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EXTRACTION AND EVALUATION OF THE BINDING PROPERTIES OF PECTIN DERIVED FROM *Azanza garckeana* FRUIT IN DICLOFENAC SODIUM BASED TABLET

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ABSTRACT

The aim of this study is to evaluate the binding ability of *Azanza garckeana* pectin. For this purpose, pectin was obtained by precipitation with 96% ethanol. Three different batches of diclofenac sodium tablets were formulated using 5%$^{w}/_{w}$ of *Azanza garckeana* (Ag) pectin in comparison to Tragacanth (Tr) and Acacia (Ac) at same concentration. Pre-compression and post-compression studies were performed for each formulation. The results obtained for pre and post-compression parameters were found within acceptable pharmacopoeial range. The results showed that at 5% $^{w}/_{w}$ concentration, hardness test was in this order: Ag>Tr>Ac, all the tablets had friability of < 1%. Disintegration time test showed that increase in hardness value increased the disintegration time with Ag, Tr and Ac disintegrating in 16.00, 15.00 and 12.00 minutes respectively. This study concludes that *Azanza garckeana* at 5%$^{w}/_{w}$ concentration gave better binding capacity than tragacanth and acacia, hence might be explored in future for introduction as a binder in the pharmaceutical industry.

KEYWORDS: Binding property, *Azanza garckeana* fruit pectin, precipitation, diclofenac sodium.

INTRODUCTION

Binders are usually polymeric materials which possess both cohesive and adhesive properties. Their presence is very important in wet granulated granules and tablets. They function by holding filler and drug particles together in agglomerates thereby converting them into granules which are free flowing.[1] There are a wide variety of substances that are used as binders in tablet formulations and are divided into three groups (i) sugars such as sucrose, glucose, sorbitol; (ii) natural gums and polymers, which include pre-gelatinized starch, starch, gum, acacia, gelatin, tragacanth and sodium alginate; and (iii) synthetic polymers which include PVP, PEG and all the semisynthetic derivations of cellulose (HPMC, HPC. CMC, EC and polymethacrylates).[2] The use of natural binders is more advantageous to the use of synthetic ones because of its availability, low cost, biocompatibility, biodegradability and environmentally friendly nature.[3]

Pectin is a structural heteropolysaccharide contained in the primary cell walls of terrestrial plants. It is an essential component in the initial growth and in the ripening process and has been found to be useful in the area of drug delivery. [4] Pectin occurs as a white to light brown powder and is odourless or has slightly characteristic odour.[5] Pectin have been previously found in apples, oranges, cherries, grapes and have been used in the food industry but recently are being explored for other pharmaceutical purposes such as binding, suspending and thickening properties. Diclofenac sodium is a non-steriodal anti-inflammatory drug (NSAID) used as an analgesic and anti-inflammatory purposes. It is freely soluble in methanol, soluble in ethanol (95%), sparingly soluble in water and in glacial acetic acid, practically insoluble in ether, in chloroform and in toluene.[6] For this study, pectin derived from *Azanza garckeana* fruit is being examined for its binding property in diclofenac sodium tablet formulation.

MATERIALS AND METHODS

Materials

Diclofenac sodium (Triveni Chemical, India), Acacia powder (S.D. Fine, Mumbai), Tragacanth gum powder (Searl Co, England), *Azanza garckeana* fruit was purchased from Gombe state in the North Eastern region of Nigeria. All other chemicals were of analytical grade.

Methods of Extraction

The extraction of pectin hydrocolloids from *Azanza garckeana* were done using the standard methods outlined by J.M. Joel et al[7] with some modifications. The dried powdered sample (60g) was weighed and blended with 300cm^3 buffer prepared from disodium hydrogen phosphate and citric acid at pH of 2.0. The

acidified mixture of the sample was heated at 90^0C for 90 minutes using a water bath and stop watch. The heated mixture was passed through four-fold muslin cloth twice and the extracts were allowed to cool to temperature of 25^0C to reduce heat degradation of pectin. The production of pectin hydrocolloids was achieved using precipitation method with 96% ethanol and mixture kept aside for 3 hours without stirring to allow the pectin float on the surface. The floated pectin was filtered through four layered muslin cloth. The precipitate was washed 2 times using 80% ethanol to further remove remaining impurities. The pectin hydrocolloids produced was dried at 40^0C in hot air circulating oven for 3 hours and allowed to cool for 24 hours. Ground samples were stored in an air tight container until ready for further analysis.

Qualitative Test for Pectin

Colour: This was established by visual observation

Solubility of *Azanza garckeana* (Ag) pectin in cold and hot water: The method described by Ogunka et al[8] was used for this test.

Solubility of Ag pectin in Cold and Hot Alkali (NaOH): The method of V.O. Aina et al[9] was used.

Preparation of Granules

The granules were prepared by wet granulation method using Ag, Ac and Tr at 5%$^w/_w$ binder concentrations for each batch. The formulae given in Table 3 were used in the formulation of diclofenac sodium granules. Appropriate weight of the drug and excipients needed to produce 50 tablets per batch was weighed. The diclofenac sodium granules were produced by tritulating the required amount of diclofenac sodium powder with other excipients in a mortar with a pestle. The wet mass was passed through a 1.7mm sieve and dried in a hot oven at 60^0C for 3 hrs. The dried granules were then passed through a 1.0mm sieve and stored in an air tight container.

Granule properties of prepared powders.

