

Isolation, Characterization and Pharmaceutical Evaluation of *Helianthus annuus* Seed Mucilage as a Binder in Solid Dosage Forms

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Abstract

Background: Natural excipients are increasingly explored as alternatives to synthetic binders in pharmaceutical formulations due to their safety, sustainability, and cost-effectiveness. Plant-derived mucilage has shown potential as a binding agent. The current investigation was designed to isolate and characterize mucilage extracted from the Sunflower seed (*Helianthus annuus*) and evaluate its binding efficiency in paracetamol (PCM) tablet formulations compared with gum *Acacia*. **Materials and Methods:** Mucilage was isolated by hot maceration and characterised physicochemically. Morphology was analyzed by scanning electron microscopy (SEM), crystalline/amorphous nature by powder X-ray diffraction (PXRD) and differential scanning calorimetry (DSC), and structural confirmation by Fourier transform infrared spectroscopy (FTIR). PCM tablets were prepared by wet granulation using four graded concentrations of mucilage 3, 5, 10, and 15% w/v, which were employed in the formulation designated as HF1–HF4. Control tablets were prepared with gum *Acacia* at identical concentrations. Standard evaluation parameters for uncoated tablets were performed, followed by *in vitro* dissolution studies. **Results:** SEM revealed irregular particle shape and size of mucilage, PXRD and DSC indicated an amorphous nature, and FTIR confirmed polysaccharide presence. Among the formulations, HF1 (3%) and HF2 (5%) showed optimal binding efficiency, releasing 99% of the drug within 25–30 min. These results were superior to tablets prepared with gum *Acacia* at equivalent concentrations. **Conclusion:** Mucilage from *H. annuus* seed demonstrated excellent binding efficiency and favorable physicochemical properties, suggesting its potential as a promising natural excipient in conventional uncoated tablet dosage forms.

Key words: Excipient, *Helianthus annuus*, mucilage, natural binder, paracetamol, tablet formulation

INTRODUCTION

In pharmaceutical drug development, inactive ingredients known as excipients play an equally important role as active drug components. Excipients improve stability, facilitate administration, mask unpleasant taste or odor, and enhance patient compliance. They control drug release, improve absorption, and ensure product quality. While both synthetic and natural excipients are used, natural excipients have gained attention due to their biodegradability, safety, and cost-effectiveness. Natural polymers, including gums and mucilage, are valuable as they are abundant and versatile. They serve as thickeners, suspending agents, emulsifiers in liquid formulations, bases in semisolid preparations, and as binders,

diluents, or release-modifying agents in solid pharmaceutical formulations.^[1,2]

Applications extend beyond pharmaceuticals to include cosmetics products, packaging material, and edible film system. Mucilages are plant-derived polysaccharides that are hydrophilic, capable of swelling and forming gels. Being

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biodegradable and non-toxic, they show promise in both conventional and novel drug delivery systems. *Helianthus annuus* Linn., commonly known as sunflower, is a widely distributed plant in the Asteraceae family. It has been used in traditional medicine for its antibacterial, antifungal, anti-inflammatory, antioxidant, and wound-healing properties. In this study, mucilage was isolated from *H. annuus* seeds and characterized using scanning electron microscopy (SEM), powder X-ray diffraction (PXRD), differential scanning calorimetry (DSC), Fourier transform infrared spectroscopy (FTIR), swelling index, and phytochemical analysis. Its binding potential was evaluated by formulating paracetamol (PCM) tablets and comparing them with those using gum *Acacia*. This work explores the suitability of *H. annuus* mucilage as a natural excipient in solid oral dosage forms.^[3,4]

Isolation of mucilage

Fresh *H. annuus* seeds were collected and cleaned to remove adhering dust and other extraneous matter, and subsequently shade dried. The dried seeds were then ground into a fine powder using a grinder. The powdered material was soaked in water at a ratio of 4 times the volume of the powder for 2–3 h and mixed to ensure proper homogenization. Heating was carried out at 70°C for about 20–25 min., enabling the extraction of mucilage into the aqueous phase.^[5,6]

Following the heating step, the extract was cooled and kept undisturbed for 1 h to allow complete mucilage extraction. The mass was then filtered through an eight-fold muslin cloth to remove the marc, and the filtrate was collected. Acetone was added to the filtrate in a 1:3 ratio (filtrate: Acetone) to facilitate mucilage precipitation. The recovered mucilage was isolated and oven-dried under controlled conditions, with the temperature maintained below 50°C. The dried sample was finely powdered, passed through a mesh #80 to obtain a fine powder, and stored in a desiccator for further use. The percentage yield of mucilage obtained from *H. annuus* seeds was 10.1%.^[7,8]

SEM

The surface morphology of *H. annuus* mucilage powder was analysed using SEM. The dried sample was mounted on an aluminum stub with adhesive tape, gold-coated for conductivity, and examined under a JEOL JSM-6100 microscope to observe particle shape and surface features.^[9,10]

