Evaluation of *Colocasia esculenta* Starch as an Alternative Tablet Excipient to Maize Starch: Assessment by Preformulation and Formulation Studies

*Kusuma. R[1], Venkat Reddy. P[2], & Samba Shiva Rao. A[3].

1. Department of Pharmacognosy & Phytochemistry, Bojjam Narsimhulu College of Pharmacy, Hyderabad.
2. Department of Pharmaceutical Analysis, Pratap Narender Reddy College of Pharmacy, Rangareddy District.
3. Department of pharmaceutics, Sri Indu Institute Of Pharmacy, Ibrahimpatnam, Rangareddy District.

kusumarudravaram@gmail.com,
+91 9908301424

ABSTRACT:

Starch isolated from *Colocasia esculenta* plant was studied as an alternative pharmaceutical excipient to maize and potato starch. The *Colocasia esculenta* starch has been evaluated by series of tests as mentioned in Indian Pharmacopoeia before being used for evaluation. It was tested along with maize and potato starch as an alternative excipient by performing battery of preformulation and formulation tests. The results obtained for *Colocasia esculenta* starch was comparable with maize starch and the *Colocasia esculenta* starch can be used as a pharmaceutical excipient in tablets preparation.

Keywords: Colocasia esculenta, starch, binder, excipient, maize starch.

INTRODUCTION:

Very often a drug is rarely administered in its original form. Most of the times a convenient dosage form is made using a formulation, which contains a number of excipients. Excipients are non-drug components of a formulation / pharmaceutical ingredients and are added to ensure acceptability, physicochemical stability during the shelf life, uniformity of composition, dosage and optimum bioavailability and functionability of the drug product. Despite their inertness and utility in the dosage form, excipients can influence absorption of drugs. Excipients used in the pharmaceutical industry includes diluents or fillers, binders or adhesives,disintegrants,lubricants, glidants or flow promoters, colors, flavors, sweeteners etc. All the excipients used in pharmaceutical industry should be acceptable to regulatory agencies, chemically stable and freeform viable micro-organisms including pathogens [1].

Starch is a polysaccharide, widely used as binder, diluent, glidant and disintegrating agent in oral solid dosage formulations and also as dusting powder and lubricant. Commercially starch is obtained from maize (Zea mays), potato (Solanum tuberosum), rice (Oryza sativa), tapico (Manihot utilissima) and wheat (Triticum aestivum) [2, 3]. Many scientists working on various sources of starch and even on modified forms, so as to present a form that will be more useful in pharmaceutical manufacturing. Hence, the search for new starches is a continuous ongoing process worldwide.

In this manuscript, we report the isolation of starch from anew plant source (*Colocasia esculenta*) and its use as an alternative binder and disintegrant to maize starch following an evaluation in preformulation and formulation studies.

Colocasia esculenta Linn. is an annual herbaceous hearty succulent plant belongs to family Araceae with a long history of usage in traditional medicine in several countries across the world, especially in the tropical and subtropical regions[4,5,6,7]. The herb has been known since

ancient times for its curative properties and has been utilized for treatment of various ailments such as asthma, arthritis, diarrhea, internal hemorrhage, neurological disorders, and skin disorders[8,9]. The juice of CE corm is widely used for treatment of body ache and baldness. It is commonly known as taro or cocoyam. The corms are popularly used; commercially the plant is cultivated for corms in various parts of the country. The corm is an important source of food. The corms are excellent source of potassium, carbohydrate and fibers [10, 11].

MATERIALS AND METHODS

Paracetamol was purchased from Hychem Labs, Hyderabad, India. Maize starch was purchased from S.D.Fine Chemicals, Mumbai, India. Talc was purchased from Accord Labs, Hyderabad. Magnesium stearate was purchased from Ottokemi, Mumbai. Aspirin was purchased from Oxford Laboratory, Mumbai.