The properties evaluated include bulk density, tapped density, Hausners ratio, compressibility index and Angle of repose according to the method reported by.[10]

Preparation of the Tablet

Diclofenac sodium was used as the active ingredient. The wet granulation method was used with starch, stearic acid and calcium carbonate as disintegrant, lubricant and bulking agents respectively. 5%$^w/_w$ concentration of both Ag, Ac and Tr were used to produce 300mg weight tablets. The compositions of the prepared formulations were shown in Table 3.

Evaluation of Diclofenac Sodium Tablet Properties

All tablets were evaluated for the following parameters which include

Hardness Test

Hardness showed the ability of a tablet to withstand shocks when handling. The hardness of the tablets were determined using Monsanto hardness tester. It was expressed in kg/f, ten tablets were randomly selected from the batches and hardness determined.

Friability Test

Tablet friability test was performed to ascertain the resistance of tablets to abrasion using Roche friabilator. This device subjects the tablets to the combined effect of shock and abrasion in a drum at a revolution of 25rpm for 4 minutes. The percentage friability was determined using the formula:

$$\text{Friability (\%)} = \frac{\text{initial weight} - \text{final weight}}{\text{nitial weight}} \times 100..1$$

Disintegration Test

The disintegration time of 6 randomly selected tablets from each batch were evaluated with water as disintegrating medium maintained at 37^oC $\pm$ 1^oC using Erweka multiple unit-disintegration apparatus.

Statistics: Microsoft Excel 2016 was used. Mean and Standard deviations for all datas were computed.

RESULTS AND DISCUSSION

Pectin was successfully produced from dried *Azanza garckeana* fruit using precipitation method with 96% ethanol. The precipitate was further washed with 80% ethanol to remove remaining impurities. The percentage yield of pectin obtained from *Azanza garckeana* fruit was 20% and this compared favourably with the result obtained by Joel et al.

Qualitative Test for Pectin

Colour: The visual observation gave a light brown powder.

Solubility Test results are shown in Table 1 below. It was observed that pectin was insoluble and dissolved rapidly in hot water. Also, the solubility of pectin in cold alkaline medium gave a yellow precipitate while in hot alkaline medium, the yellow precipitate dissolved and became creamy which conforms with earlier results obtained by Ogunka et al and Aina et al.

Table 1: Solubility Tests.

Parameter	Result
Solubility in cold water	Insoluble, suspension formed after vigorous shaking.
Solubility in Hot water	The mixture dissolved rapidly
Solubility in Cold alkali (0.1M) NaOH	Yellow precipitate was formed
Solubility in hot alkali (0.1M) NaOH	The formed yellow precipitate dissolved and turned creamy

Table 2: Pre-compression properties of granules.

S/No	Properties	Formulations		
		F1 (Ag)	F2 (Ac)	F3 (Tr)
1	Bulk density	0.55 ± 0.00	0.33 ± 0.01	0.52 ± 0.05
2	Tapped density	0.63 ± 0.01	0.40 ± 0.01	0.60 ± 0.01
3	Hausner's ratio	1.14	1.21	1.15
4	Carr's Index	13.0%	17.5%	13.3%
5	Angle of Repose	25.6% ± 0.1	28% ± 0.08	25.1% ± 0.1

Values shown are mean ± SD (n=3)

Pre-compression parameters showed the angle of repose of the formulation was in the range of 25.1% to 28% which demonstrates great stream properties of the distinctive mixes. The C.I, H.R were observed to be in the range of 13.0 to 17.5 and 1.14 to 1.21 respectively demonstrating great compressibility. The pre-compression parameters such as A.R, T.D, B.D, H.R and C.I record are inside the limit showing the agreeableness of the product to formulate into a tablet dosage form.[11]

Table 3: Formula used for the preparation of Diclofenac Sodium tablet using *Azanza garckeana,* Acacia and Tragacanth powders at 5% $^{w}/_{w}$ concentrations.

S/No	Ingredients	Formulations		
		F1	F2	F3
1	Diclofenac Sodium	50mg	50mg	50mg
2	Pectin	15mg		
3	Acacia		15mg	
4	Tragacanth			15mg
5	Starch	15mg	15mg	15mg
6	Stearic acid	6mg	6mg	6mg
7	Calcium carbonate	214mg	214mg	214mg

Properties of Prepared Tablets

As shown in table 4, the tablets prepared with *Azanza garckeana* pectin at 5% binder concentration showed good properties in terms of hardness with 8.0kg/f, a friability of < 1%, and disintegration time of 16 minutes, which conformed to the official limits set for each.[12] It was observed that increase in hardness values increased the disintegration time test with Ag, Ac and Tr disintegrating in 16.00, 12.00 and 15.00 minutes respectively.

Table 4: Tablets properties of Diclofenac sodium prepared.

Formulation Name	Hardness (kg/f)	Friability (%)	Disintegration Time (minutes)
F1 (Ag)	8.00 ± 0.58	0.13	16 ± 0.52
F2 (Ac)	5.50 ± 0.23	0.71	12 ± 0.45
F3 (Tr)	7.00 ± 0.45	0.23	15 ± 0.78

Value shown are mean ± SD (n=3).

CONCLUSION

From the results obtained by this study, it can be concluded that *Azanza garckeana* pectin at 5% $^{w}/_{w}$ concentration gave an excellent binding property and this could be employed as an alternative to other natural binders in tablet production.

RECOMMENDATION

Since it was proven from this study that *Azanza garckeana* fruit were potential alternative binder, the authors are proposing an increased research on this natural polymer especially as it concerns studies on its release properties. This will widen its acceptance as a binder in tablet dosage form.

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