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Evaluation of Trapa Natans Starch as an Excipient in Tablet Formulation

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ABSTRACT

The purpose of the study was to evaluate *Trapa natans* starch as an excipient in tablet formulation. . Granules of Diclofenac drug were prepared by wet granulation method. For the isolation of starch from *Trapa natans* maceration method was followed by centrifugation method. The phytochemical and physico-chemical properties were performed on the aqueous washings of *Trapa natans* and the pre-compression parameters like bulk density, tapped density, angle of repose, carr's index and hausner's ratio have shown that Diclofenac granules prepared using *Trapa natans* were well within the limits and comparable to those prepared using standard starch. The in vitro dissolution study was performed for Diclofenac formulations and the dissolution profile shows all the six formulations met with official specifications. The drug release from tablets prepared by *Trapa natans* starch was more than 99.7% in 1 hour.

Keywords: *Trapa natans,* Isolation, Diclofenac sodium, Dissolution.

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INTRODUCTION

Tablets are the unit dosage form containing medicament or medicaments, usually circular in shape and may be flat or biconvex conventional taken by oral route. The tablet is versatile, compact, robust, and accurate and can be mass produced consistently at high speeds. Excipients like binders or adhesives are the substances that promote cohesiveness. Binder is utilized for converting powder into granules through a process known as Granulation. Plant starch has been found useful in producing tablets with different mechanical strength and drug release properties. Since they are nontoxic, biocompatible and widely available, much attention have made on characterisation and in formulation [1&2]. Starch or amylum is a polysaccharide carbohydrate consisting of a large number of glucose units joined together by glycosidic bonds. It occurs in a variety of botanical sources including potato, wheat and maize and has found diverse applications. Starch consists of two types of molecules: the linear and helical amylase and the branched amylopectin. Depending on the plant, starch generally contains 20-25% amylase and 75-80% amylopectin [3].

Water chestnut (*Trapa natans*) is an aquatic plant, which is usually rooted in the mud; it bears a rosette of floating leaves at the tip of the submerged stem [4]. The Waterchestnut Family contains only a single genus and, depending on specific character, as many as thirty species have identified [5]. In our climate, water-chestnut is an annual aquatic plant having both vegetative reproduction and seed production take place. It is reported that seeds of water chestnut is having ample Trapa starch [6].

The main objectives of the present study were to isolate starch from the seeds of water chestnut and evaluate starch. The isolated and characterised starch was used as an excipient in the formulation of Diclofenac IP tablets. The tablets were subjected various evaluation including invitro dissolution and drug excipient interactions.

MATERIALS AND METHODS

The *Trapa natans* fruits were collected from the local market of Nagpur. All chemicals and reagents used were of good quality analytical grade. The ingredients used were diclofenac sodium, lactose, magnesium stearate, hydroxyl propyl methyl cellulose, carboxy methyl cellulose, standard starch, talc, water, ethanol (95%) etc.,

Preparation of Trapa natans starch

The collected fruits were cut into small pieces. Representative samples of 1 kg were ground in a blender with 2L of water. The slurry was filtered, sediment was re-suspended with water. The above steps were repeated until the supernatant liquid was clear and the starch was free of colour. The starch was then filtered and dried in air [7].

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Physicochemical characterisation of Extracted starch:

Table 1: Physicochemical characterisation of Trapa starch

PARMETERS		RESULTS		
Solubility		Slightly soluble in cold water. Insoluble in Alcohol, Acetone and Chloroform.		
Swelling ratio	In distilled water	Trapa starch	Standard starch	CMC
		2.8	2	4.6
Density of powder	Bulk density(g/cc)	0.2	0.23	0.30
	Tapped density(g/cc)	0.249	0.27	0.36
Compressibility index (%)		19.8	14.81	16.66
Hausner's ratio		1.24	1.18	1.2
Angle of repose		36.05º	38.3º	32.63º
Loss on drying		5%	3%	7%

The separated starch was evaluated for solubility, swelling index, angle of repose, bulk density, tapped density, compressibility index, porosity, Hausner's ratio [8]. Solubility of separated starch was studied in warm and cool distilled water and various organic solvents. Swelling index of the starch was performed as follows: One gram of starch was moistened with 0.5ml ethanol (95%) and volume was made up to 10ml with distilled water. The cylinder was shaken vigorously every 10 mins for 1hour and allowed to stand for 3hours. The volume occupied by starch was measured. The test was carried out in triplicate and the average value of swelling index was recorded [9]. The aqueous washing obtained during the starch preparation was subjected to qualitative chemical screening to detect the presence of various chemical constituents like carbohydrates, proteins, aminocaids, alkaloids, glycosides, tannins, phenolic compounds, saponins [10], cations, anions and vitamins [11].

