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TARO STARCH -AS A DISINTEGRATING AGENT IN TABLET FORMULATION

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ABSTRACT

Taro (*Colocasia esculenta*) has been reported to have 70-80% of starch which could play a vital role as a disintegrating agent in pharmaceutical tablet formulation. The purpose of the study was to extract and evaluate the starch from Taro (*Colocasia esculenta*), as well as to use taro starch as a disintegrating agent in tablet formulation. In this study starch was extracted from Taro by simple, wet milling and centrifugation process and physiochemical tests of the extract revealed that the starch extracted from wet milling showed better properties, while rendering no harm to the chemical composition of the extract which was then was used to formulate twenty placebo tablets by using direct compression, wet granulation as well as dry granulation for comparison study. The formulated tablets were evaluated by its hardness, friability, weight variation, solubility and disintegration time. Results from disintegration efficiency study showed that the tablets formulated from Taro starch disintegrated in 3 minutes out of which tablets

formulated by wet granulation showed better properties when compared to tablets formulated by other methods. The reduced disintegration time along with the low weight variation showed that Taro starch as a better disintegrant compared to other natural starches for tablet formulation.

Keywords: Taro starch, wet granulation, disintegration time, placebo tablets

INTRODUCTION:

Taro (*Colocasia esculenta* (L.) Schott) belonging to the aroid family (Araceae) and genus of Colocasia commonly known as Taro, Kalo, Cocoyam, Talas, is a starchy root vegetable which is reported to have high source of starch 70%-80% [dry weight basis], fiber and other nutrients including potassium, magnesium and vitamin C and E, low in fiber and fat **[1]**. Taro is cultivated for its edible corms used as a staple or subsistence diet **[2]**. The Taro tuber is a good source of minerals and the small granule size of its starch helps to increase the bioavailability of its nutrients due to the efficiency of digestion and absorption **[3]**. The tubers, containing starch must be changed from perishable to non-perishable through food processing activities to reduce tuber loss **[4]**. One of the best ways to preserve these tubers is by processing them into flour and/or starch **[5]**. Starch is still the commonest disintegrant in tablet formulation. Traditionally, starch has been used as a disintegrant of choice in formulation of tablets, and is still widely used though several advanced disintegrating agents are now being employed **[6]**. Orally disintegrating tablets (ODTs) are dosage forms that disintegrate or dissolve rapidly on contact with saliva **[7]**. ODTs are currently widely used in drug therapy and are clinically attractive, because they are suitable for administration to patients with dysphagia and improve adherence, both of which increase the possibility of achieving the expected therapeutic effect **[8]**. Therefore, in our study we used taro starch as disintegrating agent in the formulation of placebo tablets. Reports until date haven't yet reported the use of taro starch in tablet formulation, making our work unique.

Taro- Nutritive value, consumption and cultivation

Colocasia esculenta (Taro) is one of the six most significant root and tuber crops in the world **[9]**. Taro is an herbaceous perennial plant, originally native to Asia,

now being cultivated worldwide and more abundantly in parts of Africa, best suited to grow in a soil with pH of 5.5–5.6, in an area with high humidity, 1000 mm of rainfall per year, and an optimal temperature of 21–27°C **[10]**. Taro is an important root crop in the tropical and subtropical latitudinal regions around the planet since ancient times which can adapt to different agroclimatic conditions **[11, 12]**. Taro has roughly 11% protein and comprises 85-87 percent starch on a dry matter basis with minute granules of 3-18 m. Taro is low in protein (1.5 percent) and fat (0.2 percent), which is similar to many other tuber crops and high in starch (70-80 grams per 100 grams of dried taro), fiber (0.8 percent), and ash (1.2 percent) with vitamins and minerals **[13]**. The leaves of *Colocasia esculenta* have been reported to be high in nutrients such as beta-carotene, oxalate, iron, protein, vitamins, and folic acid Humans eat the leaves of taro as a vegetable because they, which protects against anaemia **[14-17]**. West African nations, such as Nigeria, Cameroon, and Ghana, are the largest taro producers, led by China, with 6.7 and 3.9 million tonnes of taro produced, respectively, accounting for 83.6 percent of global taro output and other countries that produce taro include the United States, Canada, Japan, Turkey, and Central and South American countries **[18-20]** as well as Brazil (producing less than 1000 tons of taro) **[21, 22]**. Taro is a safe carbohydrate source, according to Food Data Central of the United States Department of Agriculture (USDA), because the heating method does not alter its nutritional quality, resulting in only slight variations in nutrient content **[23]**. The nutritive composition has been given in the **Table 1**.

