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Performance evaluation of some crude and modified plants mucilage as binding agent in paracetamol tablets

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Abstract: Crude mucilage samples (native) and modified samples from *Cissus* mucilage powder (CMP), Wild-mango mucilage powder (WMP) and *Adasonia* fruit-pulp powder (APP) by acetylation, carboxymethylation and oxidation. The crude samples and modified ones were used to compound paracetamol tablets. The granules from which the tablets were produced was evaluated for the flow parameters such as bulk and tapped densities, *Hausner's* ratio, Carr's index and angle of repose. The values obtained indicated that the paracetamol granules have good flow properties that would enhanced their compaction to good tablets. The compacted tablets were also evaluated for the weight variation, thickness, and friability and disintegration time. The tablets were found to possess less than 1 % friability except the tablets made from acetylated APP (1.15% ± 0.39). However, it was observed that disintegration time of modified mucilage samples were higher that their corresponding crude samples. The in-vitro drug released from the tablets was found to be inversely proportional to the concentration of mucilage used as binders. More than 80 % of the drug was released with 35 minutes and this is an indication of good tablet according to the specification of British Pharmacopeia. The plants mucilages investigated were found to have good potential to be used as binders in tablet formulations and these plants mucilage could serve as replacement for the synthetic binders currently being used by most pharmaceutical companies. The plants mucilage can also be modified for their usage in novel drug formulations.

Keywords: Binders, excipients, Modification, Mucilage, Tablet properties. Ratio.

1. Introduction

Natural polysaccharides have been widely used in pharmaceutical and food industry as excipients because of their non- toxicity, biodegradability, availability and low cost of extraction. Gums and mucilage are amorphous translucent hydrocolloid substances and are homopolysaccharides or heteropolysaccharides. Being hydrophilic molecules, they can combine with water to form viscous solutions or gel. Mucilage is hydrocolloid polysaccharides that swell in aqueous solution to form viscous solution. Mucilage is produce as a result of normal physiological reactions of plants while gums are hydrocolloid compound that dissolved in water to form viscous solution. Gums are from in response to injury or stress to plants [1].

These polysaccharides are employed as excipients in pharmaceutical and food formulation to increase volume, aid flow, enable compactness and make a drug convenient to administer. They can also be used to modify the release of drug, thereby, influencing the absorption and subsequent bioavailability of the incorporated drug [2]. These excipients act as vehicles which transport the incorporated drug to the site of absorption and are expected to guarantee the stability of the incorporated drug the precision and accuracy of the dosage, and also improve on the organoleptic properties of the drugs where necessary in order to enhance patient adherence [3].

These natural polysaccharides however have shortcomings such as low shelf-life and low solubility. The shortcoming can be minimized by chemical modifications such as carboxymethylation, acetylation and oxidation. The chemical modifications are possible because of the abundant hydroxyl group (-OH) in their molecules through which other functional groups can be added during chemical

modifications. The type and number of monosaccharides, their configuration, and types of linkage give specific mucilage or gum its peculiar physicochemical characteristics. The chemical nature of a gum dictates the type of gel or texture formed [4]. The degree of polymerization influences a gums and mucilage viscosity and hydration rate. The physicochemical properties of gums and mucilage influence their functional properties which are employed in their uses in various industrial applications.

The objective of this study was to prepare paracetamol tablets with some crude plants unmodified and modified mucilages as binder and examine the pharmaceutical properties of the tablets to assess their functionality as drug excipient.

2. Materials and Methods

Paracetamol BP, corn starch, Talc powder, Magnesium stearate and lactose were obtained as gift from a local pharmaceutical industry.

2.1. Manufacture of tablets

Wet granulation method of tablet manufacturing was employed with mucilage samples as binding agent and water as the granulating liquid. Batches of paracetamol tablets were formulated using 2, 4, 6 and 8 % (w/v) of mucilage powder (crude and modified). The required amount of Paracetamol powder, lactose, mucilage dispersions and corn starch were blended to form a damp coherent mass which was screened through a sieve No 10 and dried at 50 ^{0}C for one hour. Corn starch was divided into two and incorporated during wet blending and after drying of granules to act as an intra-granular and extra-granular disintegrant. For comparative purposes, acacia gum was also used as binders at the same concentrations as the mucilage samples. The compositions of the batches are shown in Table 1.

2.2 Evaluation of granules

Granules were evaluated for pre-compression parameters such as angle of repose, bulk density, tapped density, bulkiness, *Hausner's* ratio and compressibility index. The evaluation was done using all the methods as specified in pharmacopoeias as adopted by [5].