Collection of plant material and isolation of starch

Fresh corms of *Colocasia esculenta* were purchased from the local market of Hyderabad. The fresh corms are subjected to peel off their skins. The resultant corms were cut in to pieces dried and made in to flour. The flour was steeped in water at 35ºC for 12 h. The slurry obtained was homogenized for 30 min using commercial blender. The suspension obtained was screened using 150 µm sieve and kept for sedimentation for 24 h. The crude starch was then collected and washed several times with purified water to yield pure starch by centrifugation at 3000 rpm. The purified starch was dried in a hot air oven at 50ºC for 24 h. The yield was~2.07% (w/w). The electron photograph of purified *Colocasia esculenta* starch is illustrated in Fig. 1.

Evaluation of *Colocasia esculenta* as per monograph

The *Colocasia esculenta* starch was evaluated for various parameters viz., description, solubility, identification, ash values (totalash, acid insoluble, water insoluble and sulphated ash), test for fluorescence, test for oxidizing substances, test for acidity, test for iron, loss on drying as described in IndianPhramacopoeia for starch 8 and amylose content was determined as described by Martinez and Prodolliet[12,13].

Evaluation of *Colocasia esculenta* starch by preformulationstudies

Purified starch obtained from *Colocasia esculenta* was subjected to preformulation studies like particle size, size distribution, flow properties, determination of moisture content and

Compatability with drug before using it for formulation studies[12,14].

Sieve analysis was done in order to determine the particle size distribution. 5 g of *Colocasia esculenta* starch was weighed and placed on the sieve shaker (Jayanth Industries, Hyderabad) arranged in size range of 80-1785 µm. The sieve shaker is shaken in a definite manner for a period of 10 min. Weight retained on each sieve is determined and size distribution series were plotted from the data obtained.

Micrometry was done to determine the particle size of *Colocasia esculenta* starch. The number of particles lying within a certain range is plotted against the size range/mean particle

Size known as frequency distribution curve[2,15].

The flow properties of *Colocasia esculenta* starch were assessed by the Angle of repose, Compressibility index (CI) and Hausner'sratio (HR) methods. The angle of repose was determined by the funnel method as described in literature[1] according to the relationship:

Tan Ø = 2h/d, where h is the height of the heap and d is the diameter of the heap. To determine the density of the samples, the powder was gently poured in to 10 cm3graduated cylinder to a total volume of 10 cm3. The bulk density was calculated as the ratio between weight (g) and volume (cm3). To determine the ultimate tapped density the cylinder was tapped over 1.0 inch vertical drop, at 1 s interval, until no measurable change in volume was noticed. The CI and HR were determined from the bulk density and tapped density according to the relationships:

CI = [(Þt.Þb) Þt × 100] and HR = Þt / Þb , where Þt and Þb are the tapped density and bulk density, respectively. Determination of bulk density was done on bulk density apparatus (Pathal Electrical Works, Mumbai).The obtained flow property (Angle of repose, CI and HR) values were compared with the standard values [16].

Compatibility of paracetamol and aspirin with *Colocasia esculenta* Starch was studied by IR spectra (Shimadzu FT-IR 8400S).

Formulation studies

The effect of *Colocasia esculenta* starch as a binder, disintegrant, binder & disintegrant was determined by dry and wet granulation techniques. Five types of paracetamol (wet granulation technique) and aspirin (dry granulation technique) tablets were prepared by using *Colocasia esculenta* ,maize starches in varying compositions in different formulations as binder, disintegrant, binder & disintegrant.Each batch consists of 50 tablets. The strength of paracetamol and aspirin in finished tablets was 500 and 350 mg, respectively. The composition of various formulations of paracetamol and aspirin tablets was given in Table 1 and 2respectively.