PXRD

The crystalline nature of the isolated *H. annuus* mucilage was analyzed using an X-ray diffractometer (X'Pert PRO, PANalytical, UK). The sample was examined at 25°C under operating conditions of 45 kV voltage and 40 mA current. The diffraction pattern was recorded by scanning in the range

of $2\theta = 20^\circ$ with a scan length of 50° and a step scan time of 50.16 s.^[11,12]

DSC

Thermal behavior of the isolated *H. annuus* mucilage was studied using a differential scanning calorimeter (DSC 3+, Mettler-Toledo, USA). A sample of 6.1 mg was accurately weighed and sealed in an aluminum pan with a pinhole lid. The analysis was carried out over a temperature range of 10°C–300°C at a heating rate of 10°C/min under a nitrogen atmosphere, maintained at a flow rate of 40 mL/min.^[13,14]

FTIR

The FTIR spectrum of *H. annuus* mucilage was obtained using a Shimadzu IRAffinity spectrometer. The sample was mixed with KBr, compressed into a pellet, and scanned over 4,000–400 cm^{-1} to identify functional groups.^[15]

Phytochemical examination of mucilage

The isolated mucilage from *H. annuus* seeds was subjected to preliminary phytochemical screening to identify the presence of different classes of compounds. Tests were performed for ingredients such as sugar, mucilage, along with proteins, glycosides, alkaloids, as well as resinous compounds, saponins, steroids, and tannin components.^[16,17]

Microbial quality evaluation

Bacterial and fungal growth analyses were carried out to evaluate the microbiological quality of the isolated mucilage. Sabouraud's dextrose agar medium was used for fungal growth, while nutrient agar medium was used for bacterial growth. Both media were sterilized by autoclaving at 121°C for 15 min and poured into Petri plates under aseptic conditions. The isolated mucilage was streak-inoculated onto the medium plates after pre-incubation. The petri-plates were then incubated at 27°C for 72 h to observe fungal growth and at 37°C for bacterial growth.^[18]

Physicochemical characterization of crude mucilage

Physicochemical parameters of the crude mucilage were evaluated, including pH, solubility, total ash value, water-soluble ash, acid-insoluble ash, viscosity, and loss on drying. These parameters provided insight into the quality, purity, and suitability of mucilage as a pharmaceutical excipient.^[19]

Drug–excipient interaction study

The compatibility of isolated *H. annuus* mucilage with the model drug was assessed to ensure its safety and stability

as a binder. Interaction studies were performed using FTIR spectroscopy, ultraviolet (UV) spectrophotometry, and DSC. For this purpose, a physical mixture of pure drug and mucilage in a 1:1 ratio was prepared and stored in a desiccator for 3 months before analysis. These studies helped evaluate any possible physicochemical interactions between the drug and the mucilage.^[20]

Preparation of tablets

PCM tablets were formulated using wet granulation, with *H. annuus* mucilage as the natural binder. PCM was used as the model drug, with starch as disintegrating agent, lactose as diluent, magnesium stearate as lubricant, and talc as glidant. Four batches were prepared with varying concentrations of *H. annuus* mucilage: 3%, 5%, 10%, and 15% (w/w). The active pharmaceutical ingredient (API) and excipients were weighed according to Table 1, blended uniformly, granulated using binder solution, dried, and sieved. The granules were lubricated with magnesium stearate and talc before compression into tablets. The required amounts of PCM and lactose were mixed in a mortar, and mucilage solution was added dropwise to form a wet mass.^[21,22]

Half the starch was incorporated, and the mixture was passed through a #22 mesh for granules. These were dried at 60°C until constant weight and rescreened through #44 mesh. The remaining starch, talc, and magnesium stearate were blended with dried granules before compression into 650 mg tablets using a 12 mm concave round die. For comparison, four batches of PCM tablets were prepared using *Acacia* gum as standard binder at 3%, 5%, 10%, and 15% concentrations, following identical procedures and excipient proportions. Formulations with *H. annuus* mucilage were designated HF1–HF4, while those with *Acacia* gum were labeled HA1–HA4, enabling assessment of binding efficiency under uniform conditions, as summarized in Table 1.^[23,24]

Micromeritics studies of prepared dried granules

Micromeritics studies were conducted on dried granules prepared using both *H. annuus* (sunflower seed) mucilage

and *Acacia* gum as binders. These studies were performed to evaluate and compare the micromeritic properties of the granules, which directly influence their flow behavior, compressibility, and overall suitability for tablet formulation.^[25]

Particle size distribution (PSD)

By employing the mechanical sieving technique, we were able to ascertain the PSD of the dried grains. A group of three sieves, numbered (#60, #80, and #100), was arranged on a mechanical shaker, and 35 g of granules from each batch were carefully placed on the top sieve. The shaker was operated for 10 min, after which the granules retained on each sieve were collected and weighed. Based on the weight distribution across the different sieve sizes, the granules' PSD was examined.^[26]

Flow properties of granules

The flow behavior of dried granules was evaluated for tablet suitability. Bulk density (BD) was measured from 10 g granules in a 50 mL cylinder, followed by tapped density (TD) using a ROLEX apparatus. Powder flow behavior and compressibility were assessed using Hausner's ratio and Carr's index.^[27]

BD = Mass of granules taken/bulk volume

TD = Mass of granules taken/tapped volume

Hausner's ratio = TD/BD

Carr's compressibility index = $(TD - BD/TD) \times 100$.

