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RESEARCH ARTICLE

FORMULATION AND EVALUATION OF IBUPROFEN TABLET USING ISOLATED STARCH FROM UNRIPE PAPAYA FRUITS AS A DISINTEGRANT.

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Abstract

The main objective of this research was to introduce and evaluate the disintegrate property of natural excipient like starch from unripe fruits of Papaya when used in tablet formulation. Pharmaceutical excipients developed from natural sources are economic. The unripe fruit of Papaya has high level of starch content and hence used as a raw material for starch isolation. Starch was isolated from green unripe papaya fruits using 0.5 N NaOH as Lye solution. Isolated starch was evaluated and used as a disintegrant in formulation of tablet using ibuprofen as model drug by wet granulation method. Studies indicate that starch so obtained is qualitatively and quantative comparable to corn starch. The disintegration time of formulated tablet was evaluated as per Indian Pharmacopoeia and was compare with marketed tablets. Result from various evaluations suggested characteristics of papaya starch that could be used as disintegrant in formulation.

Introduction:-

Starch is one of the most widely used excipient as filler, binder, and disintegrant in the manufacture of solid dosage forms. Starch is a relatively cheap raw material with physical and chemical properties that impart multiple uses in pharmaceutical industry like binding agent. Starch can be extracted using different processes, depending on the plant source and use of the starch. Starch from various sources has been widely used for various reasons in pharmaceutical formulations. Besides the yield of isolated starch, in order to make it economically viable, it must be accomplished without any significant modification to the starch granules. Carica papaya Linn. (C.P) (Caricaceae) is a fast-growing, semi woody tropical herb reaching 3-10 m in height. The fleshy stem is single, straight and hollow and contains prominent leaf scars. Papaya exhibits strong apical dominance rarely branching unless the apical meristem is removed, or damaged. Carica papaya contains many biologically active compounds. Since, each part of papaya tree possesses economic value; it is grown on commercial scale. Unripe pulp of Carica papaya can be ranked as carbohydrate rich fruit due to its high carbohydrate and starch contents. Unripe Carica papaya fruit contains about 45% of starch. Starch is used as multifunctional excipients in the field of pharmaceutical sciences. Swelling property of the starch is responsible for its disintegration activity. Disintegrating agents are the hydrophilic substances which when come in contact with saliva or gastric fluid absorb water, swell and cause disintegration of tablets. Although Corn starch is one of the most widely used starches in pharmaceutical formulations, starches from other botanical sources have shown difference in functional properties such as gelling, swelling and water binding capacity which influence their capacity to function effectively as binding and disintegrating agent. Due to their effect as powerful disintegrant, starches have been found useful in preparation of insoluble drug substances. In the present study starch was isolated from the unripe papaya pulp and the isolated starch was used as disintegrant for the preparation of

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tablets using Ibuprofen as a model drug. Wet granulation method was used for the preparation of tablets. The tablets were then evaluated as per Indian Pharmacopoeia and compared with marketed tablets.

Materials And Methods:-

Unripe papaya was obtained from local market and starch was isolated in laboratory. Ibuprofen drug was found Fisher Scientific, Corn starch was found central laboratory and all other chemicals were of analytical grade which were obtained from Fisher scientific, SD fine laboratory.

Isolation of Starch:-

Extraction of starch from unripe papaya was carried by alkaline extraction method using sodium hydroxide as Lye solution. The pulp of unripe papaya was isolated and dried, powdered and mixed with 0.5 N NaOH solution to prepare a slurry in ratio 1:3 (Papaya: Lye solution). The slurry was held for 3 hours, then diluted with water in ratio 1:5 (Slurry: Water). The mass was then strained through muslin cloth and washed with saline solution several times to remove soluble substances, sugar and mucilage present. The mass obtained was then washed repeatedly until the supernatant solution was clear. This residue was further filtered and centrifuged at 5000 rpm for 45 min. The sedimented starch was collected and washed with ethanol followed by water until the pH was neutral. It was then sieved, dried at room temperature and milled to fine powder.

