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Evaluation of binding efficacy of starch isolated from *Dioscorea fluribenda* tubers

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ABSTRACT

The main goal of the current study was aimed to evaluate the binding efficacy of isolated starch form *Dioscorea fluribenda* tubers as a tablet binder. The isolated starch was subjected to determination of various physicochemical parameters as well identification test to characterize the quality and purity of starch. Morphology of the isolated starch was determined by quantitative microscopy and the other various physicochemical parameter studies were performed according to the Pharmacopoeial standard procedure. After characterization the isolated starch, it was subjected to formulation of tablet, taking Paracetamol as API and compared with marketed tablet formulation. Various quality control tests for evaluation of the tablets were performed according to Indian Pharmacopoeia. From the different experimental quality control standards it was concluded that isolated starch is comparable with industrial starch.

Keywords: *Dioscorea fluribenda* tubers, Starch, Physicochemical parameters, Tablet formulation, Quality control parameters

1. Introduction

Selection of binder & disintegrators is important in solid formulations. A binder plays a great role in the disintegration & dissolution of tablets. Generally, starch is the most popular inert material that is used as a binder in solid formulations [1]. Starch is a polymer of glucose occurring naturally as granules in seeds, roots, stems of various plants. The largest source of starch is corn i.e. *Zea mays* Linn. (Family: Gramineae). Starch is not a single substance, but consists of a mixture of two main types of polysaccharides, amylose and amylopectin. Amylose (20-30 %) is linear but extended polysaccharide of α-glucosidic linkage at C-1 and C-4 atoms, sparingly soluble in hot water and responsible for blue colour in iodine test. Amylopectin (70-80 %) is compact and un-extended polysaccharide of α-glucosidic linkage at C-1 and C-4 and C-1 and C-6 linkage, water insoluble, but swells in water and is responsible for gelatinizing property [2, 3, 4].

Dioscorea flouribenda belongs to the family Dioscoreaceae is the most important species among the cultivated varieties. It is grown as garden crops in almost every part of India along with Tripura (North East India). It grows abundantly and spontaneously in several tracts and forest areas. This species is commonly distributed in medium to thick forest. It occurs throughout the North-East India ascending upto 5,500 ft. in the Himalayas [5]. Tribal peoples consume this tuber as a food and also they are using this plant to treat various diseases. Ethnomedicinaly this plant is very much important and having high demand as a food. The food value of the tubers is very high. Boiled tubers are used as alternate of cooked rice by the different tribals [6].

In the present study, starch was isolated from the tubers of *Dioscorea fluribenda* Linn. (Dioscoreaceae), a comparatively cheap starch has been chosen as a binder and studied for its effectiveness by comparing with the marketed tablet sample.

2. Materials & Methods

2.1 Instruments used

Compound microscope (Olympus), Digital Balance (MK-VI, Systronics, Ahmedabad), Hot air oven (Sisco, Thane East, Maharashtra), pH meter (MK-VI, Systronics, Ahmedabad), Pfizer hardness tester, Roche Friabilator Apparatus, Tablet disintegration test apparatus, Tablet dissolution test apparatus (Electrolab), UV-visible spectrophotometer (Model No. UV-1700 Pharmaspec, SHIMADZU, Japan).

2.2 Drugs & Chemicals Used

All the chemicals and reagents used were analytical and laboratory grade and were obtained from Rankem Laboratories (Okhla Industrial Area, Delhi). Paracetamol tablet (Calpol, Glaxo Smith Kline, Banglore), API (Paracetamol) and exipients used for tablet preparation were obtained from State Drug Testing Laboratory, Agartala, Tripura, India.

2.3 3 Isolation & identification of Starch [7, 8]

At first tubers were taken and their outer brown layers were removed and washed with water. Then 500 gm of tuber were taken and were grinded in an electronic grinder and made liquefied slurry. The grinded tubers were triturated properly with 100ml of distilled water in a mortar. The liquid mass was subjected to wet sieving in a beaker. Ammonia solution was added to reduce the viscosity. The milky liquid passing through the sieve was containing starch. Then the beaker was kept aside to settle down. The starch was collected by decantation. Then, the wet starch was washed with water for several times and every time, the starch was collected by decantation. Finally the starch was washed with ethyl alcohol. Then it was filtered and the residue (starch) present in filter paper was air dried. Yield and percentage yield was calculated.

Suspension of starch obtained was prepared in water. Then the suspension was boiled first and the cooled, thin and cloudy mucilage was produced in both the cases. To the obtained mucilage, iodine solution was added, a dark blue colour was produced in each case, which disappeared on heating and reappeared in cooling.

