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Research Article

Development of Ibuprofen tablets using plant and animal-sourced binders

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Abstract

The current research aimed to develop and formulate two batches of ibuprofen tablets (IBTs) using acacia (batch M) and gelatin (batch N) binders, processed through a wet granulation technique, and compare the effects of binders. The properties of ibuprofen granules (IBGs) were evaluated using micromeritics properties, and the compressed tablets were evaluated by disintegration crushing strength, weight uniformity active ingredient content, friability and *in vitro* drug release tests. The results showed that the granules had good flow properties. The disintegration times and crushing strength tests were within the range of 18.55 ± 5.32 and 12.68 ± 2.47 min, and 14.57 ± 12.5 and 8.12 ± 0.23 Kgf for batches M and N, respectively. Batch M (formulated with acacia binder) showed greater mechanical strength and more abrasion resistance. The % weight deviations of batches M and N were significantly ($p < 0.05$) < 5 w/w % for tablet weights > 250 mg. The *in vitro* drug release of batches M and N indicated that the time to release 40% and 80% ($T_{40\%}$ and $T_{80\%}$) of the drug content was 20 and 15 min, respectively. Therefore, acacia tablet batch M produced significantly harder tablets than gelatin and could be applied for sustained drug release, while batch N could serve as an immediate drug release, both at 3% for the production of ibuprofen tablets.

1. Introduction

Tablets are solid dosage forms that comprise a unit dose of one or more drugs. The compression of uniform volumes of powder or granule particles results in a tablet dosage form [1]. It is the most common dosage form available in the market. Oral tablets are commonly preferred by patients due to their advantages over other dosage forms [2-4]. Self-medication and ease of swallowing are the major. Advantages. The essential quality of the compressed tablet is its robustness, which enables it to withstand post-compaction handling and transportation [5]. Tablet production involves complex multistage processes which require sound knowledge and experience in the art and science. Some challenges may arise during the formulation process despite the acquisition of the process. The most prominent problems encountered in the formulation processes are cracking, sticking, picking, chipping, capping, and lamination [6]. Capping or lamination is more defective in tablet preparation, especially during handling, shipping, and dispensing. Tablet capping is the partial or complete separation of particles from the lower or upper part of the tablets, either from the die cavity ejection or during handling. The presence of air in the compression powder mix, followed by the expansion of the tablet during ejection from the die cavity of the tablet press, is a major cause of capping. Other causes of capping could be too many fines that occur due to poor granulation, too many dried granules with very low moisture content, wrong choice of binder, high plasto-elasticity of the tablet base, inordinate compression pressure, and

inadequate clearance within the punch and die cavity [7]. Lamination, one of the problems encountered during the tableting process, involves the horizontal division of tablets into two or more distinct parts. It has similar causes of–capping. To ameliorate these challenges, preformulation tests should be conducted to select the best excipients for any drug formulation. A previous report [8] presented some techniques for alleviating capping and lamination. One major technique involves the use of binding agents [9-11]. The reduction of the plasto-elasticity of the granule mix is one of the major roles of binding materials in alleviating capping and lamination.

Binders are polymeric agents that possess cohesive and adhesive properties [12, 13]. Binders' mucilage is added to the powder mix during granulation to enhance the establishment of agglomerates and improve the flow properties of the active pharmaceutical ingredient (API). Moreover, binders enhance compressibility and reduce friability. Binder films coat drug particles, and hence, the rate at which the tablet particles dissolve influences the release rate of the API [14]. Exuberant binder concentrations produce delayed disintegration and strong tablets, while low binder concentration yields soft and non-adhesive tablets with capping problems [14]. Binders provide the structural intensity necessary for tablets during production, material packaging, dispensing, and shipping–[15]. Binding agents mostly exhibit plastic compaction properties. Therefore, the incorporation of binders into elastic or fragmenting natural powders imparts plasticity characteristics, thereby reducing their plasto-elasticity [16].

Ibuprofen is a family of propionic acid derivative. It belongs to the class of nonsteroidal anti-inflammatory drugs (NSAIDs) with anti-inflammatory, analgesic, and antipyretic activities. Thus, Ibuprofen is a medication that alleviates inflammatory conditions such as fever, swelling, and redness. Therefore, NSAIDs, inhibit the effects of cyclooxygenase I and II, subsequently reducing the formation of precursors of prostaglandins and thromboxane as a result of decreased prostaglandin synthesis through the prostaglandin synthase. Ibuprofen also inhibits platelet aggregation by reducing thromboxane A_2 synthesis. Thus, this study aimed to formulate ibuprofen tablets with natural binders, acacia from plant origin and gelatin from animal sources, and compare their effects.