The angle of repose of granules from each batch, prepared using both *H. annuus* mucilage and *Acacia* gum, was measured using the funnel method. This process involved letting the granules fall freely into a fixed funnel until they formed a heap. The height and radius of the heap were measured, and the angle of repose (θ) was calculated using the formula:

Angle of repose = $\theta = \tan^{-1} (h/r)$.

Table 1: Composition table of prepared uncoated conventional tablet

Ingredients	Application in formulation	3% HF1	5% HF2	10% HF3	15% HF4	3% HA1	5% HA2	10% HA3	15% HA4
Paracetamol	API	76.9	76.9	76.9	76.9	76.9	76.9	76.9	76.9
Lactose	Diluents	13.1	11.1	6.1	1.1	13.1	11.1	6.1	1.1
<i>Helianthus annuus</i> Mucilage	Binder	3.0	5.0	10.0	15.0	0	0	0	0
<i>Acacia</i> gum	Binder	0	0	0	0	3.0	5.0	10.0	15.0
Starch	Disintegrants	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
Talc	Glidant	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Magnesium stearate	Lubricant	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0

API: Active pharmaceutical ingredient. All values in %, total weight of each tablet 650 mg

Evaluation of prepared tablets

All standard and additional tests were conducted to evaluate the quality of the prepared tablets. The standard tests were carried out following the guidelines of the Indian pharmacopoeia (IP). These included measuring the diameter and thickness of the tablets, checking the uniformity of their weight, assessing tablet hardness, performing friability tests, evaluating disintegration time (DT), and confirming uniformity of drug content.^[28,29]

In vitro release study

Tablets from each batch, prepared using both binders (isolated mucilage and *Acacia*), were tested to study the drug release profile. This was performed *in vitro* using a USP Type II (paddle) dissolution apparatus to determine how the drug is released from the tablets over time.^[30,31]

MATERIALS AND METHODS

Helianthus annuus Linn. (Family: Asteraceae) seeds used in the present study were authenticated by Prof. Nawal Kishore Dubey, Centre of Advanced Study in Botany, Banaras Hindu University (BHU), Varanasi, India, using standard taxonomic methods. A voucher specimen (Asteraceae: 2024/01) was deposited in the BHU Herbarium. Lactose, starch, magnesium stearate, and talc were used as excipients. All chemicals and reagents were of analytical grade and obtained from GLA University, Mathura. Fresh seeds were cleaned, air-dried, and powdered using a mechanical grinder. The powder was soaked in deionized water (1:4 w/v) for 2–3 h with continuous stirring to form a slurry. The slurry was heated at 70 °C for 15–20 min and allowed to stand. The mixture was filtered through muslin cloth to remove residue. Acetone (1:3) was added to the filtrate to precipitate the mucilage. The precipitate was filtered and dried below 50 °C in a hot air oven. The dried mucilage was powdered, sieved (#80), and stored in a desiccator for further use.

RESULTS

SEM

The surface morphology of the mucilage isolated from *H. annuus* was examined using SEM. The micrographs revealed that the mucilage is amorphous in nature, with particles appearing aggregated and irregular in shape, as shown in Figure 1. Understanding the surface morphology is important, as it directly influences the water-holding capacity of the mucilage.^[32,33]

PXRD

The PXRD pattern of *H. annuus* (sunflower seed) mucilage exhibited a broad halo with maximum intensity at $2\theta \approx 20^\circ$,