Formulation of Diclofenac Tablets:

Table 2: Formula for various Diclofenac formulations preparation using starch by wet granulation

Ingredients	Standard starch			Trapa natans starch		
	F1	F2	F3	Fa	Fb	Fc
Diclofenac sodium	100 mg	100 mg	100 mg	100 mg	100 mg	100 mg
Lactose	25 mg	15 mg	5 mg	25 mg	15 mg	5 mg
HPMC 5%	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.
Magnesium stearate	10 mg	10 mg	10 mg	10 mg	10 mg	10 mg
Talc	5 mg	5 mg	5 mg	5 mg	5 mg	5 mg
starch	10 mg	20 mg	30 mg	10 mg	20 mg	30 mg

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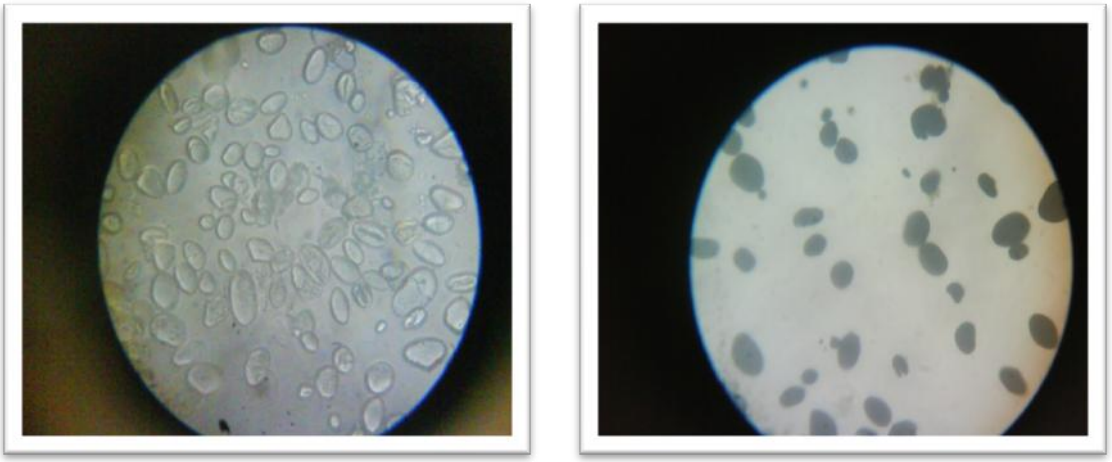
Each batch of granules was compressed using Cad mach punching machine. Six batches of tablets were prepared. Batches of Diclofenac tablets were punched using 17mm concave faced punches (Table no.2). The prepared tablets of each batch were evaluated for weight variation, hardness, friability, tensile strength, disintegration time and In-vitro dissolution profile using methods specified in Indian pharmacopeia.

***In-vitro* dissolution studies of Diclofenac formulations with standard starch and Trapa natans starch:**

The samples were withdrawn at predetermined time intervals and the same volume was replaced immediately to maintain sink condition. The study was run for 1 hour 15 minutes with the above fixed parameters. The withdrawn samples were suitably diluted and absorbance of the solution was determined at λ max 276nm.

RESULTS AND DISCUSSION



a) without staining under 45x **b) After staining under 45x**

Fig 1: Starch grains of Trapa natans

Maceration method was followed for the isolation of starch from *Trapa natans*. This method gave 40%w/w yield of starch. Starch on reacting with Iodine resulted in blue colour (as shown in fig 1(b). Single and bifurcated hilum was observed.

Description of starch grains:

The colour of starch obtained from *Trapa natans* was observed to be white and hilum is located at central position. Starch grains were abundant in number and their aggregation is simple and compound (as shown in fig 1(a). The minimum, maximum and average size of starch grains was found to be 6.25 µ, 18.75 µ and 12.8 µ respectively.

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Phytochemical study of aqueous washings of *Trapa natans*:

The phytochemical study of aqueous washings of *Trapa natans* shows the presence of non reducing polysaccharide, calcium, chlorides, bromides, vitamin k and pyridoxine. Glycosides, alkaloids, steroids, proteins and tannins were absent.

Trapa natans starch was found to be soluble in cold water and insoluble in organic solvents.

Swelling ratio was observed in the following manner - Carboxy methyl cellulose > *Trapa natans* starch > Standard starch (as shown in table no.1).