2. Materials and methods

2.1. Materials

Ibuprofen (Basf, Germany), acacia (Nexira), gelatin (Sigma Aldrich), and water (Lion Water, UNN). All other reagents were of analytical grade and used without further purification.

2.2. Methods

2.2.1. Formulation of ibuprofen tablet

An appropriate amount of each excipient was weighed and presented in Table 1. The wet granulation technique was employed in tablet production with two different binders, acacia and gelatin, at 3 % (w/w) concentration to produce 120 tablets each with batch samples M1- M5 and N1 – N5, respectively.

Table 1. Composition of ibuprofen tablets.

Ingredient	Quantity per tablet (mg)	
	M	N
Ibuprofen	200	200
Binder	9	9
Magnesium stearate	3	3
Maize starch	30	30
Lactose q. s	300 mg	300 mg

M and N are tablet batches containing acacia and gelatin as binders, respectively.

The powdered excipient samples were blended for 10 min in a tumbler mixer (Jiang Yin Lin Machinery Equipment Co., Ltd.). The mixture was then dampeded with a preselected quantity of binder prepared with warm distilled water. The damped mass was wet-screened through a 1.7 mm sieve. The wet granules were dried in a hot air oven approximately at 60 °C for 60 min. The dried granules were then screened again using a 1.0 mm sieve aperture and the granule properties were obtained. Thereafter, before compression, the granules were lubricated using magnesium stearate and then compressed within 46-48 kgf using a 9.00 mm punch die set fitted into an automated F3 Manesty Single Punch tableting machine.

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2.2.2. Evaluation of the ibuprofen granules

2.2.2.1. Determination of micromeritics properties

2.2.2.1.1. Bulk and Tapped Density

Approximately 2 g of granules from each batch were weighed and placed in a 10 mL graduated cylinder. The volume occupied by the powder was recorded in triplicate as the bulk volume. Bulk density was calculated as in Equation 1 [17-21].

$$\text{Bulk density} = \frac{\text{Mass of powder (g)}}{\text{Bulk volume of powder (mL)}} \quad (1)$$

The cylinder was tapped on a wooden platform by dropping the cylinder from a height of one inch at 2-second intervals until there was no change in volume. This volume was considered the tapped volume. The tapped density was calculated using Equation 2 [17-21].

$$\text{Tapped density} = \frac{\text{mass of powder (g)}}{\text{Tapped volume of powder (mL)}} \quad (2)$$

2.2.2.1.2. Flow rate and angle of repose

A funnel was properly supported on the retort stand and various samples with known weights were gradually poured into the funnel with the orifice of the funnel closed. Upon opening the orifice, the time taken for the entire powder sample in the funnel to flow out through the orifice was recorded. The height and radius of the powder heap were determined using a meter rule. The flow rate and angle of repose were calculated as in Equations 3 and 4 [17-21].

$$\text{The flow rate of powder (g/s)} = \frac{\text{mass of powder (g)}}{\text{Time of flow (s)}} \quad (3)$$

$$\text{The angle of repose } (\theta) = \tan^{-1} \frac{\text{Height of the pwder heap (cm)}}{\text{Radius of the powder heap (cm)}} \quad (4)$$

2.2.2.1.3. Compressibility index and Hausner's Quotient

The compressibility index and Hausner's quotient [22, 23] were calculated using Equations 5 and 6, respectively.

$$\text{Carr's index (\%)} = \frac{\text{Tapped Density} - \text{Bulk density}}{\text{Tapped density}} \times 100 \quad (5)$$

$$\text{Hausner's Quotient} = \frac{\text{Tapped Density}}{\text{bulk denstiy}} \quad (6)$$

2.2.2.2. Evaluation of compressed ibuprofen tablets

2.2.2.2.1. Hardness test

Ten tablets were randomly selected from batches M and N and their hardness was determined using a Monsanto-Stoke hardness tester (Manesty. England). Each tablet was placed between the jaws of the hardness tester and pressure was applied by adjusting the knob of the tester until the tablet integrity failed. The average of these determinations was recorded in kgf as the hardness for each batch.

