aceclofenac, a non-steroidal anti-inflammatory drug (NSAID), is widely used for pain management and inflammatory conditions but suffers from frequent dosing and potential gastrointestinal side effects. This study aims to formulate and evaluate sustained-release matrix tablets of Aceclofenac using natural polymers as matrix-forming agents. Natural polymers like *Psidium guajava* mucilage was investigated for their potential to modulate drug release and provide eco-friendly pharmaceutical alternatives. The prepared formulations were subjected to many evaluation parameters like appearance, dimension, weight variation, hardness, friability, drug content as well as in-vitro dissolution studies. A sustained delivery of medicament over a period of 12 hours is the result of an increase in the concentration of *Psidium guajava* mucilage. The investigation demonstrated that the release rate of formulation F9 from the matrix tablets is contingent upon the concentration of Psidium guajava, as drug release was observed to be delayed as the *Psidium guajava* mucilage content increased.

Keywords: sustained-release drug delivery systems, NSAID, Psidium guajava, in-vitro dissolution studies.

Introduction

Sustained-release tablets are a specialized form of drug delivery designed to release medication at a predetermined and constant rate over an extended period [1]. This mechanism allows for prolonged therapeutic action while minimizing fluctuations in drug levels within the bloodstream [2]. By delivering a specific drug at a programmed rate, sustained-release formulations can maintain therapeutic concentrations more effectively than immediate-release counterparts. This capability enhances patient outcomes by ensuring that the drug remains at effective levels for a longer duration, which is particularly beneficial in managing chronic conditions that require consistent medication levels.

The advantages of sustained-release tablets over immediate-release formulations are numerous and significant [3]. One of the primary benefits is the reduction in the frequency of administration, which can lead to improved patient compliance with medication regimens [4]. Additionally, sustained-release formulations can minimize side effects by maintaining stable drug absorption levels, thereby reducing the peaks and troughs associated with immediate-release drugs. This stability can

help prevent adverse effects related to high blood concentrations, making sustained-release tablets a safer option for many patients. Furthermore, the design of these tablets often incorporates polymers that control the release rate, enhancing their effectiveness and reliability as a medication delivery system [5,6].

This study aimed to produce Aceclofenac sustained-release matrix tablets by integrating the medication with a natural polymer. Tablets are produced by a wet granulation method, utilising a natural polymer as the release-retarding agent in conjunction with suitable additives.

This study aimed to develop and assess Aceclofenac sustained-release tablets for effective prolonged medication delivery.

Methodology

Wet granulation was employed to produce the granules for the aceclofenac matrix tablets, utilising varying concentrations of *Psidium guajava* mucilage and povidone as release-retardant polymers. All was satisfactory following the passage through filter No. 80. A granulating agent, namely an isopropyl alcoholic solution of polyvinyl pyrrolidone, was incrementally introduced while the requisite amounts of medicine, polymers, and additional ingredients were well mixed. The wet slurry was filtered through a No. 60 screen once adequate cohesiveness was achieved. Following 30 minutes of drying at 35 degrees Celsius, the granules were subjected to sieving over a No. 100 mesh screen. Ultimately, MCC and magnesium stearate, both employed as lubricants, were incorporated.

Evaluation of Prepared Matrix Tablets

Appearance, Shape and Size

The produced tablets were visually inspected for their appearance.

Dimension (thickness and diameter):

It was crucial that the tablets possess identical diameter and thickness. A vernier calliper was employed to measure the thickness and diameter of the tablets. Each formulation type employed ten tablets, and the average has been determined [7].

Weight variation

This examination is employed to verify that all manufactured tablets possess uniform weight, as the drug content correlates directly with tablet weight. Twenty pills were individually weighed throughout this operation. The average weight of a tablet was calculated by computing the mean of the averages.

Hardness

The amount of force used to fracture a tablet is referred to as its "hardness." The tablets produced were evaluated using a hardness tester. A hardness value of kg/cm² was achieved. The mean was calculated by averaging three pills from each formulation [8].

Friability

The friability of the tablets was assessed utilising a Roche friabilator. The friabilator chamber contained 20 tablets of the required weight. The friabilator operated for 4 minutes at a velocity of 25 revolutions per minute. Friability was assessed by reweighing the tablets following 100 rotations and calculating the percentage drop in their weight [9].

$$\%Friability = \frac{Initial\ weight - Final\ weight}{Initial\ weight} \times 100$$

Drug content

Ten tablets were pulverised in a mortar and pestle to obtain a powder for drug content analysis. The weight of a single tablet was converted to powder and dissolved in distilled water. The maximum absorbance (λmax) of Aceclofenac can be ascertained using a UV-Visible Spectrophotometer, with appropriate dilution if required. A standard calibration curve was employed to ascertain the precise quantity of the medication [10].