The tablets were compressed using a 10 stationed RimekMinipress using D-11 caplet punches for paracetamol and aspirin tablets were prepared by D-12 round punches. The weight of each paracetamol tablet is 635 mg and aspirin is 445mg including all excipients. The effect of *Colocasia esculenta* starch as excipient in preparation of tablets was compared with tablets prepared from maize starch. Further the tablets were evaluated for weight variation, friability, hardness, and disintegration and dissolution tests as mentioned in the Indian Pharmacopoeia [17]. The disintegration tests were performed at 37 °C ± 20C in distilled water, using Campbell Electronics disintegrator. Similarly the dissolution tests were performed using V-Scientific dissolution (rotating paddle) apparatus. Assays were made in triplicate. The optimized formulations were subjected to accelerated stability studies as per WHO and ICH guidelines under zoneII, which are temperate and subtropical climatic zone were carried out[18,19].

RESULTS AND DISCUSSION:

Evaluation of *Colocasia esculenta* starch as per monograph

Colocasia esculenta starch is a colorless powder with no taste and no odour. The granules are Irregular and polygonal shaped and 45.26 - 28.49 -13.83 µm in size. The amylose content was 19.83%, which is less than amylose content of potato and maize starch and in other analyzed parameters the results were comparable to maize starch (Table 3).

Evaluation of *Colocasia esculenta* starch by preformulationstudies:

Sieve analysis: The size of particle is expressed by the sieve number, which describes diameter of spheres that passes through the sieve aperture as asymmetric particle. The percent distribution of particles was tabulated in Table 4.

Micrometry: Table 5 shows the comparative particle size distribution of *Colocasia esculenta* starch with maize and potato starch. The comparative result shows that the 70% *Colocasia esculenta* starch cumulative size distribution is ranging from 10-40 µm, which is similar to maize starch.

Flow properties: The Angle of repose, CI and HR give qualitative assessment of the internal cohesive and frictional effects under low levels of external loading, as might be applied in powder mixing, or in the tablet die or capsule shell filling operations. The results were tabulated in Table 6. The results are similar to those obtained from maize starch

Compatibility of paracetamol and aspirin with *Colocasia esculenta*, maize starch was evaluated by IR spectra and found that both paracetamol and aspirin are compatible along with *Colocasia esculenta*, maize and potato starch (Fig 2).

Formulation studies:

Colocasia esculenta starch possesses suitable rheological properties and compressibility, permitting its use in compression technology. There by, the design of paracetamol and aspirin

tablets using *Colocasia esculenta*, maize starch in varying compositions as a binder, disintegrant, binder and disintegrant were performed.

Both paracetamol and aspirin tablets were evaluated for weight variation, friability, hardness and disintegration test as per the Indian Pharmacopoeia and results were compile in Table 7 and 8. From these two tables it is evident that the prepared paracetamol and aspirin tablets weight variation content compiles the weight variation tolerance for uncoated tablets. Similarly, the percentage friability of all the formulations was within the limits of 0.5% and the hardness was within the scope of 3-4 kg/cm^2 limits.

Paracetamol tablets prepared by wet granulation using *Colocasia esculenta* starch as binder and disintegrant possess higher disintegration time; however, the disintegration time is within the specified time of 30 min. Paracetamol tablets prepared from *Colocasia esculenta* starch as a disintegrants, is comparable with disintegration time of paracetamol tablets prepared from maize as binder and disintegrant. On the other hand the aspirin tablets prepared by dry granulation using various formulations had disintegration time in the range of 10-20 sec. The results of aspirin tablets prepared from *Colocasia esculenta* starch either as binder, disintegrant and binder and disintegrant compiles with the results of aspirin tablets prepared from maize starch.

Dissolution:

Following dissolution experiments, the cumulative and the comparative in *vitro* drug release of

Paracetamol and aspirin in different formulations were illustrated in Table 9 and 10. The graphical representations of drug release in comparative to other formulations were depicted in Fig. 3 and 4. The results presented are the mean of triplicate readings. The results of dissolution studies indicate that 80% of paracetamol and aspirin were released from tablets within 60 min. The overall dissolution time indicated that the tablets prepared from *Colocasia esculenta* starch as binder, disintegrant, binder & disintegrant was significantly comparable with drug releasing time of paracetamol and aspirin tablets prepared from maize starch.