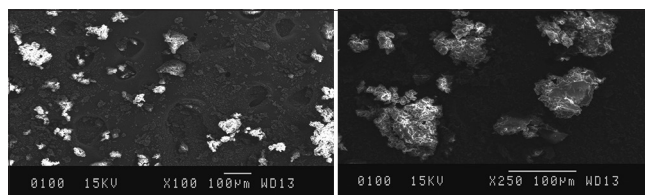


Figure 1: Scanning electron microscopy images of *Helianthus annuus* mucilage

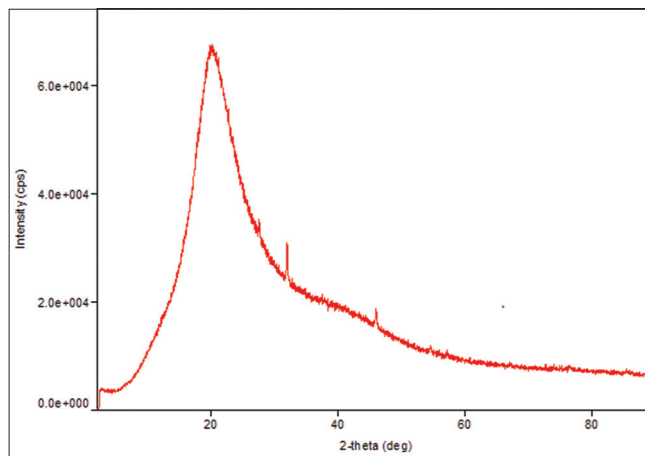


Figure 2: Powder X-ray diffractogram image of *Helianthus annuus* mucilage

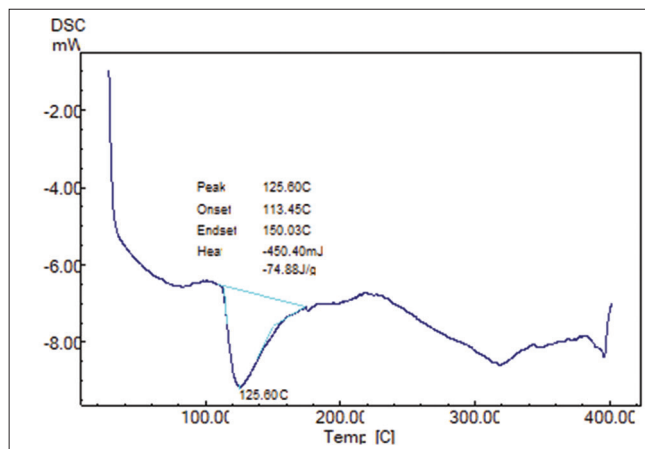


Figure 3: Differential scanning calorimetry thermogram of isolated *Helianthus annuus* mucilage

confirming its predominantly amorphous nature. A few weak peaks were detected in the range of 10–60°, but the absence of sharp crystalline reflections further supports the amorphous character of the mucilage Figure 2.^[34]

DSC

The DSC thermogram of *H. annuus* (sunflower seed) mucilage showed a prominent endothermic peak at 125.6°C with an onset at 113.4°C and an end set at 150.0°C, corresponding to the loss of bound water and thermal softening of the polymer matrix. The enthalpy change was –450.40 mJ, indicating

dehydration and polymer relaxation. The absence of any sharp melting transition confirmed the amorphous nature of the mucilage Figure 3.^[35]

FTIR

FTIR analysis was performed on the isolated *H. annuus* (Sunflower seed) mucilage, and the spectra are shown in Figure 4. The FTIR spectrum of the mucilage sample revealed a broad O–H stretching band around 3,275 cm^{-1} , indicating abundant hydroxyl groups typical of polysaccharide structures. Peaks near 2,926 cm^{-1} confirmed aliphatic C–H stretching, while strong absorptions in the 1,242–932 cm^{-1} region were characteristic of C–O and C–C stretching vibrations from the mucilage polymer backbone. The data verify the presence of complex carbohydrates with extensive hydrogen bonding, consistent with natural plant mucilage. Overall, the FTIR analysis confirms that the isolated mucilage from *H. annuus* is predominantly composed of polysaccharides.^[36]

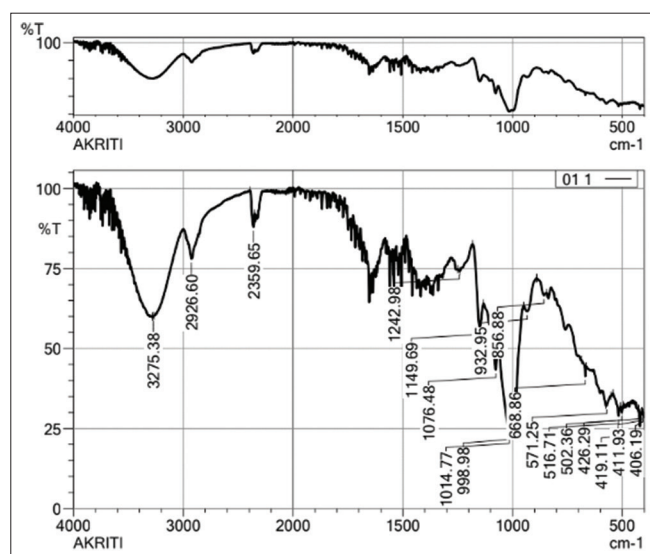


Figure 4: Fourier transform infrared spectroscopy Spectra of mucilage isolated from *Helianthus annuus* mucilage

Phytochemical examination of mucilage

Mucilages are plant-derived hydrocolloids rich in polysaccharides that affect drug release. Phytochemical screening of *H. annuus* seed powder [Table 2] confirmed the presence of mucilage and polysaccharides, validating its hydrocolloid nature.

Microbiological properties

The isolated *H. annuus* mucilage was tested for microbial contamination. As shown in Table 3, no bacterial or fungal growth was detected after 72 h, confirming its microbiological safety and stability for pharmaceutical use.^[37]

Physicochemical characterization of mucilage

As per pharmacopoeia standards, the physicochemical properties of *H. annuus* mucilage were evaluated [Table 4]. It dissolved easily in hot water, showed hydrocolloid behavior in cold water, but was unsolvable in organic solvents like chloroform, ethanol, and acetone. The viscosity of the mucilage was measured to be 1265 cP for a 3% w/v solution and 1468 cP for a 5% w/v solution, indicating good thickening ability. The pH of a 1% w/v solution was recorded as 6.2, which falls within the acceptable range for uncoated conventional tablets, making it suitable for pharmaceutical applications.^[38]

Drug excipient compatibility study

Compatibility studies are essential as natural polymers may interact with APIs, affecting formulation stability and efficacy. Hence, the isolated *H. annuus* mucilage was evaluated for drug–excipient compatibility by FTIR spectroscopy, UV spectrophotometry, and DSC, and no interaction has been observed as shown in Figure 5a and b.

