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Formulation and Evaluation of Tablet Using Air Potato Starch

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ABSTRACT

Starch, the main storage component in multiple plants, is not only an important energy source for developed seedling but also a valuable material for food and non-food industries due to its unique structure-forming properties. In the present research paper, we did isolation and evaluation of starch from air potato and used it for the formulation of ketoprofen tablet as an excipient. The binding property of Yam starch shows a good granulating agent for the formulation of the tablet. The binder concentration had an increased effect on the mechanical properties of the tablets whereas it had a decreased effect on the drug release profile. Thus depending upon the tablet strength and suitability of drug release, Yam starch can be a good alternative to other granulating agents for the formulation of tablet.

1. INTRODUCTION:

Starches are widely available, naturally occurring carbohydrate, found in almost all organs of plants, most especially in roots, rhizomes, fruits, and seeds[1]. Starch, the main storage component in multiple plants, is not only an important energy source for developed seedling but also a valuable material for food and non-food industries due to its unique structure-forming properties. Cereals, pseudocereals, legumes, roots, and tubers are the raw materials for starch extraction. The most important source of starch is corn. In the whole world, the share of starch from corn is about 83%, followed by wheat (7%), potato (6%) and tapioca (4%). The reason of this is that its cultivation is flavored by the climatic conditions; it is available at a relatively low price, and finally, exploitation of by-products of starch extraction (e.g. gluten) is possible. Nearly 53% of starch total production is used in the food sector (sweets – 18%, soft drinks – 11%, other food – 24%). Of the non-food sector (total share of 46%), 28% is used for the production of paper, cardboard, and corrugated board, and 13% is used for fermentation[2].

Figure 1: Air potato

Starch has been used as a multifunctional excipient in tablet formulations due to their relative inertness, abundance, low cost and suitable physicochemical properties. Starch and their derivatives are used as diluents, glidants, binders, and disintegrants etc. Yams are the annual or perennial tuber-bearing and climbing plants belonging to the genus Dioscorea, a genus of over 600 species of flowering plants in the family Dioscoreaceae[3]. Air potato (*Dioscorea bulbifera*), is a species of yam (Dioscoreaceae) family. It is called air potato because it produces potato-like aerial bulbs in the leaf axils of the twining stems Nigeria. It is native to Africa, Asia, and Australia. In India, D. bulbifera is classified as a wild yam and a medicinal plant. These species are not as popular as other yam species in the study area wherein it is

utilized mostly by the rural dwellers at periods of foods scarcity rather than consumed out of preference. The medicinal properties of D. bulbifera are well documented.[4] In the present research paper, we did isolation and evaluation of starch from air potato and used it for the formulation of ketoprofen tablet as an excipient.

2. MATERIALS AND METHODS:

2.1 Isolation of air potato starch

The tubers of yam were purchased from local market of Bramhpuri, District Chandrapur, Maharashtra. The starch used as a binder were Yam starch extracted and isolated from Yam (*Dioscorea bulbifera*) in the laboratory of Dr. R. G. Bhoyar Institute of Pharmaceutical Education and Research Wardha.

Method of Isolation: [6,7]

Fresh tubers of yam were collected and washed with distilled water, peeled, washed again and then cut into small pieces. The pieces were then washed with 2% w/v sodium metabisulphite in distilled water to prevent darkening and then milled into a fine paste using a laboratory mill. The slurry was strained through a muslin cloth and the filtrate was left to settle. The supernatant was decanted at 12 h. intervals and the starch slurry re-suspended in distilled water. The starch cake was collected after 3 days and dried in a hot air oven at 60ºC for 12 h. and then screened through a # 85 mesh sieve

Figure 2: Prepared air potato starch

2.2 MATERIALS FOR TABLET FORMULATION

Ketoprofen, Polyvinylpyrrolidone, Magnesium Stearate, Dicalcium Phosphate, Disodium Hydrogen phosphate, Potassium dihydrogen phosphate, Sodium chloride, The starch used as a binder were Yam starch extracted and isolated from Yam (*Dioscorea bulbifera*) in the laboratory of Dr. R. G. Bhoyar Institute of Pharmaceutical Education and Research Wardha,

Ketoprofen was obtained as a gift sample from zim B-21/22, MIDC Area, Kalmeshwar, Nagpur, Maharashtra 441501. All chemicals are obtained from Dr. R. G. Bhoyar Institute of Pharmaceutical Education and Research Wardha and are of analytical grade.