In-vitro Dissolution Studies

Dissolution tests for matrix tablets are conducted to ensure sustained release of Aceclofenac. The dissolving of matrix tablets was investigated in two phases. During the initial two hours of dissolution, an acid buffer with a pH of 1.2, simulating the gastrointestinal environment, was employed.

A phosphate buffer at pH 6.8, simulating the intestinal environment, was employed as the dissolution medium for the following ten hours. Dissolution tests were conducted utilising paddle apparatus at 50 RPM and 370 ± 0.50 °C [11].

Results and Discussions

Tablets have been assessed based on various parameters following formulation. The subsequent criteria were employed to evaluate the formulated matrix tablets:

Appearance, Shape and Size

The produced tablets were entirely consistent in dimensions and form. All formulas demonstrated a diameter ranging from 7.8 mm to 8.0 mm as well as a thickness within 3.8 mm and 4.0 mm. Mentioned in table 1.

Weight variation

Since the percentage of deviation from the average tablet weight was within the acceptable range for all tablets, all formulations passed the weight variation test according to pharmacopeial criteria. Results displayed in table 2.

Hardness

It was discovered that the tablets had a hardness ranging from 5.4±0.20 kg/cm^2 to 6.6±0.30 kg/cm^2, indicating that they are strong enough. Resulted shown in table 3.

Friability

The friability of the prepared tablets was determined to be 0.53±0.10 to 0.67±0.20, which is below the standard limit of 1%. The matrix tablets that were manufactured may be deemed effective by the friability test. Mentioned in table 4.

Drug Content

The drug content of the manufactured tablets, expressed as a percentage, was found to be within the parameters specified by the guidelines, ranging from 96.74±0.23 to 99.66±0.12%. Mentioned in table 4.

In-vitro Dissolution Studies

Polymer composition in the sustained release layer was crucial to medication release. Psidium Guajava dry mucilage polymer, povidone, and microcrystalline cellulose were used to make sustained-release formulations.

The release profile for F1 showed 98.81% drug release in 12 hours. The release profile for F2 showed 95.34% in 12 hours. The 12-hour release profile for F3 indicated 90.95% efficacy. Adding Psidium Guajava mucilage dramatically reduced Aceclofenac release.

According to F4, 80.63 percent were released after 12 hours. F5 released 77.16% gradually after 12 hours. F6 released more slowly than F5, reaching 72.01% after 12 hours.

According to release profile F7, 61.68 percent was released after 12 hours. On F8's release profile, 59.51 percent was issued after 12 hours. F9 indicated 55.63 percent release after 12 hours. Results show that F9 has better sustained release than other formulations.

When compared to other formulations, batches with higher polymer concentrations released drugs slower in-vitro. This was shown by slower release rates at greater polymer concentrations. Based on in-vitro drug release data, formulation F9 was best. The F9 formulation will undergo stability testing. Results are displayed in table 5.

Table 1: Shape and size of prepared matrix tablets

Formulation	Shape	Diameter	Thickness
F1	Round	7.8 mm	3.8 mm
F2	Round	8.0 mm	3.8 mm
F3	Round	8.0 mm	3.9 mm
F4	Round	7.9 mm	4.0 mm
F5	Round	8.0 mm	4.0 mm
F6	Round	7.8 mm	3.8 mm
F7	Round	8.0 mm	3.9 mm
F8	Round	8.0 mm	4.0 mm
F9	Round	7.9 mm	4.0 mm

Table 2: Average weight of prepared matrix tablets

Formulations	Average weight (mg) (Mean±S.D.*)
F1	299.91±0.85
F2	299.84±0.59
F3	302.13±0.66
F4	299.93±0.51
F5	301.16±0.52
F6	299.79±0.66
F7	299.87±0.97
F8	301.74±0.67
F9	301.03±0.51

Table 3: Average hardness of prepared matrix tablets

Formulation	Average Hardness (kg/cm^2) (Mean±S.D.*)	
	Monsanto type	**Pfizer type**
F1	5.7±0.20	5.4±0.20
F2	5.8±0.30	5.9±0.30
F3	6.5±0.20	6.5±0.30
F4	5.6±0.30	5.5±0.20
F5	5.7±0.20	5.8±0.10
F6	6.3±0.20	6.3±0.10
F7	6.2±0.20	6.1±0.30
F8	6.4±0.30	6.4±0.20
F9	6.6±0.20	6.6±0.10