Fig 1:-A Corn Starch

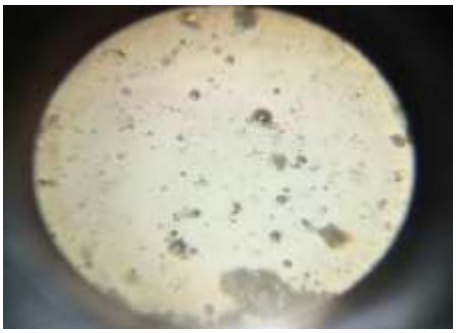

Fig 2:-B Papaya Starch

Pharmaceutical Characterization Of Starch:-

Identification Test (Iodine Test):-

One g of papaya starch and corn starch was boiled with 50 ml of water separately. After cooling to 1 ml of the mucilage, 2 drops of 0.1 N iodine solutions were added and the color change was noted. The result is shown in table. No. 1

Particle Size Determination (Optical Microscopy):-

A small amount of starch was mixed with liquid paraffin and mounted onto a microscope slide with a cover slip and examined by polarized Optical microscopy. The mean particle size of samples of starch was determined microscopically with the aid of a calibrated eyepiece. The particle size of each sample dispersed in liquid paraffin was determined. The result is shown in table no. 2, 3 and fig. 1, 2.

Paste Clarity:-

The clarity (transmittance % at 650 nm) of papaya starch paste was measured. A 1% aqueous suspension of starch near neutral pH was heated in a boiling water bath for 30 min with intermittent shaking. After the suspension was cooled for 1 hr at 25^{o}C, the light transmittance at 650 nm was read against blank. The result is shown in table no. 1

Moisture Content:-

A Three g weight each of corn and papaya starch was heated at 132^{0}C using moisture analyzer and the reading was recorded. The result is shown in table. No. 1

Swelling capacity:-

The tapped volume occupied by 10 g of each corn powder and papaya starch (*Vd)* in a 100 ml measuring cylinder was noted. This powder was then dispersed in 85 ml of distilled water and volume was made up to 100 ml with

distilled water. After 18 hrs of standing, the volume of the sediment, (*Vw)* was estimated and the swelling capacity was determined using the formula; the result is shown in table. No. 1

Swelling capacity = Vw – Vd
Vw= is weight of starch
Vd = is the volume of sediment Starch

Ash Value of starch:-
Total 2 g quantity of starch was weighed into a silica crucible and incinerated. Determination of ash value was done by measurement of the residue left after complete combustion in a muffle furnace at 550^{o} C. the result is shown table.no.1

Preformulation studies
Melting Point:
The melting point of the Ibuprofen was found 75^{0}C which is same as reported in monogram IP The Result shown Table no. 4
pH Determination:
pH of ibuprofen was found to be 5.7 which is near the range of monograph as per IP The result shown in Table no.4
Partition coefficient
Partition coefficient determination of ibuprofen was done by simple sheking flask method. The result shown in table no 4

Identification of drug by UV\ Visible Spectrophotometer
The identification of the drug was done by UV Spectrophotometric method. Small amount of drug was dissolved in 0.1 NaoH solutions and the volume was made up to 100 ml to obtain a stock solution of 100µg/ml. The one ml of this stock solution was again diluted with 0.1 NaoH up to 10 ml to obtain a solution of 10 µg/ml. the resulting solution was scanned between 240 nm to 300 nm in double beam UV/Visible Spectrophotometer and higher peak range shown in fig.no.4

IR studies:
The IR spectra were recorded using infrared spectrophotometer .the IR spectrum of pure ibuprofen interested and compared with standard. The IR spectrum is shown in fig. - 6.
Qualitative Solubility:
It was found that Ibuprofen was soluble in most of the organic solvent and insoluble in water as shown in tablet 6.

Particle size:
The result of the microscopic evolution for the measurement of particle size of the drug particles are given below in table no. 7
PREPARATION OF TABLETS

Tablets were prepared by using wet granulation technique. The formula for single tablet per batch required to prepare 500 mg of ibuprofen tablets is given in Table1. Required quantity of drug, binder, disintegrant and diluents were grinded and passed through sieve no # 40 separately and then mixed uniformly by using water as granulating agent to get a wet dough mass which was screened through sieve no # 16 to obtain coarse granules and dried at 45 ^{o}C for 1 h. The dried granules were then passed through sieve no # 20 to obtain uniform sized granules. Required quantities of glidant and lubricant was added to the granules and mixed uniformly. The resultant granules were compressed into tablets by using single punch rotary compression machine. To compare the disintegrant property, controlled tablets were prepared using papaya starch as disintegrant agent instead of isolated unripe papaya.40 tablets were prepared for each batch and stored in an air tight container for further studies.