2.3 Evaluation of Tablets

Weight variation

All prepared tablets were evaluated for weight variation among the tablets produced. Twenty tablets of each batch were used to evaluate weight variation among tablets and mean and standard deviation was calculated and the confidence interval was established by the use of *student* t- test.

Friability

The friability of the tablets was determined using the *Veego* tablet friability apparatus (*Veego* Scientific Devices, Mumbai, India) at a speed of 25 rpm for 5 minutes. The diametrical crushing strength of ten tablets per batch was determined using the *Erweka TBH 28* hardness tester (GMBH, Germany). The results of crushing strength test were accepted only if the samples split cleanly into two halves.

Hardness

A *Mosanto* tablet hardness tester was used to measure the hardness properties of the tablets. The tablet was placed between the anvil and the pressure plunger of the hardness tester and pressure was applied to the tablet until it fractured diametrically. The load causing the diametrical fracture was read from the graduated scale on the tester. The determination was carried out in five replicates and the mean values are reported.

Disintegration Test

A BP tablet disintegration unit apparatus (type MK5 Manesty Machine Ltd., Liverpool, England) was used for this analysis. The disintegration medium was distilled water maintained at 37±1 ^{0}C. Six tablets from each batch were placed in each tube and allowed to oscillate in and out of the disintegration medium. The time taken for the primary particles (tablets and its fragments) to pass through the mesh was noted. The mean values of six determinations are recorded.

In-vitro Drug Release Study

The dissolution rate of the tablets was determined using the Rotating Basket (USP Apparatus. Each tablet was placed in a cylindrical basket of stainless wire mesh attached to a variable speed drive

mechanism and suspended in a glass vessel containing 1000 mL of 0.1mol/dm^3 HCl aqueous solution (to depict the gastric medium where the tablet disintegration will occur) kept at 37 ^oC ± 0.50 ^oC. The apparatus was set to rotate at 100 rpm and was started simultaneously with a stop clock. 5 mL sample of the dissolution medium was removed at five minutes time intervals and replaced with an equal volume of fresh sample of dissolution medium. The absorbance of the removed and filtered sample was measured using a UV spectrophotometer (SP6-450 UV/VIS spectrophotometer, Pye Unicam, Middlesex, England), at 230 nm from which the concentration of drug dissolved was calculated with reference the calibration curve [6].

3. Results and Discussion

The granules formulated with mucilage powder (crude and modified) as binder had good physical properties and were suitable for tablet compression. The flow properties of the mass of granules are important to ensure uniform die filling during compression which will lead to uniform weight of the tablets compressed.

Table 1: Paracetamol Dosage Formulation Table (500 mg/tablet)

Ingredients	R1 (mg)	R2 (mg)	R3 (mg)	R4 (mg)	R5 (mg)	R6 (mg)	R7 (mg)	R8 (mg)
PCM	500	500	500	500	500	500	500	500
SCMC	40	30	20	10	-	-	-	-
Mucilage	-	-	-	-	40	30	20	10
$NaHCO_3$	12	22	32	42	12	22	32	42
Citric acid	20	20	20	20	20	20	20	20
Mg Stearate	4	4	4	4	4	4	4	4
Talc powder	4	4	4	4	4	4	4	4
Total weight (mg)	580	580	580	580	580	580	580	580

In all formulations (2 %) sodium lauryl sulphonate solution was used as granulating agent. PCM (Paracetamol powder), SCMC (Sodium carboxymetheylcellulose).

Table 2: Pre-compression parameters of paracetamol granules formulated with crude mucilage samples and reference gums

Parameters	**CMP**	**WMP**	**APP**	**AG**	**CG**
Bulk density (g/cm^3)	0.474±0.26	0.487±0.13	0.479±0.04	0.533±0.13	0.549±0.04
Tapped density (g/cm^3)	0.582±0.43	0.593±0.52	0.586±0.17	0.572±0.04	0.634±0.09
Hausner ratio	1.24±0.99	1.22±0.52	1.22±0.43	1.07±0.51	1.15±0.90
Carr's index (%)	18.61±4.39	17.92±3.06	18.3±2.75	6.81±2.34	13.41±3.49
Angle of repose (Degree)	28.41±5.21	27.20±5.29	23.42±4.86	25.45±5.77	24.12±6.11

Values are means of triplicate determinations ± standard deviation was calculated and the confidence interval was established by the use of student t- test. CMP- Cissus mucilage powder, WMP- Wild-mango mucilage powder, APP- Adansonia fruit-pulp powder.

