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Extraction and evaluation of Indian millets starch and it's comparative study with maize starch as disintegrant in tablet formulation

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Abstract
The study aimed to extract and evaluate Indian Finger Millets starch and compare its performance as disintegrant with commercially available Maize starch in tablet formulations. Indian Finger Millets starch was extracted using a wet milling method, and its physicochemical properties were characterized. Paracetamol tablets were prepared using Indian Finger Millets starch and Maize starch as disintegrants in different concentrations. The tablets were evaluated for various parameters. The extracted Indian Finger Millets starch exhibited good powder flow properties with a Carr's Index of 15.6% and an angle of repose of 27.4°. The post-compression evaluation, optimized Indian Finger Millets starch tablets (MF5) demonstrated a hardness of 6.0±0.2 kp, disintegration time of 6.0±0.30 min, and 99% drug release at 60 minutes. The optimized Maize starch tablets (PF3) showed a hardness of 6.5±0.4 kp, disintegration time of 6.5±0.20 min, and 91% drug release at 60 minutes.

Keyword: Finger millets starch, maize starch, disintegrant, paracetamol tablets, tablet formulation, in-vitro dissolution

Introduction
Starches, complex carbohydrates found abundantly in plants, are major players in a variety of industries, including textiles, even more so, in pharmaceuticals. This research is centered around the pivotal role starch plays in pharmaceutical tablet formulation, more specifically as a disintegrant. Tablet formulation is a careful science, involving a delicate balance of active pharmaceutical ingredients (APIs) with various excipients that aid in the creation of the final product. Among these excipients, disintegrants are essential. Their primary role is to guarantee that the tablet disintegrates in smaller particles in bodily fluids, enabling release of the APIs, thus facilitating their absorption within the body. A widely used disintegrant in this process is maize starch [1].

The premise of the study stems from the premise that exploring alternative and potentially superior sources of starch could have significant implications for pharmaceutical sciences. By investigating and comparing the extraction and evaluation of starch from Indian Finger millets against maize starch, this study hopes to shed light on an untapped resource with possible profound implications in the field of pharmaceuticals. Thus, this study embarks on an exploration and comparison of Indian Finger millets starch and maize starch as disintegrants in tablet formulation, seeking to uncover new possibilities in the pursuit of improved healthcare [2].q

The current research seeks to close this gap by offering a comparative analysis finger millet starch, maize starch, and cornstarch in the formulation of paracetamol tablets. Through this research, we hope to expand our understanding of these alternative starch types and their potential applications in pharmaceuticals [3].

Scientifically called as Eleusine coracana, is a robust, resilient, and nutrient-dense grain. It's a traditional crop grown predominantly in the regions of Africa and Asia that are dry or semi-arid, with India being the biggest producers of this grain worldwide. Historically, the cultivation of finger millet in India can be traced back to the Harappan civilization, approximately 5000 years ago. It was, and continues to be, a common dietary source in many Indian regions, particularly in the southern and central regions. Finger millets used in a vast range of culinary purpose, from baking, brewing. The grain is often ground into flour and used to make traditional dishes such as roti (a type of flatbread), dosa (a fermented crepe), and porridge. The versatility of this grain extends to beverages as well; it is used in the production of local alcoholic drinks in several regions [4, 5].

Finger millet, often referred to as a "super grain," is a nutrient powerhouse offering a variety of health benefits due to its rich nutritional content [5].

Protein: It is a great way to get natural protein, necessary for body growth and repair. Its protein content is greater in contrast to other common grains like rice and maize.

Dietary Fiber: This grain is packed with dietary fiber, which aids in digestion, aids in blood sugar regulation, as well as helps with feelings of fullness.

Minerals: Finger millet is renowned for its high mineral content, particularly calcium, which is crucial for bone health. Its calcium content is notably higher than in other grains, making it an excellent choice for individuals of all age groups, particularly those at risk of osteoporosis. It also contains good quantities of other minerals like iron, magnesium, and phosphorus.

Phytochemicals: Finger millet contains phytochemicals like phenolic compounds and phytic acid, which exhibit antioxidant properties, thereby potentially reducing the risk of various chronic diseases [6, 7].