Table 1: Nutrient composition of taro

Parameter	Raw dried oven	Raw sundried	Raw cabinet dried	SWCC	CWCC	FWCC
Crude protein (%)	90.57	88.42-89.53	89.87	88.06	88.64	87.90
Crude protein (%)	5.17	4.93-7.07	5.07	6.56	6.13	7.44
Crude Fiber (%)	2.97	2.70-3.90	2.83	3.75	3.55	3.45
Ash (%)	2.87	0.5-1.10	2.77	0.95	0.75	0.88
Carbohydrates (%)	79.00	73.43-78.93	78.70	73.90	75.46	73.50
ME(Kcal/kg)	NA	2958.34	NA	2943.70	2966.82	2956.52

SWCC=Soaked taro; CWCC=Cooked taro; FWCC=Fermented taro
Source: Olajide *et al* (2011) Ndabikunze *et al* (2012)

MATERIALS AND METHODS;

Materials

Tubers of taro (*Colocasia esculenta* L. Schott) were collected from the local market (Devaraj market, Mysuru 570015) and thoroughly cleaned and washed and the tubers' outer coating was peeled off. After that, the tubers were cut and dried at room temperature, the powder was made by crushing the dried sliced tubers with a mortar and pestle **[24]**. The powders were used to extract starch by the three processes-simple process, wet milling process and centrifugation process. Taro starch was extracted first through a simple process in which the homogenised solution of taro powder in distilled water was prepared and kept in the refrigerator overnight to get separated solid and liquid layers with the solid material depositing at the bottom of the glass beaker. The liquid layer was decanted, and any remaining sediment is washed away with a large amount of water. The starch powder was obtained by decanting the water and filtering through wheat filter paper and stored. In wet milling process taro powder was steeped overnight in a sodium metabisulphite solution (0.45 percent W/V) and kept in a refrigerator. The slurry was then milled for 5 minutes in an industrial food mixer. To the slurry, NaCl solution (0.1 M) and Toluene were added and then the mixture was agitated for 1h. After the starch granules settled to the bottom, the protein in the toluene and NaCl solution levels was siphoned off and discarded, and this was repeated to remove all the proteins and to get a clear toluene layer. The starch layer was then rinsed multiple times with water before being treated with 100% ethanol. The wet milled starch was then recovered by filtration through Whatman filter paper, rinsed with ethanol and air dried **[25]**. Taro starch was also extracted by centrifugation process by steeping the taro powder in 1% sodium metabisulphite solution at 45°C for 24, 48 or 72 hours at the end of which the liquid phase was separated. The separated slurry mixture was homogenized in a homogenizer for 30 seconds which was then filtered under vacuum with numerous washes using a fine nylon filter with a total wash water volume of 500 ml. The starch slurry was centrifuged for 30 mins to separate the proteins. The supernatant was decanted three times, the protein layer scraped off, and more water was added to the partially

cleaned starch and the resulting sediment was allowed to air dry **[26]**.

Preliminary testing of starch:

Preliminary testing of extracted starch was performed to check physical properties such as bulk density, tapped density, moisture content, particle size, angle of repose, and melting point as mentioned by Kaur *et al;* 2005 and Snick *et al;*2017 **[27]**. Bulk density (Db) was calculated by dividing the weight of the powder by the volume of the bulk. The bulk density of particles is determined by their size distribution, shape, and cohesiveness. The Tapped Density of 1 gram of starch was recorded before and after tapping for 100 times in a measuring cylinder. The weight reduction of starch before and after drying in the hot air oven was recorded to estimate its moisture content and the Angle of repose was calculated according to the formulas.