Table 4: Friability and Drug Content of prepared matrix tablets

Formulations	Friability (%)	Drug content (%w/w)
F1	0.67±0.20	98.87±0.05
F2	0.64±0.10	97.56±0.08
F3	0.62±0.10	98.23±0.17
F4	0.64±0.20	96.74±0.23
F5	0.60±0.20	98.63±0.14
F6	0.57±0.10	97.66±0.12
F7	0.59±0.20	98.84±0.24
F8	0.57±0.10	98.47±0.08
F9	0.53±0.10	99.66±0.12

Table 5: Dissolution profile of Aceclofenac matrix tablet formulations

Time (Min.)	Cumulative % Drug Release								
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
0	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1	6.42	8.13	6.44	5.56	5.15	5.15	4.73	4.72	4.28
2	11.57	11.59	10.28	8.59	9.02	8.56	7.73	8.13	7.71
3	22.74	22.75	22.72	15.88	15.86	13.32	13.74	13.31	12.86
4	34.75	34.75	23.18	22.76	24.04	23.18	22.75	21.48	21.04
5	43.81	43.81	34.37	31.78	31.36	28.78	28.36	27.04	25.76
6	59.72	54.55	41.69	37.82	37.37	35.67	35.21	31.83	30.52
7	68.35	61.06	52.02	48.98	46.86	43.43	36.97	36.13	35.67
8	78.72	67.97	58.94	57.18	51.18	49.88	42.58	41.32	37.86
9	84.78	78.76	70.12	61.96	57.25	53.35	49.06	48.21	43.92
10	90.76	80.47	75.72	68.83	62.83	57.24	51.22	50.36	48.63
11	96.14	90.08	83.16	72.41	67.67	65.08	56.48	56.04	52.14
12	98.81	95.34	90.95	80.63	77.16	72.01	61.68	59.51	55.63

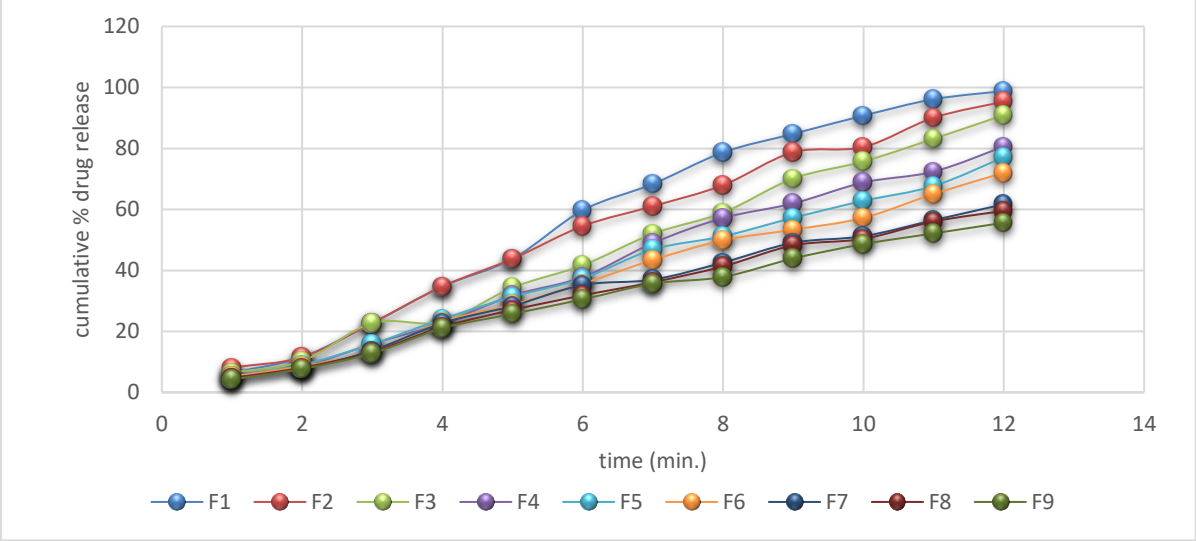

Fig. 1: *In-vitro* release profile of Aceclofenac Matrix tablet(F1-F9)

Conclusion

Sustained-release matrix tablets of Aceclofenac using natural polymers were successfully formulated and evaluated. The study demonstrated that natural polymers, particularly when used in combination, can effectively control drug release and offer a sustainable approach to drug delivery. This formulation holds potential for improving patient compliance, reducing dosing frequency, and minimizing side effects associated with conventional Aceclofenac tablets.

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