2.2.2.2.2. Friability test

Twenty tablets from each batch were randomly selected and the adhering particles were blown off. They were weighed together using an analytical balance (Adventurer, Ohaus, China) and the tablets were subjected to abrasion using an Erweka friabilator (Erweka GmbH, Germany) set at about 25 rpm for 4 min, after which the tablets were recovered, dedusted and reweighed. The percentage of friability was obtained using Equation 7.

$$\text{Friability (\%)} = \left(\frac{\text{Original weight} - \text{Final weight}}{\text{Original weight}}\right) \times 100 \quad (7)$$

2.2.2.2.3. Disintegration test

The disintegration time was determined using the B.P. method and adopted by using a disintegration test apparatus (Erweka, Germany) [24]. Approximately 500 mL of distilled water was used as the disintegration medium, and maintained at 37 ± 1 °C. The time taken for all the tablet particles to completely pass through the mesh screen into the medium was recorded as the disintegration time.

2.2.2.2.4. Weight uniformity test

Twenty tablets from each batch were randomly selected, weighed individually and together using an analytical balance (Ohaus, Adventurer, China). The mean tablet weight was calculated and compared with the individually weighed tablets for different batches [24]. The % deviation/difference was determined using Equation 8.

$$\text{Deviation (\%)} = \left(\frac{\text{Weight variation}}{\text{Mean weight}}\right) \times 100 \quad (8)$$

2.2.2.2.5. Content of active ingredient

The calibration curve of ibuprofen was obtained at a concentration range of 0.1 to 0.9 mg in simulated intestinal fluid (SIF, pH, 6.8) at a predetermined wavelength of 291 nm. Twenty tablets were randomly selected from each batch (M and N) for analysis. The tablets were weighed and crushed in a mortar using a pestle. An amount equivalent to the average weight of

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Table 2. Micromeritics properties of ibuprofen granules (IBGs).

Sample	BD (g/mL ± SD)	TD (g/mL ± SD)	FR (g/s ± SD)	AOR (° ± SD)	CI	HQ
M1	0.60 ± 0.11	0.77 ± 0.04	7.20 ± 0.14	24.58 ± 0.01	22.07	1.16
M2	0.59 ± 0.01	0.74 ± 0.04	7.22 ±0.14	22.77 ± 0.21	15.00	1.25
M3	0.61 ± 0.01	0.75 ± 0.04	7.23 ±0.14	25.18 ± 0.31	14.00	1.22
M4	0.62 ± 0.11	0.73 ± 0.04	7.24 ±0.14	25.11 ± 0.11	11.00	1.18
M5	0.61 ± 0.03	0.76 ± 0.04	7.26 ± 0.14	24.15 ± 0.32	15.00	1.25
N1	0.56 ± 0.10	0.61 ± 0.03	9.57 ± 0.20	26.59 ± 0.12	5.00	1.09
N2	0.54 ± 0.20	0.63 ± 0.02	9.79 ± 0.14	27.79 ± 0.10	9.00	1.17
N3	0.55 ± 0.11	0.62 ± 0.07	9.87 ± 0.19	28.99 ± 0.03	7.00	1.13
N4	0.56 ± 0.03	0.64 ± 0.11	9.89 ± 0.13	27.89 ± 0.12	8.00	1.14
N5	0.53 ± 0.12	0.61 ± 0.10	9.67 ± 0.15	27.99 ± 0.11	8.00	1.15

Values are shown as mean ± SD at n=5. M1 – M5 and N1 – N5 are tablet batches containing acacia and gelatin as binders, respectively; SD (standard deviation); BD (Bulk density); TD (Tapped density); FR (flow rate); AOR (angle of repose); CI (Carr's compressibility index); HQ (Hausner's quotient).

the crushed tablet was weighed, dispersed in the medium and filtered with a non-adsorbent filter paper (Whatman No. 1). An aliquot of the filtrate was assayed using a UV spectrophotometer (Jenway 6305, UK). The absorbance readings were recorded and the concentration of ibuprofen in each batch was calculated.

2.2.2.2.6. In vitro release

The compressed tablets were selected and subjected to the paddle dissolution method using 900 mL of SIF (pH 6.8) as the dissolution medium, placed in a dissolution apparatus set to rotate at about 100 rpm and at a temperature of 37 ± 1 °C. At various time intervals, a 5 mL aliquot of the dissolution medium was collected and immediately replaced with 5 mL freshly prepared SIF (pH 6.8). The withdrawn samples were analyzed using a UV-spectrophotometer (Jenway, 6305, UK) at 291 nm wavelength of Ibuprofen. The procedure was repeated thrice, and the average was determined. The percentage of drug released was plotted against time.