Table 2: Phytochemical properties of *Helianthus annuus* isolated mucilage

Key ingredients	Examination	Statement	Results
Carbohydrate	Molisch's test, iodine test	Rusty-brown shade	Positive
Proteins	Biuret test	It was a dark purple color	Positive
Resin	Resin test	No pink color developed when using HCl. FeCl ₃ did not produce any greenish-blue tint	Negative
Tannins	Ferric chloride test	A bright yellow tint remained the same deep purple color for the +ve outcome	Negative
Mucilage	Ruthenium red test	The color pink emerged	Positive
Glycosides	Baljet's test	A yellow to orange tone was visible	Positive
Saponin	Forth formation test	There was no foam present	Negative
Alkaloids	Mayer's reagent test	There was no evidence of cream precipitate	Negative
Flavonoids	Shinoda test	Red to pink tone	Positive

Further, DSC analysis supported these findings, as the thermogram of the 1:1 mixture displayed no major differences compared with pure PCM. Together, these results confirmed that the isolated mucilage of *H. annuus* is chemically and

physically compatible with PCM, making it a suitable excipient for tablet formulations.

Table 3: Microbial examination of the mucilage of *Helianthus annuus*

Parameters	Fungal	Bacterial
Growth media	Sabouraud's dextrose agar media	Nutrient agar media
Temperature during incubation	27°C	37°C
Observed after 24 h	No growth	No growth
Observed after 72 h	No growth	No growth

Table 4: Physicochemical evaluation of isolated mucilage from *Helianthus annuus*

Parameters (<i>Helianthus annuus</i>)	Remark
Solubility in water	Although it dissolves easily in heated water, it forms a colloidal solution when exposed to cold water. Not soluble in chloroform, acetone, or ethanol
pH of 1% (w/v) solution	6.2
Total Ash content (%)±SD	8.5±0.20
Acid insoluble ash (%)±SD	2.5±0.18
Water soluble ash (%)±SD	8.36±0.27
Viscosity of 3% and 5% (w/v) solution	1265 cP and 1468 cP, correspondingly
Loss on drying	2.80
Swelling index	5

SD: Standard deviation. Data are expressed as mean±SD for n=3

Micromeritics studies of prepared dried granules

Dried granules prepared with *H. annuus*. Particle size was assessed in the mucilage. Particle size distribution (PSD) and flow properties are key factors influencing tablet compression, hardness, and drug release. PSD increased with higher binder concentration, and flow properties (bulk/TD, Hausner's ratio, Carr's index, angle of repose) indicated excellent compressibility and flow for granules with 3–15% mucilage [Table 5]. Comparisons with gum *Acacia* showed similar results, with only minor differences in Carr's index at 15%, suggesting *H. annuus* mucilage is an effective natural binder suitable for tablet formulation.^[39]

Evaluation of prepared tablets

The prepared tablets were subjected to both compendial and non-compendial evaluation tests to assess their overall quality and performance. The evaluation parameters included tablet diameter and thickness, weight variation, hardness, friability, DT, and drug content uniformity, as well as *in vitro* dissolution behavior [Table 6]. Presents the comparative results of all batches formulated using *H. annuus* (Sunflower seed) mucilage and gum *Acacia* as binders.^[40]

The tablets prepared using *H. annuus* mucilage (HF1–HF4) and gum *Acacia* (HA1–HA4) were evaluated for their physical and mechanical properties. The thickness of HF1–HF4 formulations ranged between 5.5 and 5.6 mm, while HA1–HA4 tablets showed slightly higher thickness values between 5.6 and 5.8 mm. The diameter of HF1–HF4 was between 12.4 and 12.7 mm, whereas HA1–HA4 showed values ranging from 12.4 to 12.7 mm, indicating uniform dimensions across both binder groups. The hardness of all

Table 5: Flowability characterization of granules prepared from mucilage of *Helianthus annuus* and gum *Acacia*

Parameters	Data are expressed as mean±SD for n=3							
	<i>Helianthus annuus</i> mucilage				<i>Acacia</i> gum			
	HF1	HF2	HF3	HF4	HA1	HA2	HA3	HA4
Bulk density (g/mL) ±SD	0.55±0.05	0.50±0.03	0.47±0.03	0.45±0.03	0.65±0.02	0.58±0.05	0.51±0.05	0.45±0.03
Tapped density (g/mL) ±SD	0.62±0.02	0.58±0.01	0.55±0.02	0.52±0.03	0.72±0.02	0.65±0.02	0.58±0.05	0.53±0.04
Carr's Compressibility index (%) ±SD	11.2±0.25	13.7±0.36	14.5±0.42	13.4±0.32	9.7±0.22	10.7±0.24	12.06±0.35	15.09±0.42
Hausner ratio±SD	1.08±0.05	1.07±0.04	1.08±0.05	1.1±0.07	1.10±0.05	1.12±0.05	1.13±0.07	1.17±0.07
Angle of repose (°) ±SD	29.74±0.78	28.02±0.74	31.66±0.9	32.61±0.95	29.02±0.8	31.27±0.85	31.56±0.9	32.25±0.9