While the pharmaceutical applications of finger millet starch have been underexplored, early studies and the inherent properties of this grain suggest promising potential. Starch extracted from finger millets shares several key properties with other types of starch used in pharmaceuticals, indicating its possible use as a filler, or disintegrant in tablet composition. Disintegration and binding capabilities of starch possibly credited to its water absorption, swelling abilities, similar to other starch types. The structure and composition of finger millet starch may provide unique qualities that could differentiate it from commonly used starches like maize starch. For example, research has shown that the ratio of amylose to amylopectin in finger millet starch differs from that of maize starch [8].

There may also be additional advantages to using finger millet starch in pharmaceutical applications. For instance, the rich nutritional profile of finger millets, although not directly contributing to its functionality as a starch, could introduce ancillary health benefits in certain pharmaceutical applications [9].

Materials and Methods

Materials

The materials used in the experiment include finger millet and maize starch, both serving as tablet disintegrants. Finger millet was procured from the local market of Gadhinglaj, while maize starch was obtained from R.L. Fine Chem. Ind., Mumbai. Paracetamol, the active pharmaceutical ingredient (API), was also sourced from R.L. Fine Chem. Ind., Mumbai. Acacia was used as a binder and was purchased from Unique Biological and Chemical, Kolhapur. Magnesium stearate and talc, used as a lubricant and glidant respectively, were acquired from S.D. Lab Chemical Centre, Mumbai. Lactose, used as a diluent, was also obtained from Unique Biological and Chemical, Kolhapur [10].

Equipment's

The equipment used in the study includes a digital weighing balance from WENSAR, a hot air oven from Adarsh ISO 960/J, a UV-Visible spectrophotometer (UV-1900) from Shimadzu CORP, and an FTIR (IRTracer-100) also from Shimadzu. The dissolution apparatus was sourced from Electrolab, while the digital pH meter (Equiptronic MODEL EQ610) was provided by Equiptronic. Additionally, a tablet compression machine (Shanti LLP-17), a disintegration apparatus (VEGO VID-DV), and a hardness tester from MONSANTO were used in the experiment [11].

Calibration Curve of Paracetamol

The calibration curve for Paracetamol was established by scanning solutions of varying concentrations (from 10 to 60 ppm) within a range of 800 to 200 nm in corresponding mode(spectrum) of a UV-Visible spectrophotometer. The absorbance of the solutions in range 10ppm-60ppm determined, with ethanol as reference blank [12].

FTIR Analysis

The pure Paracetamol drug was the first to undergo the analysis, with the resulting spectrum serving as a reference for subsequent analyses. Subsequently, FTIR spectra of mixtures of the pure drug with Indian Finger millet starch and maize starch were obtained. Across all analyses, each sample was prepared by grinding it with spectroscopic grade KBr to form a pellet, in the wave no. range of 4000-400 cm^{-1}, spectra were collected [13].

Extraction of Indian Finger Millets Starch

Initially wash Indian Finger millets to remove any impurities, foreign materials. After washing, soak the millets in water (distilled) at a ratio of 1:5 (w/v) for about 12-16 hours at room temperature. Once the millets are adequately soaked, they are drained and then ground using a blender or a wet grinder. The resulting slurry then went via a number of sieves, starting with a coarse sieve and progressing to finer sieves [14].

The sieved slurry is then allowed to stand undisturbed in a container for a few hours to enable the sedimentation of the starch granules. The supernatant liquid containing suspended solids is carefully decanted, leaving behind [6].

Once the starch has been sufficiently separated, it is washed with a small amount of distilled water to remove any remaining impurities, followed by another round of sedimentation and decantation. The clean, wet starch is then spread evenly onto a clean, flat surface or trays and allow it to air-dry at R.temp. Or using hot air oven at low temp. (40-50°C) until desired moisture content is reached. The dried Indian Finger Millets Starch can then be collected, ground into a fine powder, and stored in airtight containers for future use in various applications, including tablet formulations [15].