Table No.4 Formulation of Tablet By Wet Granulation

Sr.No.	Ingredients	F1	F2	F3	F4	F5
1	Ibuprofen	200	200	200	200	200
2	Papaya starch	10	5	-	-	2
3	Corn starch	-	-	10	5	-
4	Polyvinyl	30	30	30	30	30

	pyrollidone					
5	Dicalcium Phosphate	153	158	153	158	155
6	Magnesium stearate	2	2	2	2	2
7	Talc	5	5	5	5	5

Pre-Compressibity Studies:-

Angle of Repose:

The angle of repose was determined using funnel method. Funnel that can be fit vertically with stand at 6.3 cm. height. The opening end of funnel is closed with thumb until drug is poured. The 5 gm of powder blend was poured into funnel that can be raised vertically until a maximum cone height (h) was obtained. Radius of the heap (r) was measured and the angle of repose (ɵ) was calculated using the formula. the result is shown table no. 8

$$\Theta = \tan^{-1} (h / r)$$

Bulk Density

Apparent bulk density was determined by pouring the 10 gm of powder blend from each formula into 100 ml granulated cylinder. The bulk volume (V) poured power blend from each formula was determined. The bulk density was calculated using the formula. The result is shown in table. No. 8

$$\boldsymbol{\rho_b = M / V}$$

Where

ρ_b = Bulk Density

M - Is the weight of powder drug.

V - Is the volume of powder drug.

Tapped Density:

Weight Ten g. of powder blends and placed in a measuring cylinder. Measuring cylinder containing known mass (10gm) of was tapped for 100 time or fixed time. The minimum volume (V_t) occupied was measured. The tapped density was calculated using following formula. The result is shown in table.no.9

$$\rho_t = M / V_t$$

Where

ρ_t = Tapped Density

M – Is the weight of Powder

V_t - Is the volume of Powder

Compressibility Index

The simplest way for measurement of free flow of powder is compressibility index was determined by this formula. The result is shown in table. No. 8

$$C.I.(\%) = \rho_t - \rho_b \times 100/\rho_t$$

Where

C.I = Compressible Index

ρ_t = Tapped Density

ρ_b = Bulk Density

Hausner Ratio

It was studied by following formula. The result is shown in Table.no.8

$$\textbf{Hausner ratio} = \rho_t / \rho_t$$

Where

ρ_t - Tapped Density

ρ_b - Bulk Density

POST COMPRESSIBILITY STUDIES

Weight Variation Test:

The weight variation test of the tablet was performed as per I.P. twenty tablets were selected randomly from each batch and weighed individually on electronic balance. The individual weighted is then compared with average weight for the weight variations. 9

Thickness:
Table thickness of ibuprofen tablet was measured using Vanier calipers.the result is shown in table no.9

Hardness:
The hardness of the tablets was determined using Monsanto hardness tester. It is expressed in kg/cm^2. The result is shown in table. No.9

Friability Test:
Friability of the tablet was determined using Roche friability. The friability (f) is given by the formula. The result is shown in table. No.10.

$$\% F = (1- W_0 / W)_x 100$$

% friability of tablets led then % is considered acceptable.

Where,

$\mathbf{W_0}$ is weight of the tablet before the test and **W** is the weight of the tablet after the test.

Wetting Time:
A piece of tissue paper folded twice was kept in a Petridis containing 6 ml of purified water. The tablet was placed on the tissue paper and allowed to wet completely. The time required for complete wetting of the tablet was then recorded. the result is shown in table. no.9

In Vitro Disintegration Time:
Disintegration test was perform using basket- rack assembly from electro lab. Tablet was placed in each of six tubes of the basket and test was performed using water as the immersion fluid maintained at 37±2.time for complete disintegration of all six tablets was noted. the result is shown in table.no.10

Drug Content:
Ten randomly selected tablets were weighed and average weight is calculated, the tablet was powdered in a glass mortar. The weight equivalent to 400 mg of ibuprofen was accurately weighed and transferred into a 100 ml volumetric flask. It was dissolved and made up the volume with phosphate buffer pH 7.4. Subsequently the solution in volumetric flask was filtered and suitable dilutions were made and analyzed at 221 nm using UV – Visible spectrophotometer (shimadzu UV-1800). The drug content of each sample was estimated from standard curve of ibuprofen using phosphate buffer pH 7.4.the result is shown in table.no.9