SD: Standard deviation. HF1–HF4=sunflower seed mucilage and HA1–HA4=*Acacia* Gum

Table 6: Compendial and non-compendial evaluation parameters of all prepared formulations

Parameters	Helianthus annuus mucilage				Acacia gum			
	HF1 3%	HF2 5%	HF3 10%	HF4 15%	HA1 3%	HA2 5%	HA3 10%	HA4 15%
Diameter (mm) ±SD	12.7±0.11	12.5±0.10	12.4±0.12	12.4±0.11	12.4±0.12	12.7±0.11	12.5±0.12	12.7±0.12
Thickness (mm) ±SD	5.5±0.05	5.6±0.06	5.6±0.05	5.5±0.06	5.6±0.05	5.7±0.07	5.6±0.05	5.8±0.07
Hardness (kg/cm ²) ±SD	5.00±0.41	5.6±0.31	5.7±0.32	6.5±0.45	3.5±0.43	4.9±0.3	5.5±0.41	7.1±0.5
Uniformity of weight (mg) ±SD	649.5±0.008	649.9±0.014	650.3±0.010	650.4±0.011	649.1±0.01	649.8±0.09	650.8±0.01	651.1±0.01
Disintegration of time (minutes) ±SD	1.0±0.02	2.1±0.06	3.45±0.1	3.5±0.12	2.2±0.06	2.9±0.08	3.4±0.1	3.7±0.15
Drug content (%) ±SD	99.8±0.4	92.5±0.4	98.4±0.5	97.8±0.5	95.6±0.5	97.3±0.5	93.8±0.4	97.9±0.5
Friability (%) ±SD								

<1% in all formulations

SD: Standard deviation

HF1–HF4 tablets was above the minimum pharmacopeial requirement of 4 kg/cm², with values ranging from 5.0 to 6.5 kg/cm².

Similarly, three formulations prepared with gum *Acacia* (HA2–HA4) demonstrated hardness between 4.9 and 7.1 kg/cm², while HA1 had a slightly lower hardness of 3.5 kg/cm², falling below the standard limit. According to the IP (1996), uncoated tablets should have friability <1%, and all formulations in this study (HF1–HF4 and HA1–HA4) complied with this requirement. Weight variation tests also confirmed that all batches met the pharmacopeial limits, as none of the tablets deviated beyond the acceptable range of 5% for average tablet weight above 250 mg.

The DT is a critical factor influencing drug release and subsequent absorption, as it is the rate-limiting step for bioavailability in conventional dosage forms. As per pharmacopeial standards, uncoated tablets must disintegrate within 15 min. All formulations in this study exhibited rapid disintegration well within the specified limit, with values below 4 min. Among the batches, HF1 and HA1 disintegrated fastest at 1.0 and 2.2 min, respectively. HF2 and HA2 showed DTs of 2.1 and 2.9 min, HF3 and HA3 at 3.45 and 3.4 min, while HF4 and HA4 disintegrated at 3.5 and 3.7 min, respectively. These results confirm that tablets formulated with isolated *H. annuus* mucilage meet the required quality control standards and are comparable to those prepared with gum *Acacia* as a binder. Another critical pharmacopeial requirement for tablets is uniformity of content, which ensures that each unit contains the amount of drug claimed on the label. The drug content of formulations prepared with *H. annuus* mucilage (HF1–HF4) was found to be within 92.5–99.8%, while those prepared with gum *Acacia* (HA1–HA2) showed values between 93.8% and 97.9%, thus complying with official standards. Considering the overall results of both compendial parameters (uniformity of weight, drug content, DT, and friability) and non-compendial parameters (thickness, diameter, and hardness), formulations HF1 and HF2 prepared with *H. annuus* mucilage can be regarded as the most optimized batches, exhibiting superior balance between mechanical strength and disintegration behavior.

In vitro release study

For achieving good bioavailability, a drug must exhibit an appropriate release pattern from its dosage form. To examine this, an *in vitro* dissolution study was carried out on all batches of uncoated tablets (HF1–HF4) prepared using isolated mucilage of *H. annuus* and compared with tablets (HA1–HA4) prepared using gum *Acacia*. According to the IP, a minimum of 25–30% drug should be released within the first interval, at least half by the second cutoff, and over 80% by the third.