Stability studies evaluations under zone II, i.e. 40±20C;75±5% RH were carried out for six months, there is no changes in physical appearance of optimized tablets as well as the content uniformity and dissolution profile of tablets where within the limits of monograph.

CONCLUSIONS:

Colocasia esculenta starch was evaluated as an alternative natural starch along with maize starch following its isolation from *Colocasia esculenta* plant. The battery of tests done on *Colocasia esculenta* starch met the specification mentioned in Indian Pharmacopoeia. Following this, the preformulation studies results suggest that *Colocasia esculenta* starch has similar properties like maize starch. Besides it has shown compatibility with paracetamol and aspirin. Finally the dissolution results did not preclude us to state that *Colocasia esculenta* be used as an alternative pharmaceutical excipient (especially as a binder and disintegrant) to maize starch for tablets preparation.

Table 1:Composition of paracetamol tablets

Ingredients	**Ingredients quantity in grams**			
	F1	**F2**	**F3**	**F4**
Paracetamol	0.5	0.5	0.5	0.5
C. esculenta starch (binder)	-	0.05	0.05	-
C. esculenta starch (disintegrant)	0.05	-	0.05	-
Maize starch (binder)	0.05	-	-	0.05
Maize starch (disintegrant)	-	0.05	-	0.05
Magnesium stearate	0.0025	0.0025	0.0025	0.0025
Talc	0.005	0.005	0.005	0.005

Table 2: Composition of aspirin tablets

Ingredients	**Ingredients quantity in grams**			
	F1	**F2**	**F3**	**F4**
Aspirin	0.350	0.350	0.350	0.350
C. esculenta starch (binder)	-	0.035	0.035	-
C. esculenta starch (disintegrant)	0.035	-	0.035	-
Maize starch (binder)	0.035	-	-	0.035
Maize starch (disintegrant)	-	0.035	-	0.035
Magnesium stearate	0.0017	0.0017	0.0017	0.0017
Talc	0.0035	0.0035	0.0035	0.0035

Table 3: Evaluation of *Colocasia esculenta* and maize starches

Parameters	***C.esculenta* starch**	**Maize starch**
Source	*Colocasia esculenta*	Zea mays
Description	Coarse, fine colorless powder	Very fine, colorless powder
Odor	Odorless	Odorless
Taste	Tasteless	Tasteless
Solubility	Insoluble in water and 95% ethanol	Insoluble in water and 95% ethanol
Size	45.26µm–28.49µm–13.83 µm	29.4µm- 19.50µm- 14.70µm
Shape	Irregular and polygonal shaped	Polyhedral or sub spherical
Test for iron	Passes the limit	Passes the limit
Loss on drying	6%	11.4%
Test of mucilage	+ve	+ve
h	0.4%	0.3%
Acid insoluble ash	0.03%	0.05%
Water insoluble ash	0.16%	0.04%
Sulphated ash	0.5%	0.8%
Test for fluorescence	- ve	- ve
Test for oxidizing substances	+ ve	+ ve
Amylose content	8.36%	19.83 %
Swelling index	0.4 ml	0.6 ml
P^H	6.54	6.02
Viscosity	13.6 m Pa	14.5m Pa
Density	1.036	1.3

Table 4: Size distribution of *C.esculenta* starch by sieve analysis

Sieve no.	**Particle size range(µm)**	**Amount of spheres retained**	**Percentage of weight retained**	**Cumulative percentage retained**
8/16	4000-2057 µm	0 mg	0%	0%
16/30	2057-1003 µm	0.020 mg	0.08%	0.08%
30/60	1003-500 µm	0.110 mg	0.04%	0.52%
60/100	500-250 µm	0.710mg	2.84%	3.36%
100/150	250-150µm	13.540 mg	54.16%	57.52%
150/170	150-105µm	9.030mg	36.12%	93.64%
		23.41mg	93.64%	93.64%

Values are mean of triplicate, 6.36% loss of material during sieving.