2.4 Pre-formulation studies of isolated starch [9-13]

Various physical parameters like particle size, particle shape, solubility, pH, fluorescence, UV-absorbance, ash-value, moisture content of the isolated starch were determined to access purity and quality of the isolated starch. Particle size and shape was determined using optical microscope and ocular micrometer. Solubility was determined by dissolving starch in a range of organic and aqueous solvents. pH, UV absorbance, fluorescence, ash value, moisture content, angle of repose, bulk density, tapped density, Carr's index, Hausner's ratio, Swelling capacity etc. were performed according to Pharmacopoeial methods.

2.5 5 Preparation of Paracetamol tablet using isolated starch [11]

Various ingredients of paracetamol tablet were collected and weighed as per given formula, fixed by trial and error method. The tablets were prepared according to wet granulation method using Dioscorea starch. Methodology was confirmed by referencing the Pharmacopoeial standards.

Table 1: Formula used for the preparation of Paracetamol tablet.

SL. NO.	Ingredients	Amount Per Tablet (mg)
1	Paracetamol	500
2	Lactose	6
3	Starch Anhydrous (Dioscorea starch)	60
4	Starch Paste (Dioscorea starch)	40
5	Talc	10
6	Magnesium Stearate	4
7	Titanium dioxadie (Colouring agent)	3

2.6 Evaluation of prepared tablet and comparison with the marketed sample [11, 14]

2.6.1 ight Variation Test

Twenty tablets were weighed individually and average weight was calculated. The weight of not more than two tablets must not deviate from the average weight by more than the percentage given in the standard table and no tablet should deviate more than double the percentage.

2.6.2 Hardness Test

Hardness was tested by Pfizer tablet hardness tester. A tablet withstanding a force of 4 kg is known to be a good tablet according to Pharmacopoeial standard.

2.6.3 Friability Test

20 tablets were weighed and placed at Roche Friabilator and allowed to rotate at 25 rpm for 4 minutes. After 4 minutes tablets were reweighed. Final weight was subtracted from the initial weight. Result was divided by initial weight and dividing result is multiplied by 100 to get percentage loss. Percentage loss, less than 0.5 to 1 % of initial weight are the characteristic of a good quality tablet.

2.6.4 Disintegration Test

Five tablets were placed in tubes bottom, covered with 10 mesh screen. Tubes were moved up and down in water, maintained at 37±2°C with frequency 28-32 cycles/ minute through a distance 5-6 cm. Uncoated tablets have disintegration time standard as low as 5 minutes.

2.6.5 Content Uniformity

20 tablets were weighed and powdered. Weighed accurately a quantity of powder equivalent to about 0.15 gm of Paracetamol, added 50 ml of 0.1 N sodium hydroxide, diluted with 100 ml of water, shaken for 15 minutes, and added sufficient water to produce 200 ml. Mixed, filtered and diluted 10 ml of filtrate to 100 ml with water. Then, add 10 ml of the resultant solution to10 ml of sodium hydroxide (0.1 N) solution and diluted to 100 ml with

water and mixed. The absorbance of prepared solution was taken at 257 nm range. Paracetamol tablets should contain not less than 95.0 % and not more than 105.0 % of the stated amount of Paracetamol.

2.6.6 Dissolution Test

According to monograph 900 ml potassium dihydrogen phosphate buffer (KH_2PO_4) of P^H 5.8, prepared and warmed to 37±2°C. Additional 100 ml buffer solution was prepared for replacement of withdrawn sample. Tablet was placed in the basket and motor is started so that it reaches to 50 rpm. 1 ml of sample was withdrawn from the vessel at interval 10, 20, 30, 40, 50 and 60 minutes. Sample diluted up to 100 ml with buffer solution and withdrawn sample is replaced with fresh buffer in dissolution vessel. The absorbance was measured at 257 nm by spectrophotometer. Dissolution rate was determined according to the given equation at a particular time interval.

$$\text{Dissolution rate} = \frac{\text{Absorbance of Test/concentration of Test}}{\text{Absorbance of standard/ concentration of standard}} \times 100$$

3. Results & Discussion

Physicochemical characteristics or pre-formulation parameters of the isolated starch showed in the table-2, which is essential for the determination of identity and the quality of the starch used as a binder.

Table 2: Physicochemical parameters of the isolated starch.

Parameters Studied	Result
% Yield	59 %
Particle shape	Spherical
Particle size	7 ± 0.11 µ
pH	5.83
Ash value (%)	0.33 ± 0.04
Moisture content	0.15 ± 0.01%
UV-Absorbance	Nil
Fluorescence	No sample exhibits Fluorescence
Iodine test	All gives blue colour
Solubility	Slightly soluble in Water, Soluble in boiled water, insoluble in organic solvents like Methanol, Ethanol, Butanol, Ethyl acetate and Chloroform.
Angle of repose	28.16°±0.22
Bulk density	0.59 ±0.016
Tapped density	0.71 ±0.011
Carr's index	13.21 ±0.21
Hausner's ratio	1.16 ±0.11
Swelling capacity	Nil

Various parameters studied for the evaluation of prepared tablets and their comparison with market formulation is given in the table-3, 4 & 5 respectively.