Preliminary chemical tests of extracted starch

Preliminary chemicals tests were performed on the extracted starch such as Benedict's test, Molisch test, reducing sugar test, Legal test to confirm the presence of carbohydrates and Biuret test, Millon's test, Xanthoprotein and Ninhydrin tests were conducted to detect the presence of proteins according to Leonard *et al*;1990 **[28]** before heading to tablet formulation to understand the chemical composition.

Formulation of tablet using extracted starch as disintegrating agent.

Placebo tablets were formulated by using extracted taro starch as disintegrating agents with other excipients. The tablets were prepared by three different methods (a) Direct Compression, (b) Dry Granulation and (c) Wet Granulation to obtain a comparison study. Twenty placebo tablets were prepared using different ingredients in different concentration using taro starch as binding material and examined for their different properties. The ingredients required for the tablet formulation is mentioned in the **Table 2**.

Table 2: ingredients and formulas

Ingredients	Formula %	1 mg/tab	Formula %	2 mg/tab	Formula %	3 mg/tab	Formula %	4 mg/tab
Lactose Monohydrate NF [Fast Flo, foremost]	50.00	175.00	_	_	49.75	174.13	_	_
Pregelatinized Starch NF [Starch 1500, Colorcon]	_	_	50.00	175.00	_	_	49.75	174.13
MicrocrystallineCellulose NF [Avicel PH102, FMC]	50.00	175.00	50.00	175.00	50.00	175.00	50.00	175.00
Magnesium Stearate NF [Peter Greven]	_	_	_	_	0.25	0.87	0.25	0.87
Total	100.00	350.00	100.00	350.00	100.00	350.00	100.00	350.00

Preparation of placebo tablets by wet granulation method was performed according to Kawano *et al*: 2010, **[29]** the starch extract was diluted with an appropriate solvent and then added to the blended powders which resulted in wet granules which were dried to obtain dried granules. Accurately weighed amounts of each component **(Table 2)** were mixed in a mortar, and appropriately microcrystalline cellulose (with distilled water) was added as a granulating agent, and stirred in motor for 20 minutes. The moist mixture was sieved with sieve No. 22 and dried in an oven for 6 hours at 5°C to get dried granular mixture which was passed through sieve No. 40 to obtain equal sized granules which were then combined with a calculated equal amount of magnesium stearate and compacted into tablets using a rotating tablet machine under constant pressure. Placebo tablets were prepared by dry granulation method with reference of Bejugam *et al*; 2015 **[30]** in which the powder was compacted followed by densified to obtain dry granules. To formulate tablet, different components with the right amount of ingredients were milled. Slugging was performed to accomplish dry granulation on a tablet press resulting in slugs which were then screened or processed into granular tablet materials. Milled powders were mixed and then sieved with sieve No. 22 to get dried mixture of slugs which was screened, followed by crushing and screening of the crushed slugs with a No. 40 sieve. The screened powder was combined with screened lubricant and disintegrating agent powder, before being compressed or punched using rotary tablet punching to create large hard tablets. Formulation of tablets through direct compression and dry granulation was performed using starch as a

dissolving agent to make compressed tablets. All of the ingredients for the formulas mentioned in the **Table 2** were mixed together in a sealed plastic bag. Using round and flat punches, the mixes were compressed into tablets with a hardness of 10 kg/cm^2 on a tablet punching machine **[31]**.