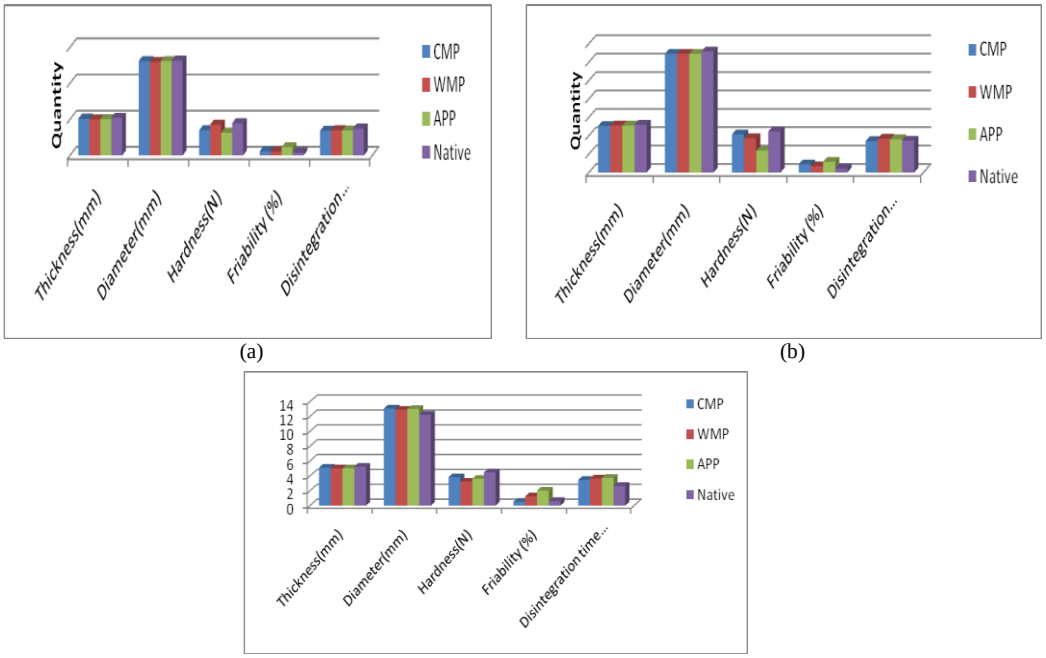

Figure 1: Evaluation parameters of tablets with modified and crude (native) mucilages as binding agent. CMP-*Cissus* mucilage powder, WMP-Wild-mango mucilage powder, APP- *Adasonia* fruit-pulp powder. (a): acetylated, (b): carboxymethylated and (c); oxidized mucilage.

The flow properties of the various batches of paracetamol granules prepared from crude *Cissus* mucilage powder (CMP), Wild-mango mucilage powder (WMP), *Adansonia* fruit-pulp powder (APP) and their modified forms (Acetylated, Carboxymethylated and Oxidized) exhibited good flow properties as observed from the results: *Hausner* ratio (1.33 – 1.24), Carr's index (17.92 – 18.61 %) and angle of repose (23.42 – 28.41 %) values. The flow properties of the plants mucilage being investigated were comparable to that of acacia gum and cashew gum used as reference gums in the present study [7].

Paracetamol tablets produced using the plants mucilage as binders passed the weight uniformity, hardness, friability and disintegration tests. The tablets passed uniformity of weight test due to the good flow properties of the granules that ensured the uniform filling of the tablet dies during tablet compaction. The values ranged within that of the British pharmacopoeia limits. Friability results were majorly less than 1 %, which indicates that the tablets are good enough to withstand the rigor of packing and transportation without appreciable loss of dosage by tablet chipping. oreover, all batches containing mucilage showed comparable results to the reference batch in term of one or more parameters [8].

An increase in the binder concentration in tablets leads to the formation of harder tablets with increased disintegration times. The formulated tablets showed good dissolution profiles however, the dissolution rate was inversely proportional to the mucilage concentration used as binder which is agreement with previous study on shear gum mucilage [9]. Tablets formulation with both crude and modified mucilage showed good dissolution profiles.