In-Vitro Drug Release:
Dissolution was carried out using IP dissolution apparatus I (paddle apparatus). Dissolution of tablets was carried out in 900 ml-dissolution medium. The dissolution medium for Ibuprofen tablet was phosphate buffer pH 7.4. The temperature of dissolution medium was maintained at 37º C ± 2º C. The agitation intensity was 100 rpm. The samples of dissolution medium were withdrawn at every interval of 10 min for 1 hr. samples were analyzed spectrophotometrically (UV-1800 Shimadzu) at 221 nm and the percentage drug release was calculated. The result shown in table.no.11

Result And Dissection:-
Pharmaceutical characterization
Table no.1 Pharmaceutical Characterization of Starch

Sr. No.	Characterization of Starch	Papaya Starch	Corn Starch
1	Iodine test	+Ve	+Ve
2	Paste Clarity	40%	33%
3	Average grain size(µ)	7.35	4.828
4	Ash Value (%w/w)	17.2±0.8	16.12±0.2
5	Moisture Content	4.95±0.2	7.21±0.3
6	Swelling Capacity	2.7±0.87	2.1±0.55

7	Angle Of Repose	27.40°±1.51	25.24°±1.32
8	Bulk density (g/ml)	0.55±0.42	0.49±0.51
9	Tapped density (g/ml)	0.71±0.30	0.65±0.52
10	Carr'index	29.09±1.22	24.61±1.46
11	Hausner's ratio	1.29±0.28	1.32±0.67

Starch extracted from Carica papaya had a light yellowish tinge hence bleaching was carried out with ethanol. On dry basis 45.5% starch was obtained. Grains of Carica papaya starch were found to be smaller in size compared to Corn starch (**Fig. 1a**) and (**Fig. 1b**) They were round & oval in shape not much difference was observed in loss of drying ash value, pH value of carica papaya starch & corn starch. The loss on drying &acidity values was well within official limit. The bulk density, angle of repose & compressibility index of both starches was comparable. In all the cases the value of angle of repose were $\leq 30^{o}$, which indicate that both the starches were free flowing Table.1.

Particle size of corn starch

The result of the microscopic evolution for the measurement of particle size of the drug particles are given below in table

Table no. 2 Particle Size Distribution of Corn Starch

S.No	Size Range	Mid point (M.P)	No. of particle (N)	M.P × N	M.P×N×L.C (d)
1	0-1	0.5	05	2.5	3.62
2	1-2	1.5	11	16.5	23.92
3	2-3	2.5	15	37.5	54.37
4	2-4	3.5	18	63	91.35
5	4-5	4.5	23	103.5	150.07
6	5-6	5.5	28	110	159.5
			∑n= 100		∑d=482.8