Evaluation of finger Millet's starch

Swelling Index

In two distinct graduated test tubes, 5 ml of H_2O and light liq. paraffin were combined with 100 mg of prepared starch. For twelve hours, it was decided to let the dispersion in the tubes stand. Records were kept of the sediment volumes within the tubes [16, 17].

$$S.I.\% = \left[\frac{VW - VL}{VL}\right] \times 100$$

Determining moisture content

The lidded container was first dried for three hours at 105 ºC in the oven. A sample of 5 g was weighed and evenly distributed. The plate containing sample put into oven- 105 ºC upto three hrs. To dry it out. After that, dish put into cooling

desiccator. Weighing was done on the plate and its desiccated example. Calculate % moisture content using formula.

$$Moisture\ \% = \left[\frac{W1 - W2}{W1}\right] \times 100$$

Table 1: Formulation of Tablet [18, 19]

Ingredient (mg)	MF 1	MF 2	MF 3	MF 4	MF 5	MF 6	MF 7	MF 8	MF 9
Paracetamol	325	325	325	325	325	325	325	325	325
Finger Millets Starch	20	40	60	20	40	60	20	40	60
Acacia (%w/w)	2	2	2	5	5	5	8	8	8
Magnesium St.	3	3	3	3	3	3	3	3	3
Talc	1	1	1	1	1	1	1	1	1
Lactose	q.s to 500mg	q.s to 500mg	q.s to 500mg	q.s to 500mg	q.s to 500mg	q.s to 500mg	q.s to 500mg	q.s to 500mg	q.s to 500mg

1. Weigh the required amounts of ingredients as per the composition.
2. Sift paracetamol, starch, and lactose separately through a #40 sieve.
3. In a suitable mixer, blend paracetamol, Indian Finger millets starch, and lactose together.
4. Dissolve the required amount of acacia in distilled water to prepare a binder solution with the appropriate concentration.
5. Start adding the binder solution slowly to the homogenous mixture of paracetamol, Indian Finger millets starch, and lactose.
6. To obtain wet granules, pass the wet mixture through a #16 sieve.
7. Let the granules to dry in a dryer at 40-45°C for 4-6 hours. Sieve the granules through a #20 sieve & Combine the granules with lubricant and glidant.
8. Using a tablet compression machine compress the granules into tablets & assess them for various quality control aspects [20].

Evaluation of pre-compression evaluation [16, 17]

Bulk Density- Weigh out exactly 2 g of granules, and then run them through a 20# sieve transfer them to a 10 mL graduated cylinder. After gently leveling it, measure the apparent volume (V0). Calculate the apparent bulk density in g/ml using the following formula.

$$B.D = \frac{Weight\ of\ powder}{Bulk\ volume}$$

Tapped Density: Exactly 2g of granules were previously placed into a 10 ml graduated cylinder. Using a mechanically tapped density tester, mechanically tap the cylinder. Measure the tapped volume to the nearest graded units.

$$\text{Tapped Density} = \frac{Weight\ of\ powder}{Tapped\ volume}$$

Angle of Repose

The height of the funnel was adjusted. The powder combination was allowed to spill freely onto the ground since the hopper was left open. After measuring the diameter of the powder cone, the angle of repose was calculated using the equation below.

$$\theta = \text{Tan}^{-1}\frac{h}{r}$$

Post-Compression Evaluation [21-23]

Content Uniformity

Ten tablets were crushed, 100 milliliters of 0.1 N HCl and powder equal to 325 mg of paracetamol were shaken for thirty minutes. A UV/VIS double beam spectrophotometer was used to filter the contents via a 0.45 μm membrane filter, dilute it, and measure its wavelength at 327 nm [15].

Disintegration test

One tablet was put into each of the six disintegrating tablet tubes, and covered with a disc, ran (30 cycles/min) at 37°C and 6.8 pH. The amount of time required for complete disintegration with no discernible mass left was noted.