Instruments were used: Electronic weighing balance, USP dissolution test apparatus, Disintegration test apparatus, Friabilator. All the instruments were obtained from Dr. R. G. Bhoyar Institute of Pharmaceutical Education and Research Wardha.

3. EXPERIMENTAL AND RESULTS [7, 8,9,10,11,12,13,14]

3.1 Evaluation of Yam Starch[3].

The tests performed were to determine the presence of polysaccharides. From the tests, it was confirmed as starch

Table 1: Evaluation of Yam Starch

<table>
<tr><th>particulars</th><th colspan="4">Tests</th></tr>
<tr><td rowspan="6">Dioscorea bulbifera</td><td>Molish test</td><td>Iodine test</td><td colspan="2">Solubility test</td></tr>
<tr><td rowspan="5">A violate colure complex was obtained</td><td rowspan="5">Blue colure was obtained</td><td>Alcohol</td><td rowspan="5">Insoluble</td></tr>
<tr><td>Chloroform</td></tr>
<tr><td>Acetone</td></tr>
<tr><td>Methyl chloride</td></tr>
<tr><td>Hot water Jelly was obtained</td></tr>
</table>

Table 2: Micrometrics studies of yam starch

Parameters*	Air potato starch
Bulk density	0.504gm/cc
Tap density	0.6gm/cc
Carr's index	18.70%
Hausner's ratio	1.23
Angle of repose	33º5'

From the result obtained from Micrometrics studies of yam starch, it shows good excipient property hence we used it in the formulation of tablet

3.2 Preliminary Study

Characteristics of Ketoprofen

- **Nature:** Amorphous powder
- **Color:** White
- **Odor:** Odorless

Melting Point: The melting point of the drug sample was determined and found to be 94ºC (93º-96ºC).

- **Solubility:** Soluble in ethanol, methanol, sparingly soluble in water
- **pH:** 8, determined in 1% w/v solution

3.4 Analytical Methodology

A standard curve of Ketoprofen.

A standard curve of Ketoprofen was prepared in phosphate buffer pH 7.4. Ketoprofen was dissolved in phosphate buffer pH 7.4. By using ethanol as a co-solvent to get the stock solution. From this stock solution, serial dilution was done to get drug concentration 5 to 40 µg/ml. The absorbance of the solutions was measured against phosphate buffer pH 7.4 as a blank at 260nm, using UV- Visible spectrophotometer. The absorbance of Ketoprofen is shown in **table no.1.** The standard calibration curve is depicted in f**igure no.2**

Table 3: Absorbance values of Ketoprofen in phosphate buffer pH 7.4 at 260nm.

Sr. No.	Concentration (µg/ml)	Absorbance 260 nm
1	0	0
2	5	0.314
3	10	0.526
4	15	0.759
5	20	0.824
6	25	0.98
7	30	1.503
8	35	1.609
9	40	1.907

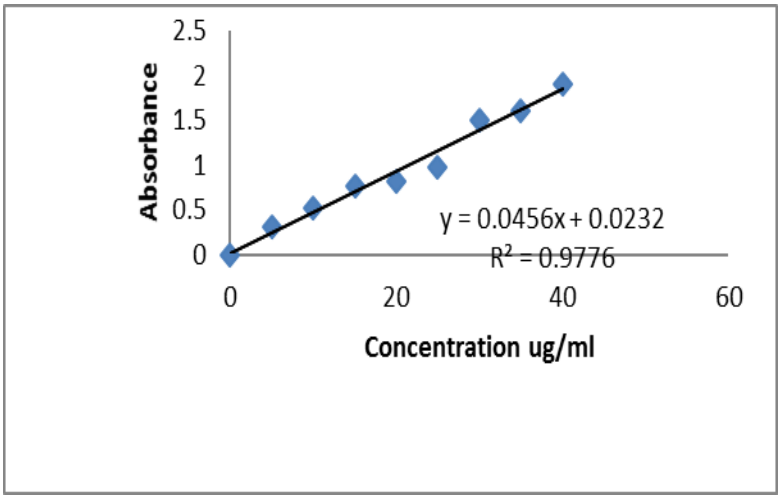

Figure 3: Standard Calibration Curve of Ketoprofen in phosphate buffer pH 7.4

3.5 Preparation of Ketoprofen Tablet

Formulation (F) of Ketoprofen Tablets using isolated Yam starch as a binder:

The conventional tablets of Ketoprofen were prepared by using isolated starch from yam (5-15%w/w of the tablet) by aqueous wet granulation method as shown in Table-4.