2.3. Data and statistical analysis

Data were analyzed and expressed as mean ± SD and CV by ANOVA and Student t-tests. Differences were considered significant at $p < 0.05$.

3. Results and discussion

3.1. Micromeritics properties of IBGs

The micromeritic characteristics of the ibuprofen granules (IBGs) prepared using two different binder types are presented in Table 2. The flow parameters, such as bulk density, tapped density, flow rate, and angle of repose, ranged within 0.61 ± 0.01 g/mL, 0.75 ± 0.04 g/mL, 7.23 ± 0.14 g/s, 25.18 ± 0.31° for batch M and 0.55 ± 0.11 g/mL, 0.62 ± 0.07 g/mL, 9.87 ± 0.19 g/s, 28.99 ± 0.11° for batch N, respectively. The results of flow rate, bulk, and tapped densities were within acceptable limits. A granule with a high bulk density, that is low porosity, will cause a low deformation potential, while inadequate space for deformation during compression causes less intimate contact between the particles within the tablets, producing weaker tablets [25, 13]. The angle of repose results indicated that the granules had low inter-particulate friction and therefore, good flow properties. The compressibility index (CI) and Hausner's quotient (HQ) ranged from 11 - 22%, 1.16 - 1.25, and 05 - 09%, 1.09 - 1.17 for batches M and N, respectively. The CI indicated that the prepared granules had good flowability with consolidation qualities, except for tablets M2 and M5. A granule with adequate HQ and CI flows at a low bulk density. A CI within the range of 5 - 16 % equally shows good flow, 18 - 21% indicates fair flow, and > 38 % indicates very poor flow [21], whereas Hausner's ratio ≤ 1.25 indicates good flow, and values > 1.25 indicates poor flow [25]. Batches M and N had HQ values below 1.25, except for M2 and M5, indicating better flowability (Table 2). Therefore, batch N exhibited good flow properties within the specified limits for the preparation of high quality tablets.

3.2. Properties of ibuprofen tablets (IBTs)

The results of the quality control tests for the IBTs are presented in Table 3. The average hardnesses of

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Table 3. Quantity control tests of the ibuprofen tablets.

Sample	HT (Kgf ± SD)	DT (min ± SD)	F (%)	TW (mg ± CV)
M1	14.64±12.5	18.50±5.32	0.10	300.96±1.20
M2	14.48±12.5	18.57±5.32	0.10	302.99±1.20
M3	14.57±12.5	18.55±5.32	0.10	300.98±1.20
M4	14.58±12.5	18.56±5.32	0.10	298.99±1.20
M5	14.57±12.5	18.56±5.32	0.10	300.98±1.20
N1	8.14±0.23	12.67±2.47	1.00	303.00±1.31
N2	8.13±0.23	12.66±2.47	0.98	301.00±1.31
N3	8.12±0.23	12.68±2.47	0.97	301.00±1.31
N4	8.13±0.23	12.69±2.47	0.98	299.00±1.31
N5	8.11±0.23	12.70±2.47	0.97	301.00±1.31

Values (mean ± SD, n=5); M1 – M5 and N1 – N5 (tablets containing acacia and gelatin as binders, respectively); HT (hardness test); DT (disintegration time); F (friability); TW (tablet weight uniformity); CV (coefficient of variation); SD (standard deviation).

batches M and N were 14.57 ± 12.5 and 8.12 ± 0.23 Kgf, respectively. The results of the hardness test for batch M significantly ($p < 0.05$) varied from those of batch N. This means that the batch formulated with the acacia binder had higher mechanical strength and showed higher resistance to crushing. The mean disintegration times of 18.55 ± 5.32 and 12.68 ± 2.47 min were obtained for batches M and N, respectively. Batch N prepared with gelatin, complied with the B.P. guidelines for the disintegration of immediately released tablets [24]. The deviation of batch M may be due to the significant effect of tablet hardness. The % friability test results were 0.10 and 0.98 % for acacia (batch M) and gelatin (batch N), respectively. Table 3 indicates that batch N can withstand any shock or stress during material packaging and shipping. The B.P. stated that the friability losses of tablets formulated by wet granulation would be within the acceptable range of 0.8 – 1% [25].