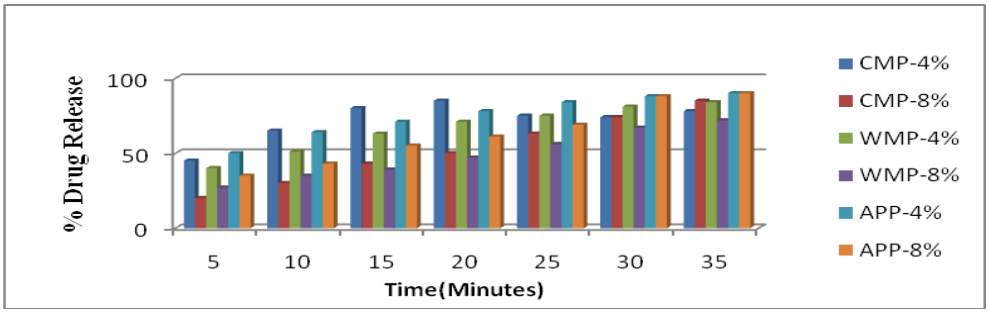

Figure 2: Drug release profile of paracetamol tablets with crude mucilages as binders at different concentrations.

From the *In-vitro* drug release profiles (Fig.2) it was observed that more than 75 % of the drug was released after 30 minutes. It was observed that the drug release was directly proportional to time and inversely proportional to the concentration of native binders used [10]. However, the amount of drug release with time was found to decrease when modified mucilages were used as binders. Adasonia fruit-pulp powder (APP) was found to show the highest reduction in released drug compared to other modified mucilages. This implied that modified APP could be further investigated for formulation of controlled release of drugs.

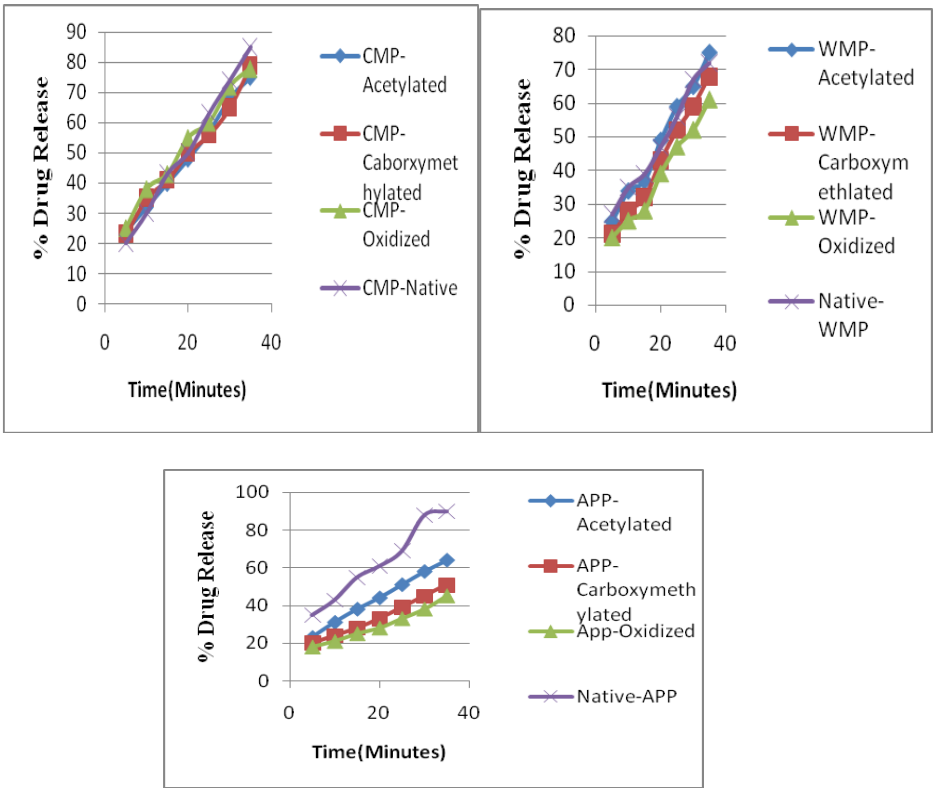

Figure 3: *In-vitro* drug Release profile of paracetamol tablets with modified and crude mucilages as Binders

4. Conclusions

A major conclusion can be derived from the study was that the plants mucilage (*Cissus populnea* mucilage powder, *Irvingia gabonensis* seed mucilage and *Adansonia* fruit-pulp mucilage) possessed good

potential to replace the commercially existing polymers used as binders in tablet dosage from and they can be easily modified and explore in the formulation of novel drugs.

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