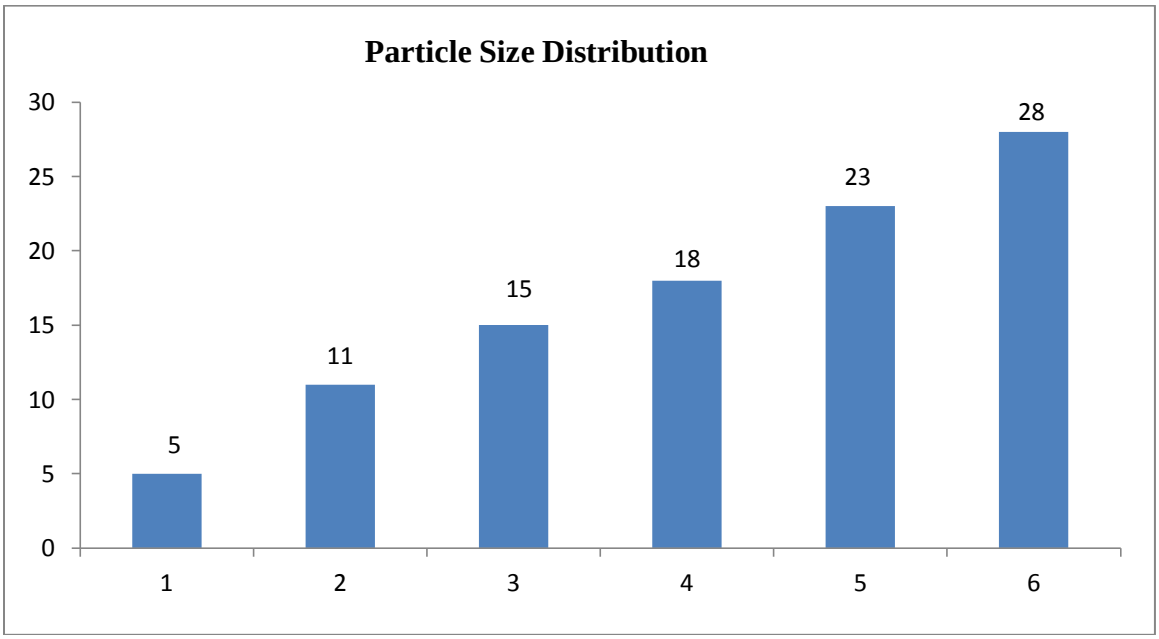

Fig. 2 particle size of corn starch

Least count (L.C) = 1.45

Particle size of Corn starch = ∑d \ ∑n
= 482.8\ 100
= 4.828

Particle size was found to be 4.828 µm. Particle size distribution pattern depicted in fig. show that drug particle are distributed in range of 1-6 µm and maximum number of particle are present in size range of 4-6µm. This distribution pattern also indicates that the starch is amorphous in nature.

Table no.-3 Particle Size Distribution Of Papaya Starch

S.No	Size Range	Mid point (M.P)	No. of particle (N)	M.P × N	M.P×N×L.C (d)
1	0-1	0.5	06	3	5.88
2	1-2	1.5	09	13.5	26.46
3	2-3	2.5	14	35	68.6
4	2-4	3.5	20	70	137.2
5	4-5	4.5	27	121.5	238.14
6	5-6	5.5	24	132	258.72
			∑n= 100		∑d=735

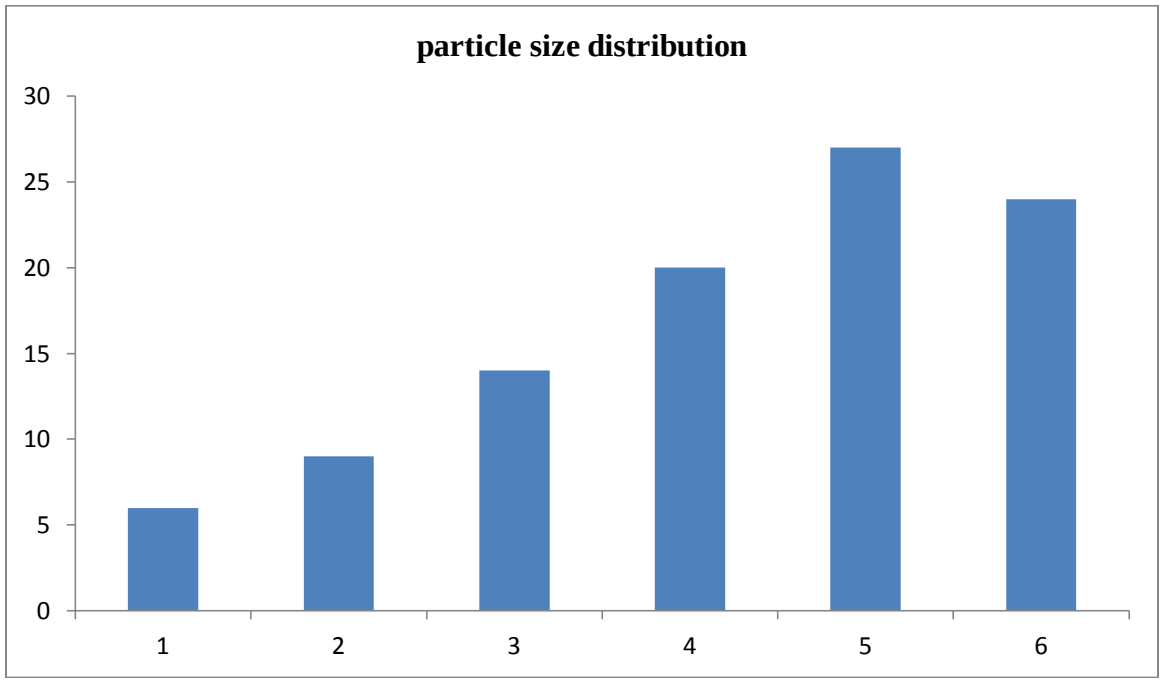

Fig. 3 Particle Size Distribution of Papaya Starch

Least count (L.C) = 1.96

Particle size of Papaya starch = ∑d \ ∑n
= 735\ 100
= 7.35

Particle size was found to be 7.35 µm. Particle size distribution pattern depicted in fig. show that drug particle are distributed in range of 1-6 µm and maximum number of particle are present in size range of 4-6µm. This distribution pattern also indicates that the starch is amorphous in nature.