The weight uniformity tests obtained for batches M and N were in the range of 298.99 ± 1.20 - 303.00 ± 1.31, respectively. The weight uniformity of the batches met the BP standards of > 5% deviation for tablets weighing 250 mg or more [12]. Consistency in tablet weight is essential, as variations can lead to different drug amounts and affect the drug's bioavailability.

The drug contents of batches M and N were within the range of 190 – 195 mg. This indicates that the two batches passed the assay test. The good value also indicated that the binders did not interact with the drug, as they maintained their inertness.

3.3. *In vitro* release of IBTs

The ibuprofen release results of batches M and N, as presented in Figs. 1 and 2, indicated that the time to release T_{40} and T_{80} of the drug content was obtained as 20 and 15 min for T_{40} and 35 and 30 min for T_{80}, respectively by the tablet with the highest drug release.

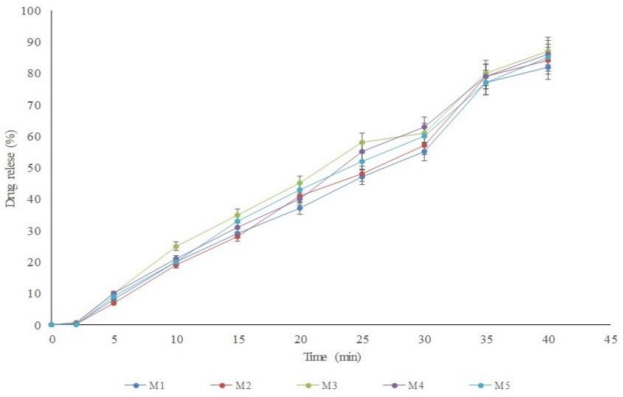

Figure 1. The release profile of ibuprofen in acacia tablets. Batches M (batch containing acacia)

The results showed good release profiles for both batches. However, an immediate-release tablet is expected to release about 85 % (T_{85}) of its content within 30 min of dissolution, as stated by the US-FDA guidelines [26]. Therefore, batch N (containing gelatin) had a good release profile as it met the specifications, while batch M (containing acacia) had a slight delay in release, which might be associated with the hardness of the tablets. This indicates that batch M acts as a sustained drug tablet at 3% acacia, which is suitable for ibuprofen delivery since it has a short half-life.

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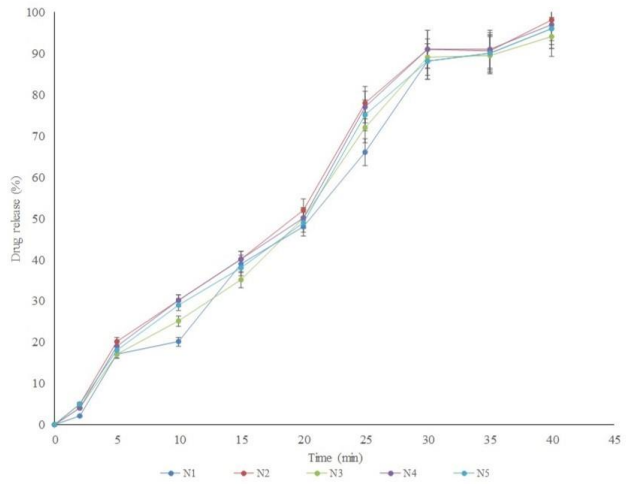

Figure 2. Release profile of ibuprofen in gelatin tablets. Batches N (batch containing gelatin)

4. Conclusions

The formulation of IBTs using two binders from plant (batch M) and animal origins (batch N) were successfully prepared by the wet granulation technique. The IBGs and IBTs characteristics were within the limits of specifications, with only a few exceptions for batch M due to a significant difference in the hardness and disintegration tests of the tablets. This indicates that the formulation of ibuprofen tablets with 3% acacia can be used to prepare sustained-release ibuprofen tablets. This study indicates that 3% concentrations of gelatin and acacia are potential candidates for immediate-release and sustained-release ibuprofen tablets for fast and controlled drug delivery, respectively. It is recommended to vary the binder concentrations to determine the different properties.

Disclaimer (artificial intelligence)

Author(s) hereby state that no generative AI tools such as Large Language Models (ChatGPT, Copilot, etc.) and text-to-image generators were utilized in the preparation or editing of this manuscript.

Authors' contributions

Calister E. Ugwu conceived, designed and performed the experiments. Analyzed and interpreted the data and then wrote the paper.

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Availability of data and materials

All relevant data are within the paper. Additional data will be made and available on request according to the journal policy.

Conflicts of interest

The author declares no conflict of interest.

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