In-vitro dissolution study

A USP Type II (paddle) dissolution testing device was used for the in-vitro dissolution investigation. Each tablet formulation was added to the dissolution media separately. This medium is typically a pH-specific buffer meant to mimic intestinal or stomach fluid. The paddle was designed to rotate at a speed of 50 or 100 revolutions per minute. Samples were removed from the dissolution media using a syringe equipped. The removed volume was quickly restored with new medium. After filtering each sample, the drug concentration was determined using UV-Visible spectrophotometry [24].

Results

Table 2: Solubility analysis of Paracetamol

Sr. No.	Solvent	Results
1.	Water	Sparingly soluble
2.	Acetone	Freely Soluble
3.	Methanol	Slightly soluble

Table 3: Melting point determination

Drug	Melting Point
Paracetamol	168-170 °C

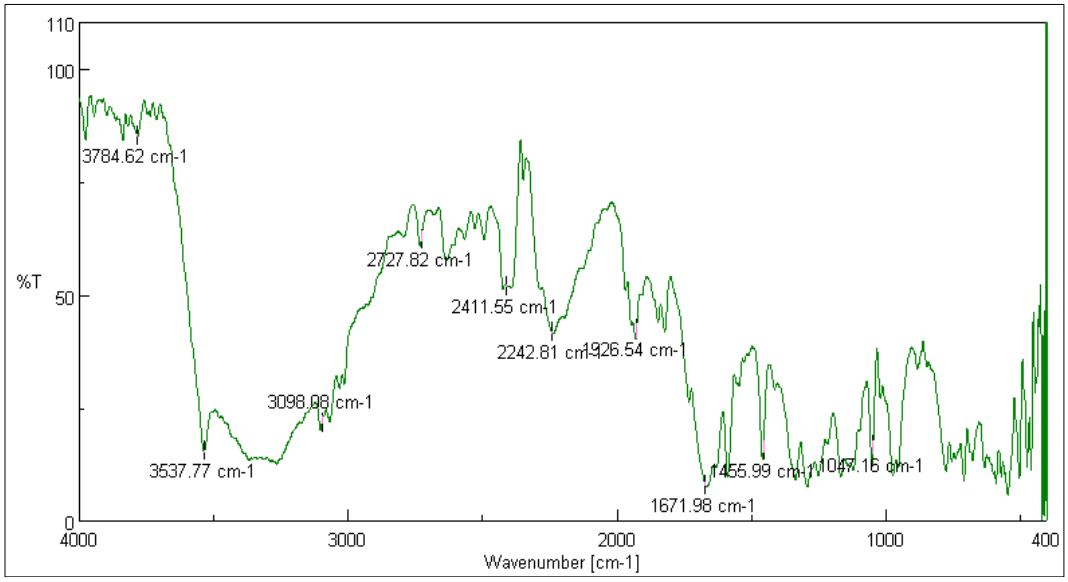

Fig 1: FTIR Spectra of physical mixture of finger millets starch tablet

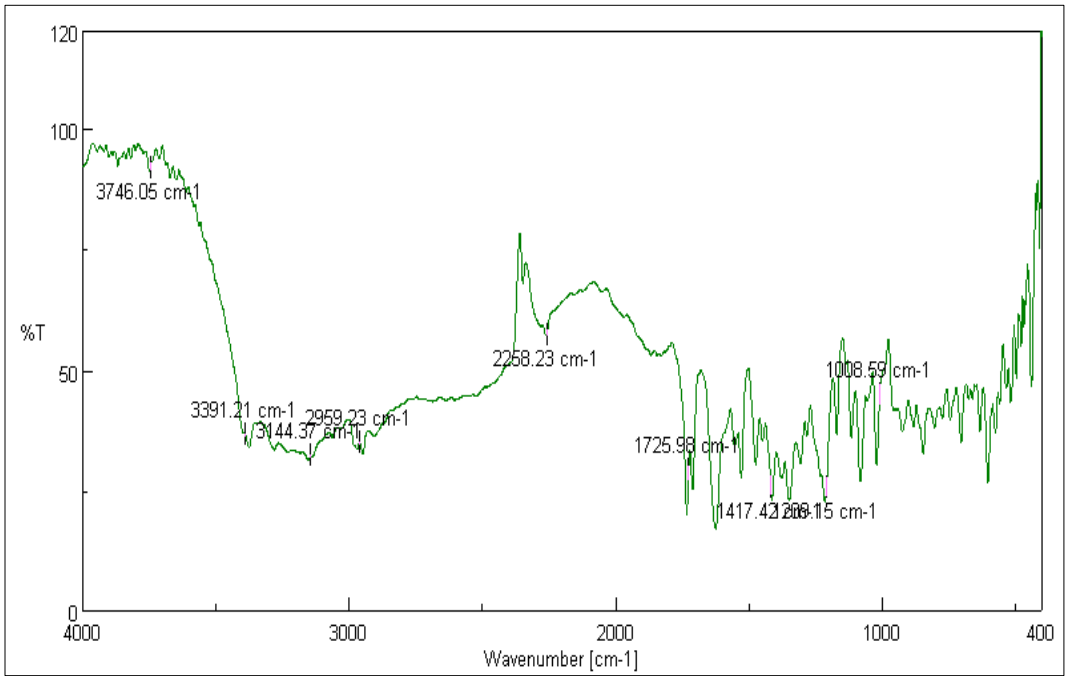

Fig 2: FTIR Spectra of physical mixture of Maize Starch Tablet

Table 4: FTIR spectra

Functional Group	Physical Mixture of Indian Finger Millets Starch Tablet	Physical Mixture of Maize Starch Tablet
O-H Stretch (cm^{-1})	3784.62	3784.62
N-H Stretch (cm^{-1})	3537.77	3537.77
C-H Stretch (cm^{-1})	3098.08	3098.08
C=O Stretch (cm^{-1})	2242.81	2242.81
C=C Stretch (cm^{-1})	1926.54	1926.54