Table 3: Weight variation of the marketed sample and test sample.

Parameters	Test sample	Marketed sample
Weight of 20 tablets	12.37 gm	12.43gm
Average weight	618.5mg	621.62mg
% of maximum deviation	± 5 %	± 5 %
Deviation allowed in terms of mg	587.6 - 649.4 mg	652.7 - 590.5 mg
Maximum weight of the tablet	645 mg	627.5 mg
Minimum weight of the tablet	600 mg	615.5 mg
No. of tablets showing deviation	None	None

Table 4: Evaluation parameters for determination of binding efficacy.

Parameters	Test sample	Marketed sample
Hardness	3.7± 0.5 kg	4.05± 0.11 kg
Percentage loss	0.8±0.03%	0.6± 0.22 %
Disintegration time	3.43 ±0.03 minutes	3.9± 0.11 minutes
Paracetamol content	96.16± 0.21 %	97.74± 0.33 %

Table 5: Dissolution profile of marketed and test samples.

Time in min	% release of drug in time interval					
	10	20	30	40	50	60
Test Sample	16.98±2.32	33.69±2.20	48.28±3.12	61.30±2.15	71.99±2.61	78.30±3.19
Marketed Sample	13.92±1.12	27.81±3.11	38.21±2.01	45.59±2.40	58.31±1.98	67.56±2.33

Data are expressed a mean ± SEM (n = 3)

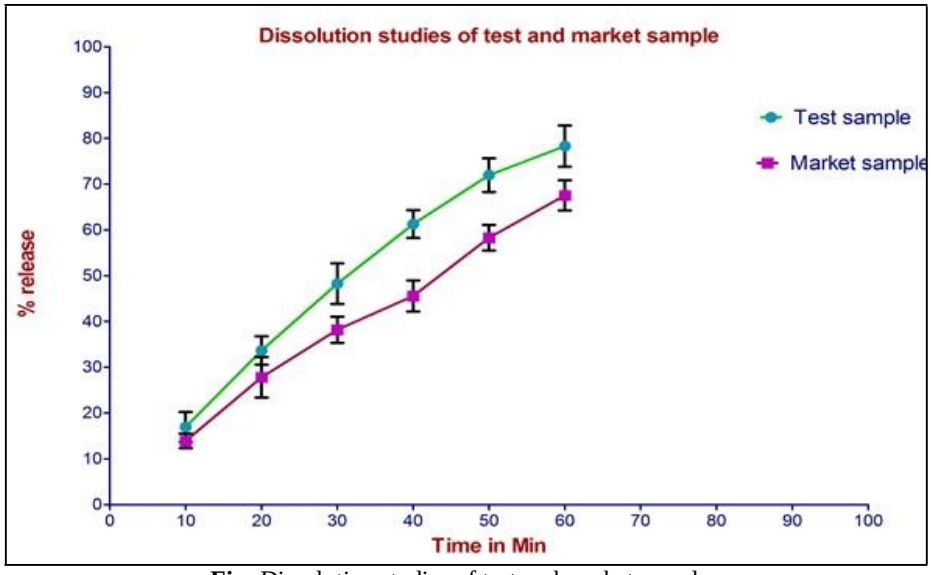

Fig: Dissolution studies of test and market sample.

During the investigation of physical parameter of the isolated starch such as particle size, particle shape, solubility, ash value, loss on drying, spectral absorbance, fluorescence property, pH & iodine test and it was found that the properties are in order. These tablet prepared in our laboratory was compared with marketed (Calpol; Glaxo Smith Kline) preparation of same tablet with regard to the official requirement such as size, shape, weight variation, hardness, friability, disintegration, content uniformity, dissolution etc. and was found that the tablet prepared with isolated starch is comparable in every respect with the marketed preparation and also meet the official requirement. Moreover our prepared tablet showed less disintegration time which has more beneficial effect for designing mouth dissolved tablet to be used for paediatric and geriatric patients.

4. Conclusion

From the outcomes of the present work it can be concluded that the isolated starch possesses good additive property as a binder in tablet formulation. The entitled work was performed with a view to use of less costly materials for the preparation of pharmaceutical products specially binder. If this could be proved, then it is very much beneficial to the tablet manufacturing industry as it is cheap and abundantly available in Tripura as well as worldwide.

5. Acknowledgement

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6. Authors' Statements

Competing Interests

The authors declare no conflict of interest.

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