The dissolution profiles demonstrated that with increasing

Table 7: *In vitro* drug release study

Time (minute)	Release of drug cumulatives (%)							
	HF1	HF2	HF3	HF4	HA1	HA2	HA3	HA4
5	30.17	27.29	27.26	26.25	28.25	28.43	29.52	18.54
10	60.28	53.34	47.44	50.92	55.32	59.52	61.63	36.57
15	95.33	86.49	85.04	71.74	85.56	87.65	90.68	56.66
20	97.67	92.59	86.78	86.69	93.62	91.72	94.77	72.78
25	98.89	95.85	94.08	95.32	92.75	91.85	94.85	89.81
30	99.96	98.92	99.0	96.55	90.94	91.92	93.91	97.91

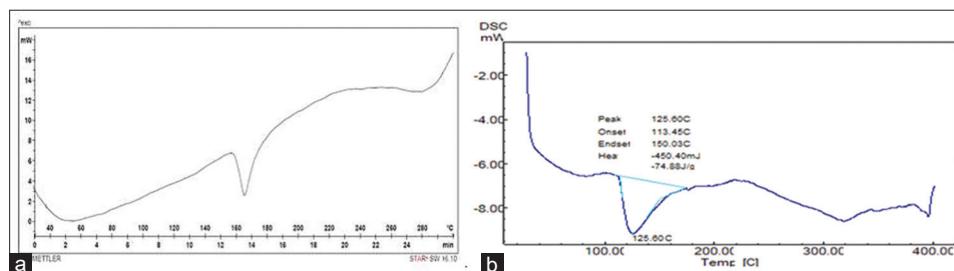


Figure 5: (a) Differential scanning calorimetry thermogram of pure (drug paracetamol). (b) Differential scanning calorimetry thermogram of drug (Paracetamol) and mucilage (*Helianthus annuus*) in 1:1 ratio

binder concentration, the release rate of the drug decreased in tablets prepared with both sunflower seed mucilage and gum *Acacia*. The drug release profiles are depicted in Figure 6a-f.

Among the formulations, HF1 (containing 3% mucilage) exhibited a cumulative release of nearly 99% within 30 min, while HF2 (containing 5% mucilage) showed around 98% release at the same time. HF3 (containing 10% mucilage) exhibited a cumulative release of nearly 98% within 30 min, while HF4 (containing 15% mucilage) showed around 96% release at the same time.

In comparison, formulations HA1 and HA2 prepared with 3% and 5% *Acacia* gum as binder showed 95% and 93% release, respectively, at 30 min. Moreover, formulations HA3 and HA4, prepared with 10% and 15% *Acacia* gum as binder, showed 96% and 97% release, respectively, at 30 min. Overall, all formulations demonstrated linear release patterns, confirming that isolated mucilage from the seed of *H. annuus* provides an effective natural binding agent comparable to gum *Acacia* for tablet formulation. As shown in Table 7.

DISCUSSION

This investigation suggested the feasibility of using *H. annuus* seed mucilage as a natural binder in traditional uncoated tablet formulations, responding to the increasing need for sustainable and biocompatible pharmaceutical excipients. Natural polymers are gaining preference over synthetic alternatives because of their biodegradability, safety profile,

and economic advantages. The physicochemical analysis of the isolated mucilage demonstrated characteristics that are advantageous for pharmaceutical applications. The near-neutral pH of 6.2 suggests compatibility with oral dosage forms, thereby reducing the potential for gastrointestinal irritation. Furthermore, its solubility profile, which includes free solubility in hot water and the formation of a colloidal dispersion in cold water, supports its application in wet granulation processes.

DSC thermal analysis confirmed the mucilage's thermal stability; the absence of a distinct melting peak corroborated its amorphous character. This observation was further validated by PXRD data, which presented a broad diffraction halo, indicative of a non-crystalline structure. Amorphous polymers typically demonstrate improved swelling and binding capabilities, thereby facilitating granule cohesion during tablet compression. SEM analysis revealed irregular, aggregated particles, potentially fostering enhanced interparticulate bonding and, consequently, improved tablet hardness and mechanical strength.

Micromeritic analyses revealed that granules formulated with *H. annuus* mucilage demonstrated superior flow characteristics, especially when lower binder concentrations (3–5%) were employed. The observed values of Carr's index, Hausner's ratio, and angle of repose indicated favorable compressibility, a critical attribute for ensuring consistent tablet manufacturing. These findings were on par with, and in certain instances surpassed, those observed with gum *Acacia*, a frequently utilized natural binder.