FTIR spectroscopy is a valuable tool in understanding the molecular interactions between drug and excipients in a formulation, which can have significant implications for the drug's stability, dissolution, and overall performance. The pure paracetamol, has distinct peaks in its FTIR spectrum that correspond to different functional groups. The measurements of the O-H, N-H, and C-H stretches are 3784.62 cm^{-1}, 3537.77 cm^{-1}, and 3098.08 cm^{-1}, respectively. Furthermore, C=O stretch is seen in the spectrum at 2242.81 cm^{-1} and C=C stretch at 1926.54 cm^{-1}. There are no discernible alterations in the spectra of the pure medicine or elimination of distinctive peaks when comparing it with the combinations including starch from Indian Finger millets and maize. This implies that there isn't much of a molecular interaction between paracetamol and the starch excipients. For instance, all samples show the presence of the O-H, N-H, and C=O stretch peaks, which show that the carbonyl groups and hydrogen bonding remains intact.

Table 5: Pre & Post Evaluation tests of formulations

Formulations	Bulk Density (g/cm^3)	Tapped Density (g/cm^3)	Angle of Repose (°)	Content Uniformity (%)	Disintegration Time (min)
Finger millet starch formulation	0.45	0.55	30	96.50±0.3	6.5±0.2
	0.47	0.58	31	96.59±0.5	5.8±0.3
	0.50	0.61	32	99.1±0.15	5.0±0.2
	0.48	0.57	29	98.99±0.2	6.0±0.3
	0.49	0.60	30	99.1±0.15	5.5±0.3
	0.52	0.63	31	96.50±0.3	4.8±0.2
	0.46	0.56	28	97.27±0.9	7.0±0.3
	0.48	0.59	29	98.35±0.2	6.2±0.2
	0.51	0.62	30	99.15±0.1	5.3±0.3
Maize starch formulation	0.45	0.58	30.5	98.45±0.43	5.5±0.30
	0.48	0.60	28.0	97.76±0.76	6.0±0.25
	0.50	0.64	29.5	98.53±0.63	6.5±0.20
	0.47	0.59	29.0	99.64±0.23	8.2±0.35
	0.46	0.58	29.2	96.75±0.54	6.0±0.30
	0.51	0.63	27.5	98.57±0.35	6.6±0.25
	0.49	0.61	27.8	97.79±0.43	7.0±0.20
	0.48	0.60	28.0	99.43±0.43	4.5±0.35
	0.50	0.62	27.7	97.23±0.32	3.5±0.30