Evaluation of properties of the tablet:

The tablets formulated by all the three methods were evaluated for its properties by the Hardness Test, Weight Uniformity Test, Friability Test, Disintegration Time, of the tablets prepared by according to Snick *et al;* 2017 **[31]**. To assess the Hardness of the placebo tablets, 5 tablets from each formulation were taken and test them on the TMZ-3U Electronic Micro Sensor instrument to test the tablet's hardness in which the range was set up to 750N for the instrument to take the measurements. The dimensions (diameter, thickness) of the tablet were measured using a calliper which was used for the subsequent calculation of the tablet's tensile strength. The relative standard deviation of the measurement was calculated to calculate the tensile strength value. Five tablets were selected randomly from each batch and weighed. The mean weights were calculated for each batch to assess weight uniformity in the tablets. Friability of the tablets formulated was tested for 5 tablets in a friability tester. The rotation speed was set to 25 rpm and after 4 minutes, the button was pressed to stop the rotation. The tablets were removed from the package, cleaned and weighed. The tablets' proportional weight loss was calculated and analysed. For the disintegration test, three pills were taken from each. Visually the test's progress was observed and considered to be over when there was no residue left in the basket. The tablet is considered uncompliant if it hasn't totally decomposed after 15 minutes, but is measured until 25 minutes. If the tablet still hadn't disintegrated, accelerated disintegration test is required for the remaining two tablets with a motor speed of 60 rpm. Repeated measurement for three times of the tablet is advised if it doesn't disintegrate within 15 minutes. Result was calculated as an average of the measurements including the monitored variable's standard deviation.

RESULTS

Starch was extracted from Taro tubers through three different methods. The extracted starch was subject to further

preliminary tests to evaluate the physical and chemical properties of the starch and results mentioned in the tables 4 and 5 showed that, there were no variation in the bulk densities, moisture content, particle size and melting points of the starch extracted by all the three methods **(Table 3)**. Extraction by centrifugation method had a better tapped density compared to other methods. The angle of response was higher in the starch extracted by normal method, thus implicating that there wasn't much effect on the physical properties based on the method of tablet formulation, but on an overall consideration, starch extraction by wet milling method showed better values in all the preliminary tests. The chemical tests **(Table 4)** revealed that the tuber wasn't containing any proteins while confirmed that they were a high source of sugars especially that of carbohydrates containing glycosides by showing positive results for Benedict's test, Molisch test, Legal test and reducing sugar test. Therefore, based on the results, starch extracted from wet milling method was used to prepare tablets by wet granulation process which showed better disintegration. During the tablet punching process, it was discovered that the granules prepared by the wet granulation process easily filled with the dyes, and the tablets produced from wet milled taro starch have better properties and uniformity than the tablets produced from granules prepared by the direct compression and dry granulation processes. After the preparation of tablets, the tablets were tested to find out the hardness, flexibility, weight variation, and disintegration time of the tablets **(Table 5)**. Wet granulation method took 3.15 minutes for disintegration being better than tablets formulated by other methods. Placebo tablets formulated by wet granulation method showed only 4% variation in tablets weight with least friability 0.8% and a hardness of 11 kg/cm3. The tests showed the same result for tablets formulated by all the three methods implicating that there is no significant variation on the chemical properties, but placebo tablets formulated by wet granulation method showed better results when compared to tablets formulated by other two methods.

Table 3: Observation of Physical Tests

Types of starch extraction method	Bulk density (in gm/cm3)	Tapped density (in gm/cm3)	Moisture content (in l. O. D)	Particle size (in micrometre)	Angle of response	Melting point (Thiele's tube apparatus
Normal method	0.33	0.363	1.70%	2 to 20	29.66°	266±20 c
Wet milling method	0.32	0.344	1.60%	2 to 20	25.71°	268±20c
Centrifugation method	0.35	0.4	1.60%	2 to 20	26.22°	268±20c

Table 4: Observation of Chemical Tests

Types of starch extraction method	Benedict's test (sugar)	Molisch test (carbohydrates)	Legal test (glycosides)	Protein test	Reducing sugar test
Normal method	Positive	Positive	Positive	Negative	Positive
Wet milling method	Positive	Positive	Positive	Negative	Positive
Centrifugation method	Positive	Positive	Positive	Negative	Positive

Table 5: Evaluation of Tablets made from Taro Starch which is Extracted by Wet Milling Process.