Table 5: Particle size distribution of starches by micrometry

Mean size range	**Size range (µm)**	**Maize starch**			***Colocasia esculenta* starch**		
		Avg of 5 samples	%	% Cumulative	Avg of 5 samples	%	% Cumulative
5	0-10	-	-	-	-	-	-
15	10-20	48	48	48	18	18	18
25	20-30	42	42	90	32	32	50
35	30-40	55	55	145	24	24	74
45	40-50	-	-	-	19	19	93
55	50-60	-	-	-	-	-	-
65	60-70	-	-	-	-	-	-

Table 6: Flow properties of starches

Parameter	***C.esculenta* starch**	**Maize starch**
Moisture content	6.0%	2.8%
Carr's index	29.68 (Passable)	30.92 (Poor)
Hausner's ratio	1.32 (Passable)	1.453 (Poor)
Angle of repose	31.9 (Good)	37.3 (Fair)
Bulk density	0.462 gm/cm^3	0.43 gm/cm^3
Tapped density	0.657	0.625

Table 7: Evaluation of Paracetamol tablets:

TESTS	**Maize starch as binder &disintegrant**	***C.esculenta* starch as disintegrant**	***C.esculenta* starch as binder**	***C.esculenta* starch as binder &disintegrant**
Hardness (kg/cm^2)	4.0 – 4.5	4.0 – 4.5	4.0 – 4.5	4.0 – 4.5
Friability	0.64	0.68	0.70	0.74
Weight variation	Complies	Complies	Complies	Complies
Disintegration time (Sec ± SEM)	42.6 ±0.33	62.5 ±0. 47	±0 .32	40.8±0. 21

Table 8: Evaluation of Aspirin tablets

TESTS	**Maize starch as binder &disintegrant**	***C.esculenta* starch as disintegrant**	***C.esculenta* starch as binder**	***C.esculenta* starch as binder &disintegrant**
Hardness (kg/cm^2)	3-4	3-4	3-4	3-4
Friability (%)	0.67	0.67	0.66	0.64
Weight variation	Complies	Complies	Complies	Complies
Disintegration time (Sec ± SEM)	24.3 ± 0.43	23.5 ± 0.34	26.7 ± 0.12	22.9 ±0.44

Table 9: Comparative *In vitro* release of Paracetamol from different formulations:

	F1	F2	F3	F4
Time (in min)	**% Cumulative drug released**	**% Cumulative drug released**	**% Cumulative drug released**	**% Cumulative drug released**
5	62	60.6	69.3	66.2
10	68.2	64.2	72.2	68.6
15	70.4	69.6	75.0	74.4
20	73.6	76.4	76.7	75.2
25	78.2	79.8	79.6	78.6
30	80.6	83.4	82.4	80.4
40	86.2	90.2	88.5	89.4
50	90.6	92.3	91.5	90.2
60	93.2	93.0	97.3	96.4
SEM values	±0.4	±0.3	±0.6	±0.5

F1 = *C.esculenta* starch as disintegrant.

F2 = *C.esculenta* starch as binder.

F3 = *C.esculenta* starch as binder and disintegrant.

F4 = Maize starch as binder and disintegrant.

Table 10: Comparative *In vitro* release of Aspirin from different formulations

	F1	F2	F3	F4
Time (in min)	**% Cumulative drug released**	**% Cumulative drug released**	**% Cumulative drug released**	**% Cumulative drug released**
5	49.8	45.4	52.7	50.6
10	56.2	54.8	60.8	58.2
15	64.6	66.4	69.5	66.4
20	72.3	73.8	73.9	70.6
25	74.6	75.6	78.6	76.8
30	80.8	86.2	84.1	83.4
40	86.2	88.9	88.7	86.8
50	91.4	90.4	92.1	93.2
60	92.6	93.2	95.1	94.6
SEM values	±0.5	±0.4	±0.6	±0.4

F1 = *C.esculenta* starch as disintegrant.