Table no.4 Determination of pH \ melting point \ Partition coefficient

pH \ melting point \ partition coefficient	
pH	5.7 (acidic)
Melting Point	76°C (drug is pure)
Partition Coefficient	3.5 (drug is lipophilic)

Identification of drug by
UV/Visible spectrophotometer

UV Spectrophotometric method was used for the analysis of ibuprofen. The UV scan of the drug sample showed highest peak at 256 nm which is nearby to the standard value. This

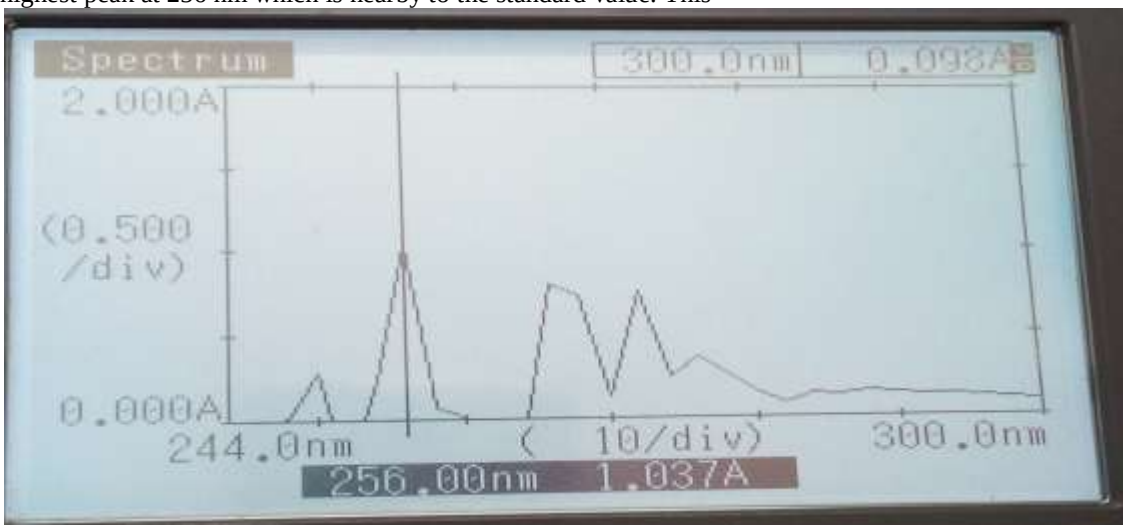

Fig. 4 peak detection λ_{max} for ibuprofen in 0.1 NaoH

UV Spectrophotometric method was used for the analysis of ibuprofen. The UV scan of the drug sample showed highest peak at 256 nm which is nearby to the standard value. This

Standard curve calibration of ibuprofen was prepared in 0.1 NaoH at 256 nm in UV Spectrophotometer.

Table no. 5 Standard Curve of Ibuprofen In 0.1 NaoH

S.NO.	Concentration (µg/ml)	Absorbance
1	5	0.0754
2	10	0.172
3	15	0.278
4	20	0.384
5	25	0.464
6	30	0.587