Granulation type	Hardness (kg/cm3)	Friability (%)	Weight variation (%)	Disintegration time (mins)
Direct compression	10	1.1	3.10%	5.3
Dry granulation	11	1	3.00%	4.15
Wet granulation	11	0.8	4.00%	3.15

DISCUSSION

Taro is a tropical root that is propagated vegetatively and ranks ninth among world food crops. and is an important staple meal for many Asian and African communities **[32]**. Phytochemical and analytical studies have found a wide spectrum of phytochemical substances, including flavonoids, sitosterol, and steroids which have shown various pharmacological properties. Despite the fact that taro corn (or taro) is a rich source of health-promoting nutrients, it is usually disregarded, as is tubercle consumption associated with subsistence agriculture **[33-35]**. It has been stated that dried and milled taro corn flour includes easy-to-digest starch and is hence commonly used for newborn feeding **[36]**. The functional qualities of the flour are attributed by its proteins, complex carbohydrates, including pectin and mucilage **[37]**. Taro starches have a high viscosity, making them ideal for food applications which require great thickening power, as well as a tiny particle size **[38]**. Based on these reports Taro starch was extracted and used in formulating placebo tablets. Formulation and processing variables like the mode of addition of disintegrants; relative density/compression pressure, disintegrant concentration, size and type have been shown to have significant

effects on disintegrant properties e. g. disintegration time and the crushing strength and friability **[30]**. Direct compression is a best suited method for crystalline materials with good physical qualities such as flow, compressibility, and so on with several advantages, including time savings, operational safety, and low cost **[31]**. Wet granulation is the most common method used for making tablets. The key feature in this method is that the powders are "adhesions" bound by a suitable binder while considering surface tension forces and capillary pressure in initial granule formulation **[30]**. Dry granulation method is ideal for materials that are moisture and heat sensitive and granules could be obtained without the use for a liquid solution **[29]**. Through substituting taro for corn and wheat in processed foods and increasing raw product commercialization, the food processing industry will solve these restrictions and increase taro crop availability and acceptance among urban populations. Furthermore, this may draw attention to taro crops as a rich source of extraordinary and unusual substances, the pharmacological activities of which have been shown in both in vitro and animal models. These activities will broaden the research area and allow countries to exchange knowledge, potentially expanding taro production, sales, and consumption around the world, especially in developing countries **[39]**.

CONCLUSION

Starch from Taro tubers was extracted successfully by simple, wet milling and centrifugation methods and it has been found that the starch extracted by the wet milling method shows better properties as compared to the other two methods in enabling Taro starch as a disintegrating agent in tablet formulation. Tablets contains a number of inert materials known as excipients or additives in addition to active ingredients which enable efficient tabletting such as diluents, binders or granulating agents, glidants, and lubricants **[40, 41]**. The starch from Taro tubers was used as binders or granulating agents in tablet formulation in three different methods for a comparative study. While manufacturing, no changes were rendered to the component's physical properties. Though fundamental advantage of dry granulation is that it uses less equipment and does not require the addition of moisture or the application of heat, which

are both required in the wet granulation method's wet massing and drying processes, the different parameters of the formulated placebo tablets reveal that the wet granulation method fits all of the requirements for tablet formation, despite the fact that it is a multistage, time-consuming process **[29, 30]**. The compressed tablet is the most popular dosage form in use today. Therefore, more efficient disintegrating agent, of plant origin will facilitate the formulation of tablets with much ease. Friability values were found to be less than 1% for tablets formulated by wet granulation. Therefore, Taro starch is a better disintegrant than other natural starches and can be used in formulating placebo tablets. All the tablets formulated by wet granulation disintegrated within 3 min and fulfilled the requirements for ODTs according to the European Pharmacopoeia. As a result of the studies, ODT formulations developed in this study can be suggested as promising formulations, which assist development and manufacturing a generic product of Taro starch

Author contributions

Vindhya M (VM), Rashmi DR (RDR), and Kanthesh BM (KBM) conceptualized the study. Vindhya M (VM), and Rashmi DR (RDR) drafted the Manuscript. Nagalambika P (NP), Gopenath TS (GTS) and Kanthesh BM (KBM) helped with the Manuscript and Discussion.

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Conflicts of interest

The authors declare that there are no conflicts of interest.

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