F2 = *C.esculenta* starch as binder.

F3 = *C.esculenta* starch as binder and disintegrant.

F4 = Maize starch as binder and disintegrant

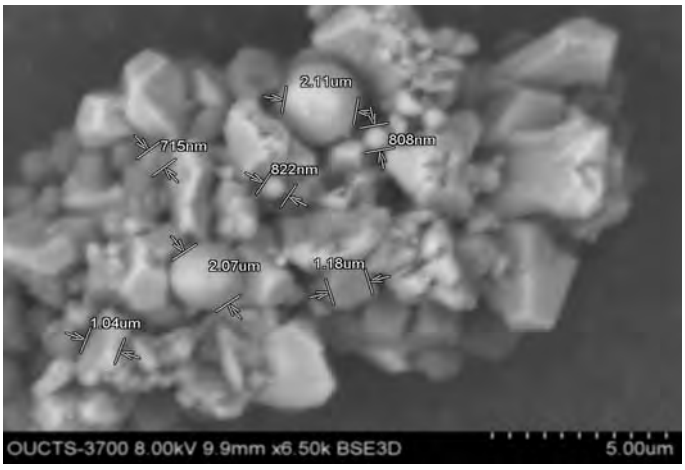

Figure 1: Electron microscopic photographs of *Colocasia esculenta starch*

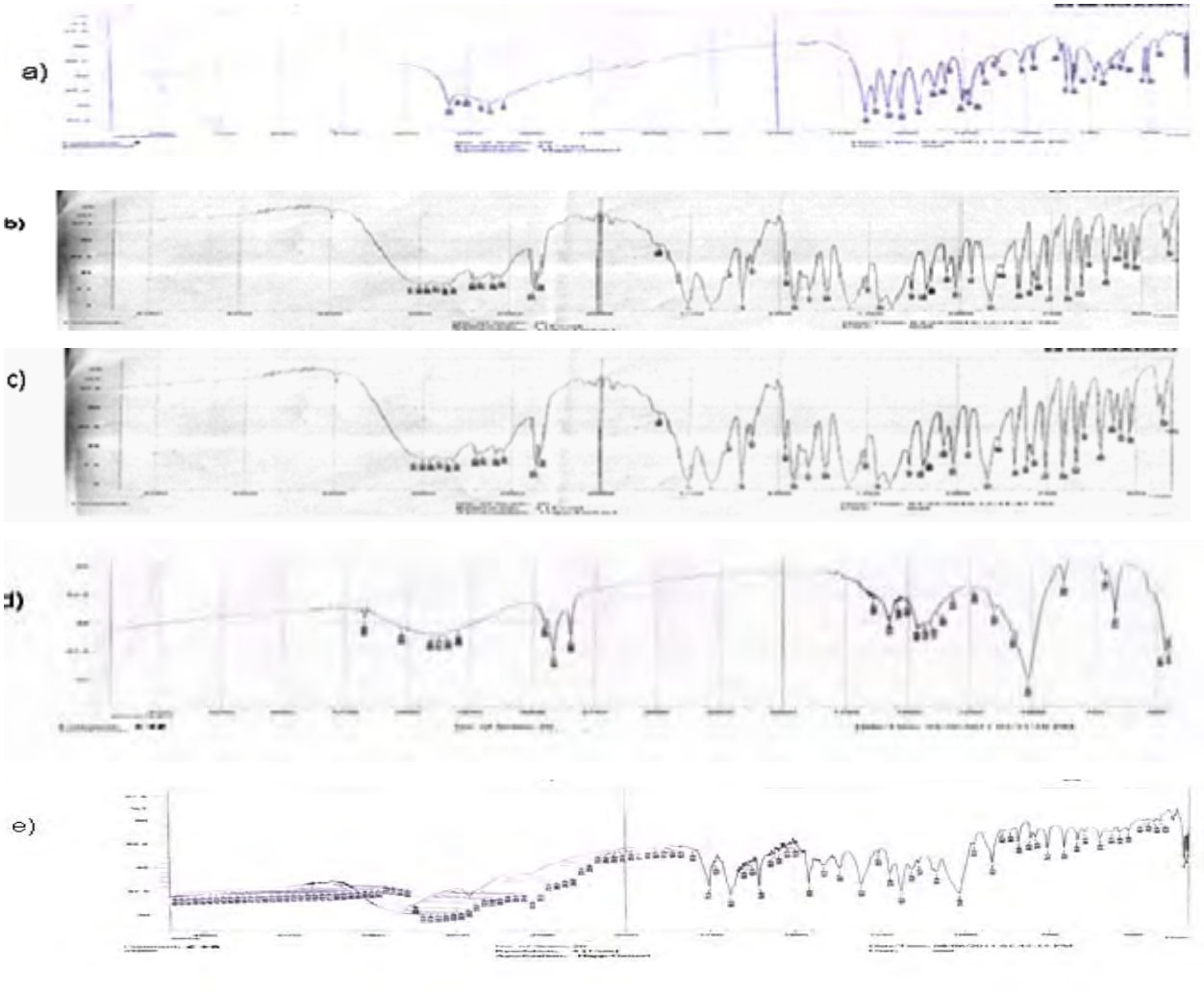

Figure2:IR Spectras of compatibility studies

a) IR spectra of paracetamol.
b) IR spectra of aspirin.