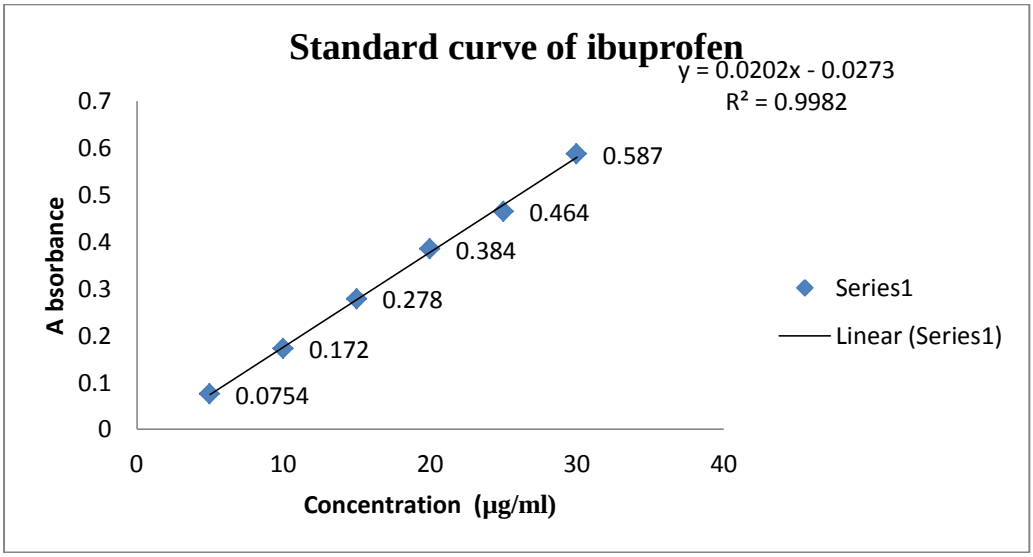

Fig. 5 Standard curve calibration of ibuprofen

Equation

$$Y = 0.020x – 0.027$$

$R^2 = 0.998$

X = concentration in micro gram

For preparation of standard curve, solution of drug sample were prepared in 0.1 NaoH and there were measured at 256 nm the linearity range were found to 0.1-0.5.

IR studies:

The IR spectra were recorded using infrared spectrophotometer .the IR spectrum of pure ibuprofen interested and compared with standard. The IR spectrum is shown in fig. - 4.

IR Spectrum Of Ibuprofen

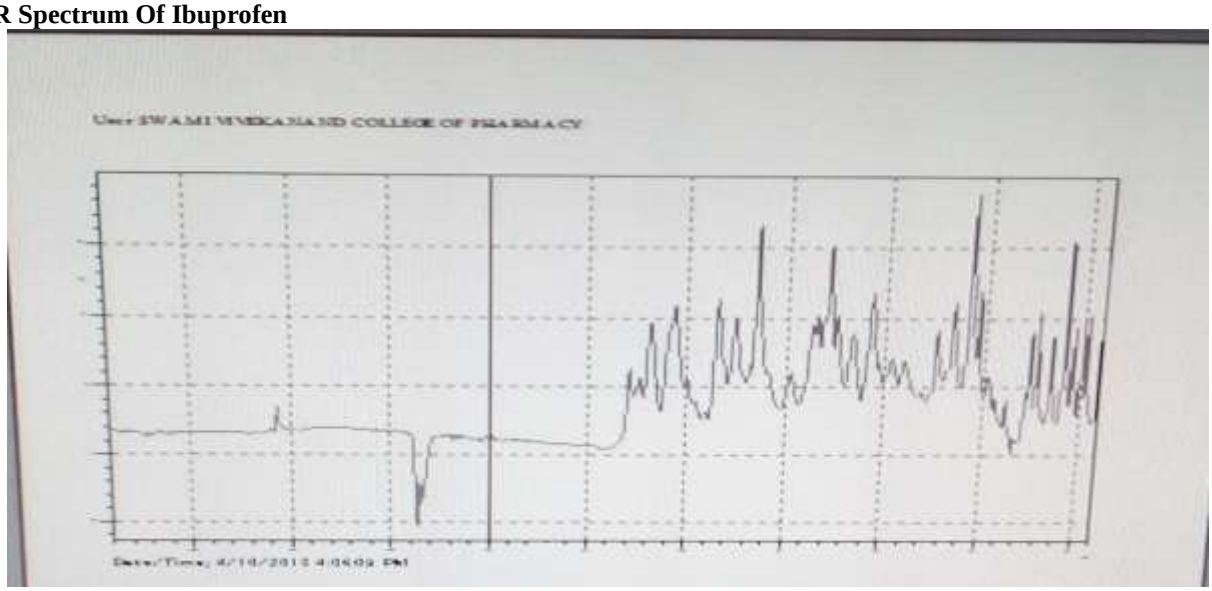

Fig. 6 IR Spectrum Of Ibuprofen Drug

An IR spectrum of drug sample has been interpreted and correlate with standard IR spectrum of ibuprofen. There is no change in functional group of drug sample or same with standard shows that the drug sample is Ibuprofen.

Solubility properties

Qualitative Solubility:

It was found that Ibuprofen was soluble in most of the organic solvent and insoluble in water as shown in tablet 7.