Table 3: Preformulation parameters of Diclofenac granules

Parameters	Standard starch			Trapa natans starch		
	F_1	F_2	F_3	F_a	F_b	F_c
Angle of repose	14.47	13.95	15.46	12.99	13.02	15.14
Bulk density (g/cc)	0.79	0.70	0.34	0.76	0.47	0.77
Tapped density (g/cc)	0.90	0.78	0.36	0.81	0.52	0.81
Carr's index (%)	12.22	10.26	5.55	6.17	9.62	4.94
Hausner's ratio	1.14	1.11	1.06	1.72	1.10	1.05

Precompression parameters like bulk density, tapped density, angle of repose, carr's index and hausner's ratio have showed that Diclofenac granules prepared using *Trapa natans* starch were found to be within the limits and comparable to those prepared using standard starch (as shown in table no 3).

Table 4: Post-formulation parameters –Evaluation of mechanical properties of tablets

parameters	F_1	F_2	F_3	F_a	F_b	F_c
Thickness (mm)	4.25±0.26	4.36±0.35	4.3±0.12	4.4±0.34	4.2±0.63	4.2±0.4
Hardness (kg/cm2)	1.56	1.16	1.3	1.24	1.38	1.82
Friability (%)	0.63	0.86	0.27	0.42	0.41	0.55
Disintegration time (mins)	13.2	22	14.33	14.5	15	12.7

Post compression parameters like hardness, thickness, weight variation, disintegration and dissolution tests were carried out. Hardness was found to be more for *Trapa natans* starch formulations than standard starch formulations. As regard to the disintegration time, tablets prepared with *Trapa natans* starch, showed an increase in disintegration time when compared to those with standard starch (as shown in table no 4).

The in-vitro dissolution profile shows that drug release decreased in the order Fa > F_2 > F_b > Fc > F_3 > F_1. This study revealed that the drug release from tablets prepared by *Trapa*

natans starch was more than 99.7 % in 1 hour which is comparable with the formulation using standard starch (as shown in fig 2 & 3). The drug release in the formulation was found to be uniform for all the batches.

CONCLUSION

In this current study complete physicochemical properties of *Trapa natans* starch and the granulating and release properties of the *Trapa natans* starch in comparison with a standard starch in a tablet formulations using Diclofenac as model drug were studied. Pre-formulation and post formulation parameters were found to be within limits for all formulations. The drug release was found to be maximum for F_a batch and minimum for F_1 batch and no interactions were found which was proved by FTIR reports (as shown in fig 4 & 5). The *Trapa natans* starch can be used as a diluent in various oral tablet dosage formulations.

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REFERENCES

[1] Leon Lachman, Herbert Liberman A, Joseph Kanig L. The Theory of practice of Industrial pharmacy. Varghese publishing house, Mumbai, 1991, pp. 297-301.
[2] Mehta RM. Pharmaceutics-I. Vallabh prakashan publishers, Delhi, 2005, pp.286-291.
[3] http://en.wikipedia.org/wiki/starch.
[4] http://www1.1sbu.ac.uk/water/hysta.html.
[5] Kritikar and Basu. Indian Medicinal Plants. International book distributors, Delhi, 2005, pp.1090 -1092.
[6] Nandkarni AD. Indian Materia Medica. Bombay popular prakashan, Mumbai, 2002, pp.1227.
[7] Vanna Tulyathan, Khajee Boondee, Thanachan Mahawanich. Characteristics of starch from water chestnut (Trapa bispinosa ROXB.). The J Food Biochem 2005; 29: 337-348.
[8] Odeku AO, Itiola OA. Drug Development and Indian Pharma 2003; 29: 311-320
[9] Arul kumaran KSG, Palanisamy, Rajasekaran S, Ahil Hari. Int J Pharma Sci and Nanotech 2010; 2(4): 726-733.
[10] Khandelwal K R, Practical Pharmacognosy, Nirali prakashan, pune, pp.157- 160.
[11] Qadry JS, Qadry SZ. A text book of Inorganic Pharmaceutical & Medicinal Chemistry. 8th edn, pp.228.
[12] Choudhary K, Singh M , Pillai U. American-Eurasian J Botany 2008; 1 (2): 38-45.
[13] Sabine karg. Env Archaeol 11(1):125-130.
[14] Parekh J, Chanda S. African J Biotech 2007; 6(6): 766-770.
[15] Charles Neill. New York Sea Grant Invasive Species Factsheet Series, 06-1
[16] Shafee Mohd and Sarin J L. Industrial Eng Chem 1937; 29(12): 1436-1438.

[17] Chiun Wang CR, Po-Yuaan Chiang et.al. Carbohydrate Polymers 2008; 71(2): 310-315.
[18] Bailey JM and Whelan WJ. The J Bio Chem 1981; 236(4): 969-973.
[19] Hizukuri S, Takeda Y et.al. Wiley Interscience 2006; 40(5): 165-171.