c) IR spectra of *Colocasia esculenta*.
d) IR spectra of paracetamol with *Colocasia esculenta.*
e) IR spectra of with aspirin *Colocasia esculenta*

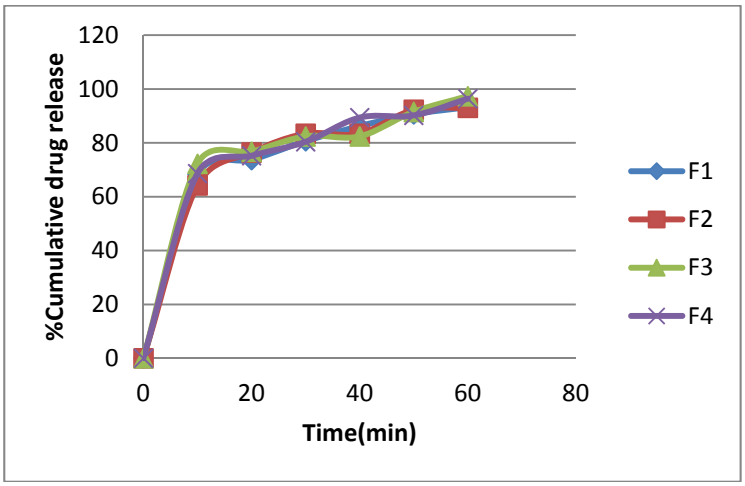

Figure 3: Comparative *In vitro* release of Paracetamol from different formulations:

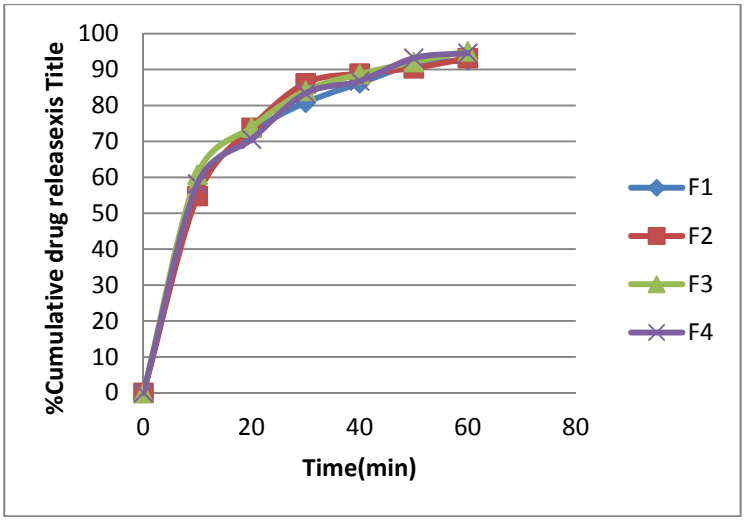

Figure 4: Comparative *In vitro* release of Aspirin from different formulations:

REFERENCES:

[1] [1] Lieberman HA, Lachmann L, Schwortz JB, editors.Pharmaceutical Dosage Forms: Tablets. 1st ed. Vol. 2.Marcel Dekker: New York; 1989; p. 151-70.

[2] [2] Wallis TE. Text book of Pharmacognosy. 5th ed. New Delhi: CBS Publications and Distributor; 1985; p. 7-19;

[3] [3] Wade A, Weller PJ, editors. Hand book of Pharmaceutical Excipients. 2n d ed. Washington: American Pharmaceutical Association; 1994; p. 483-8.

[4] [4]Kritikar KR and Basu BD, Indian Medicinal Plants (International Book Distributors, Dehradun), 2nd ed., Vol. 4, 1996, pp. 2597, 2613-2615.

[5] [5]Varier's PS, Indian Medicinal Plants: A compendium of 500 species, (Orient Longman ltd, Madras), Vol. 2, 2004, pp.160.

[6] [6]Potgieter M, Taro (Colocasia esculenta) as a food, Amer J Dietetic Assoc, 16, 1940, 536-540.

[7] [7]Sunell LA, and Arditti J, Physiology and Phytochemistry. In Wang JK (ed), Taro: A review of colocasia esculenta and its potentials. Univ. of Hawai'i Press, Honolulu, 1983, 134-139.

[8] [8]Kalariya M, Parmar S and Sheth N, Neuropharmacological activity of hydro alcoholic of Colocasia esculenta, Pharm Bio, 2010.

[9] [9]Deshmukh TA, Chaudhari SP and Kumawat NS, Antidiabetic activity of ethanol extract of Colocasia esculenta leaves in alloxan induced diabetic rats, International Journal of Pharm Tech Research, 2, 2010, 1246-124.

[10] [10]Aboubakar YN, Njintang JS and Mbofung CMF, Physicochemical, thermal properties and microstructure of six varieties of taro (Colocasia esculenta L. Schott) flours and starches, Journal of Food Engineering, 86, 2008, 294-305.

[11] [11] Anonymous, The Ayurvedic Pharmacopoeia of India, part 1, Vol. 4, 1st ed., 2006, 116 – 117.

[12] [12]Anonymous. Indian Pharmacopoeia. Vol. 2, New Delhi: The Controller of Publications, Govt of India; 1996; p.A43-A109.139.

[13] [13]Martinez, Prodolliet. Determination of amylose in cereal and non-cereal starches by a colorimetric assay: collaborative study. Starch 1996; 48: 81-5.

[14] [14] Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy. 3rd ed. Bombay: Varghese Publication House; 1987; p.176-94.

[15] [15]Kokate CK. Practical Pharmacognosy, 4th ed. Delhi: Vallabh Prakshan; 2004; p. 113-4.

[16] [16] Schmidt PC, Rubensdorfer P. Evaluation of Ludipress 'Multipurpose Excipient' for direct compression. Part I: Powder characteristics and Tableting properties. DrugDev Ind Pharm 1994; 20: 2899-925.

[17] [17] Jennifer D, Johannes K, editors. Pharmaceutical Dissolution Testing. London: Taylor & Francis, 2005; P.315-40.

[18] [18 Carstensen JT, Rhodes CT, editors. Drug Stability Principles and Practices. 3rd ed. Vol 107, New York: Marcel Dekker, 2000; p.612-3.

[19] [19]Mazzo DJ, editor. International stability testing. Illinois: Interpharm Press, 1999; p.255-7.