Table 4: Composition of Ketoprofen tablet

Ingredients (mg/tablet)	F1	F2	F3
Ketoprofen(drug)	100	100	100
Yam starch (Binder)	13	25	38
Polyvinylpyrrolidone (Disintegrant)	6.5	6.5	6.5
Magnesium stearate (Glident)	4	4	4
Talc (Lubricant)	6.5	6.5	6.5
Dicalcium Phosphate(Diluent) q.s.	260	260	260

Table 5: Average weight of the tablet

Sr. No.	Batch	The average weight of tablet (mg)
1	F1	259.5
2	F2	259
3	F3	259.5

3.6 Preparation of granules:

Batches of granules containing Ketoprofen and varying concentrations of 5, 10 and 15 % w/w of *Dioscorea bulbifera* starch as a binder were prepared using 0.5 % w/w each of talc and magnesium stearate as lubricants. The Ketoprofen powder, *Dioscorea bulbifera* starches were dry mixed for 5 min in a ceramic mortar and pestle and massed with little water added by sprinkling. The mass was kneaded for 5 min. The wet mass was granulated by forcing them through stainless steel sieve, meshes number 10 and drying it in the hot air oven at 60ºC for 1 hour. The dried mass was screened with stainless steel sieve, mesh number 16.

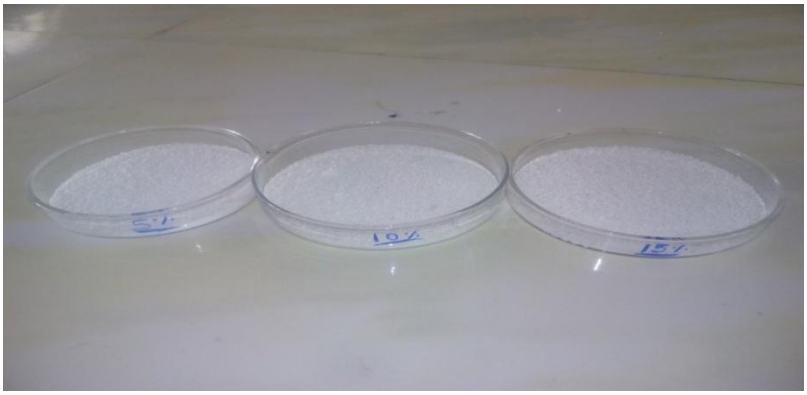

Figure.4: Granules of different concentration of starch

3.7 Pre compression evaluation

Various granular properties of the formulation like bulk density, tap density, the angle of repose, Hausner's ratio, Carr's index, and bulkiness were determined according to the procedure as follows,

Table 6: Results showing of pre-compression studies

Bulk Density (g/cc)			Tapped Density (g/cc)			Carr's Index (%)			Hausner's ratio		
F1	F2	F3	F1	F2	F3	F1	F2	F3	F1	F2	F3
0.399	0.43	0.457	0.630	0.752	0.771	17.52	18.60	18.98	1.077	1.027	1.030

Bulkiness			Angle of Repose		
F1	**F2**	**F3**	**F1**	**F2**	**F3**
2.506	2.325	2.188	$24^0\ 8^{|}$	$28^0\ 6^{|}$	$27^0\ 12^{|}$

3.8 Post Compression Evaluation

Table 7: Result of weight variation, hardness, thickness

Weight variation test				Hardness test (Kg/cm^2)			Thickness (mm)		
F1	**F2**	**F3**	**Result**	**F1**	**F2**	**F3**	**F1**	**F2**	**F3**
259.5mg.	259mg.	259.5mg.	Pass	2.25	2.317	3.163	4	4	4

Table 8: Result of % Friability

Sr. No	Formulation	% Friability
1	F1	0.8
2	F2	0.6
3	F3	0.6

Table 9: Drug content of formulated tablets

Sr. No	Formulation	%Drug Content
1	F1	98.52
2	F2	99.10
3	F3	99.45

3.9 *In-vitro* disintegration time

A tablet was placed in each of the six tubes of the disintegration test apparatus. The assembly was suspended in water maintained at a temperature of 37ºC ± 2 ºC and operated simultaneously. The time taken for the tablets to disintegrate completely was noted by using a stopwatch.