Tablet evaluation metrics confirmed that all formulations

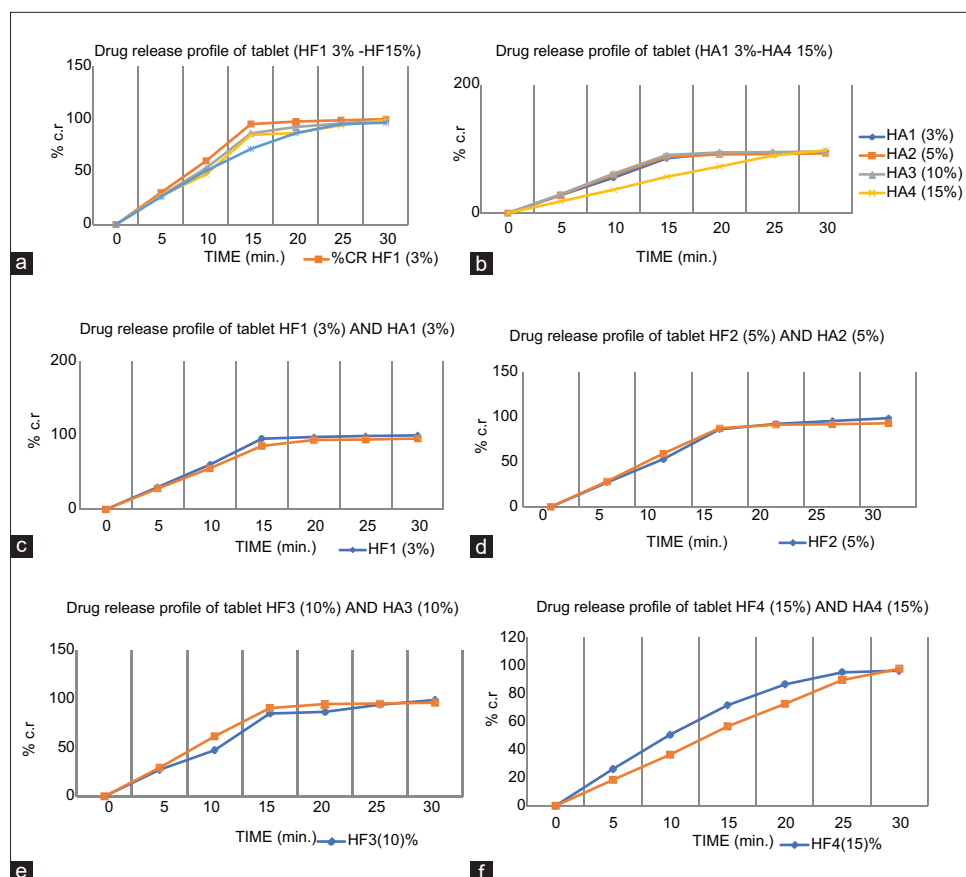


Figure 6: (a) *In vitro* % cumulative drug released profile of paracetamol tablets prepared using *Helianthus annuus* mucilage as a binder (HF1–HF4); (b) *In vitro* % cumulative drug release profile of paracetamol tablet prepared using gum *Acacia* as a binder (HA1–HA4); (c) Comparative *in vitro* drug release profile of formulation prepared using 3% w/v binder of *H. annuus* mucilage (HF1) and *Acacia* gum (HA1); (d) Comparative *in vitro* drug release profile of formulation prepared using 5% w/v binder of *H. annuus* mucilage (HF2) and *Acacia* gum (HA2); (e) Comparative *in vitro* drug release profile of formulation prepared using 10% w/v binder of *H. annuus* mucilage (HF3) and *Acacia* gum (HA3); (f) Comparative *in vitro* drug release profile of formulation prepared using 15% w/v binder of *H. annuus* mucilage (HF4) and *Acacia* gum (HA4)

met pharmacopeial standards regarding hardness, friability, weight variation, and drug content uniformity. The accelerated disintegration observed in the 3% and 5% mucilage formulations can be explained by the polymer's hydrophilic characteristics and substantial swelling capacity, which promotes more rapid water penetration. *In vitro* dissolution studies additionally revealed enhanced drug release profiles for the mucilage-based tablets, with nearly complete release occurring within 30 min. This performance exceeded that of tablets formulated with gum *Acacia*, thereby underscoring the efficacy of *H. annuus* mucilage as a binder.

The results, in sum, indicate that sunflower seed mucilage represents a potentially valuable natural excipient, characterized by superior binding capabilities, thereby presenting a sustainable substitute for traditional binders. Furthermore, its performance, which is contingent upon concentration, suggests potential utility in modified release formulations, thus broadening its applicability within the pharmaceutical domain.

CONCLUSION

The present study aimed to extract mucilage from *H. annuus* (sunflower seed) and evaluate its suitability as a natural pharmaceutical excipient. Physicochemical, phytochemical, microbiological, and thermal analyses were performed alongside tablet evaluation parameters and *in vitro* dissolution studies. The isolated mucilage yielded 10.1% and was non-toxic, biodegradable, and thermally stable, as confirmed by DSC thermograms. PXRD and DSC studies indicated its amorphous nature, while spectroscopic analysis confirmed non-reducing sugars. PSD and flow property analyses showed that the mucilage is suited for wet granulation in tablet formulations. Granules prepared using sunflower seed mucilage showed good micromeritic properties, including favorable angle of repose and compressibility index. Tablets formulated with the mucilage passed quality control tests, including hardness, friability, weight variation, drug content, and disintegration. *In vitro* dissolution studies revealed that tablets with isolated mucilage exhibited rapid drug release, even at lower binder concentrations, outperforming those

with gum *Acacia*. The findings suggest that isolated mucilage from *H. annuus* can serve as a natural binding agent for uncoated tablets, with potential applications in modified drug delivery systems as a versatile, eco-friendly excipient.

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AUTHOR'S CONTRIBUTIONS

All authors contributed significantly to the conception, design, execution, and interpretation of this research. They have accepted full responsibility for the content of the manuscript, thoroughly reviewed all experimental results, and provided critical revisions to enhance the quality of the work. All authors approved the final version of the manuscript and consented to its submission for publication.

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