The pre-compression evaluation provides essential information about the flow properties of the powder mixtures. All formulations of the Indian Finger Millets starch tablet formulations & Maize starch tablet formulation had bulk densities 0.45-0.52 g/cm³, 0.45 to 0.51 g/cm³ and tapped densities 0.55 and 0.63 g/cm³, 0.58 to 0.64 g/cm³. respectively. Hausner's ratio between 1.19-1.23, 1.24-1.29 and their Carr's index values fell between 15.8%-18.9%, 19.05% to 22.41%. Angle of repose readings fell between 28°-32° & 27.5° -30.5. According to these findings, the powder mixes appear to have good to moderate flow characteristics. The tablet disintegration times ranged from 3.5 to 8.2 minutes, indicating a reasonably swift disintegration rate for the formulations-a crucial component in guaranteeing quick drug release. The comparative analysis of the optimized batches of Indian Finger Millet starch Tablet and Maize starch Tablet is presented, which provides the in-vitro dissolution data for both tablet formulations. The data shows that the dissolution profiles of both formulated tablets are different, with the Indian Finger Millet starch Tablet (MF5) generally having a faster dissolution rate compared to the Maize starch Tablet (PF3). The graph illustrates the differences in dissolution profiles between MF5 and PF3 tablets over time. At each time point, the percentage of drug released from the Indian Finger Millet starch Tablet (MF5) is higher than that of the Maize starch Tablet (PF3). Specifically, at 60 minutes, the MF5 tablet shows 99±1.1% drug release, while the PF3 tablet shows a lower drug release of 93±1.0%. At 90 minutes, the MF5 tablet reaches 100±1.0% drug release, while the PF3 tablet still lags behind at 97±1.2% drug release.

Conclusion

The comparative analysis of the optimized batches of Indian Finger Millet starch Tablet (MF5) and Maize starch Tablet (PF3) reveals a faster dissolution rate for the Indian Finger Millet starch Tablet (MF5). This could lead to better drug release characteristics and potentially enhanced bioavailability for the Indian Finger Millet starch Tablet compared to the Maize starch Tablet. Further studies, such as in-vivo pharmacokinetic evaluations, could help to confirm these findings and determine the suitability of each formulation for specific therapeutic applications.

Table 6: In-Vitro dissolution data of optimized batches of tablet formulations

Batch	Maize starch Tablet	Finger Millet starch Tablet
5 min (%)	15±1.5	15±0.5
15 min (%)	42±3.5	44±1.0
30 min (%)	62±3	66±1.0
45 min (%)	78±3.5	82±2.0
60 min (%)	91±2.0	99±1.1
90 min (%)	100±0	100±1.0

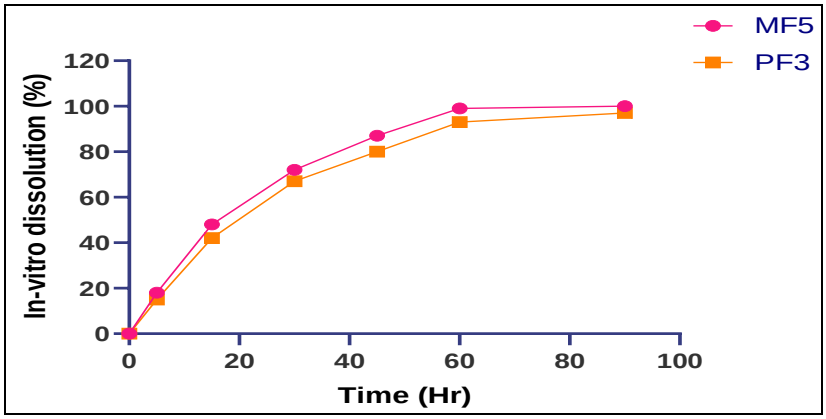

Fig 3: Graphical representation of In-Vitro dissolution data of optimized batch of Indian Finger Millet starch Tablet and Maize starch Tablets

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