Table 10: Disintegration time

Sr. No	Formulation	Disintegration time (min.)
1	F1	4.2
2	F2	5.5
3	F3	6.1

3.1.1 *In-vitro* Dissolution study

Drug release study was carried out using the dissolution rate test apparatus USP XXIII (Type II). The dissolution medium used was 900ml of phosphate buffer pH 7.4 and the study conducted at 37^0 C with 50 rpm. The sample was withdrawn at different time intervals and replaced with fresh medium in order to maintain sink condition. The withdrawn samples were diluted suitably and drug content was estimated using U.V-spectrophotometer at 260nm. The study was carried out for 4 hours. **Table 11** shows the data of release profile of drug from tablet and **Figure 5** shows the release profile of drug from the tablet.

Table 11: Data showing release profile of Ketoprofen from tablet

Time (min.)	Cumulative % drug released		
	F1	F2	F3
30	51.25	45.55	42.39
60	59.21	52.39	51.89
120	72.65	70.48	59.35
180	89.51	86.84	75.56
240	98.12	92.54	85.66

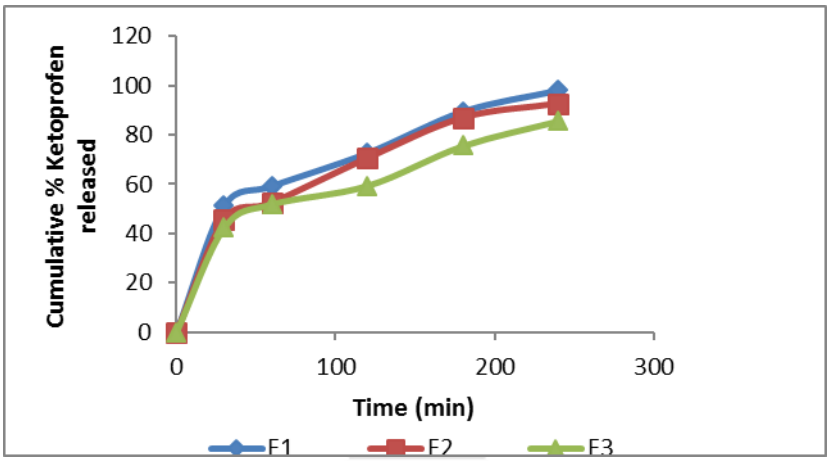

Figure 5: Release profile of Ketoprofen from tablet formulation F1 (5% binder), F2 (10% binder) and F3 (15% binder)

DISCUSSION

The drug sample was characterized on the basis of physicochemical analysis to examine its authenticity. The standard curve of Ketoprofen at 260 nm followed Beer-Lambert's Law in the concentration ranging from 0-40 ug/ml. The isolation of starch from yam of the genus *Dioscorea bulbifera* was successfully established. For determining a cohesive property of yam starch as a binder, the granules possessing the drug Ketoprofen and other ingredients using a different concentration of yam as a binder (5-15% of tablet weight) was evaluated for various properties. The formulated granule blends of different formulations (F1 to F3) were evaluated for angle of repose, tapped density bulk density, Carr's index and Hausner ratio. The result of the angle of repose is between 24 to 28 indicated good flow properties of the entire formulated granule blend with sufficient compressibility which are shown in table no.6 The tablets of different formulations were subjected to post-compression evaluation tests. The

drug content of all formulations ranged from 98.52 to 99.10. The drug content of the tablet is shown in table no.9. The results of weight variation indicated that all the batches of tablets were uniform. The hardness of the tablets increased with the increase in the binder concentration of yam starch, the result of % friability is shown in table no 7 which is within the limit. The effect of concentration of starch binders reflected in the disintegration and dissolution tests also. The disintegration time for binder (5% w/w of the tablet) in F1 is 4.2 minutes and of F2 (10% w/w of the tablet) and F3 (15% w/w of the tablet) is 5.5 and 6.1 respectively. As the concentration of starch (Yam starch) is increased the disintegration of the tablet is decreased which shows the increased binding properties of yam starch. The comparative drug release profile of the formulations using binders (5%, 10%, 15w/w of the tablet) showed that the drug release was complete within 4h with yam starch. The drug release was 98.12% with starch having 5% w/w of tablet and 92.54% and 85.66% having 10% w/w of tablet and 15% w/w of the tablet. The effect of different binder concentration of yam starch revealed that there was an increase in the cohesiveness, hardness and disintegration time with decreased drug release profile in the tablets.

CONCLUSION

The concentration of yam starch as a binder can be optimized for the manufacture of the various tablet dosage form. The binding property of Yam starch shows a good granulating agent for the formulation of the tablet. The binder concentration had an increased effect on the mechanical properties of the tablets whereas it had a decreased effect on the drug release profile. Thus depending upon the tablet strength and suitability of drug release, Yam starch can be a good alternative to other granulating agents for the formulation of tablet.

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