Table no. 6 Qualitative solubility of Ibuprofen

S.NO.	SOLVENT	SOLUBILITY
1	Methanol	++++
2	Ethanol	++++
3	Chloroform	+++
4	Acetone	++++
5	7.2 phosphate buffer	+++
6	Octanol	++++
7	0.1 NaoH	++++
8	Water	+

\+ Insoluble
++ Poorly soluble
+++ Slightly soluble
++++ Freely soluble

Qualitative solubility studies of drug shown in table 4 depicted that the drug is more soluble in organic solvent as compare to hydrophilic solvents so it can be concluded that drug is lipophilic in nature.

Particle size:

The result of the microscopic evolution for the measurement of particle size of the drug particles are given below in table

Table no. 7 particle size distribution of ibuprofen

S.No	Size Range	Mid point (M.p)	No. of particle (N)	M.P × N	M.P×N×L.C
1	0-1	0.5	04	2	2.6
2	1-2	1.5	09	13.5	17.55
3	2-3	2.5	18	45	58.5
4	2-4	3.5	22	77	100.01
5	4-5	4.5	25	112.5	135
6	5-6	5.5	22	121	157.3
			∑n= 100		∑d=470.96

Least count (L.C) = 1.3

Particle size of ibuprofen = ∑d \ ∑n

= 470.96\ 100

= 4.70

Particle size was found to be 4.70 µm. Particle size distribution pattern depicted in fig. show that drug particle are distributed in range of 1-6 µm and maximum number of particle are present in size range of 4-6µm. This distribution pattern also indicates that the drug is crystalline in nature.

Pre-Compression Parameters of formulation

Table no.8 Pre-Compression Parameters of Formulations by wet Granulation Method

Formulation code	Bulk Density (gm/ml)	Tapped Density (gm/ml)	Hausner Ratio	Compressibility Index (%)	Angle of Repose
F1	0.581	0.682	1.17	14.66	$27^o.22'$
F2	0.579	0.652	1.12	12.26	$26^o.92'$
F3	0.577	0.674	1.16	14.39	$27^o.83'$
F4	0.568	0.678	1.19	16.22	$24^o.32'$
F5	0.585	0.681	1.16	14.09	$23^o.44'$

The Bulk density of all the formulation was within the range of 0.580±0.003 to 0.585±0.005gm. /ml and Tapped density was found to be in the range of 0.682±0.003 to 0.681±0.007 (good flow property). The angle of repose of powder blends of all formulation was found to be in the range of $23^0.44'$±0.002 to $27^o.22'$±0.12 (good flow property). The calculated Carr's index of all formulation was found to within the range of 14.66±0.15 to 14.09±0.16 (good flow property).The calculated Hausners ratio of all formulation was found to within the range of1.17±0.12 to 1.16±0.13 (good flow property). The values of pre- compression parameters evaluated were within the prescribed limits and indicated good free flowing properties. Evaluation of formulated granules showed significant increase in bulk and tapped density with increase in concentration of starch and the good correlation was observed between the concentrations of disintegrant.

Post-compression evaluation parameter of tablet

Table 9. Post-Compression Parameters of Formulation Prepared By Wet Granulation

Evaluation parameter	Formulation code				
	F_1	F_2	F_3	F_4	F_5
Thickness(mm)	4.854±0.034	4.792±0.049	4.792±0.049	4.792±0.049	4.792±0.049
Hardness (kg/cm^2)	3.05±0.42	3.12±0.46	3.70±0.41	3.56±0.46	3.32±0.40
Friability (%)	0.65	0.71	0.73	0.70	0.73
Weight variation	0.399±0.02	0.400±0.02	0.400±0.02	0.401±0.02	0.400±0.02
Wetting time(sec.)	53	55	51	54	55
Disintegration time	8	10	12	11	14

% Drug content	92	90	93	86	88

It was observed that ibuprofen tablets prepared with papaya and corn starch passes the friability test and was found to be well within acceptable limits for all the formulation. The friability test showed that the Corn starch had slightly less binding strength than that of Carica papaya starch.

Comparative Study Of In Disintegration Time And Hardness Of Marketed Product And Optimized Formulation

Table 10 Comparative Study Of In Disintegration Time And Hardness Of Marketed Product And Optimized Formulation

Sr.no.	Ibuprofen tablet	Disintegration Time(min.)	Hardness (kg/cm^2)
1	Marketed tablet	12	3.68
2	Batch F_1	8	3.05
3	Batch F_2	10	3.12
4	Batch F_3	12	3.70
5	Batch F_4	11	3.56
6	Batch F_5	14	3.32

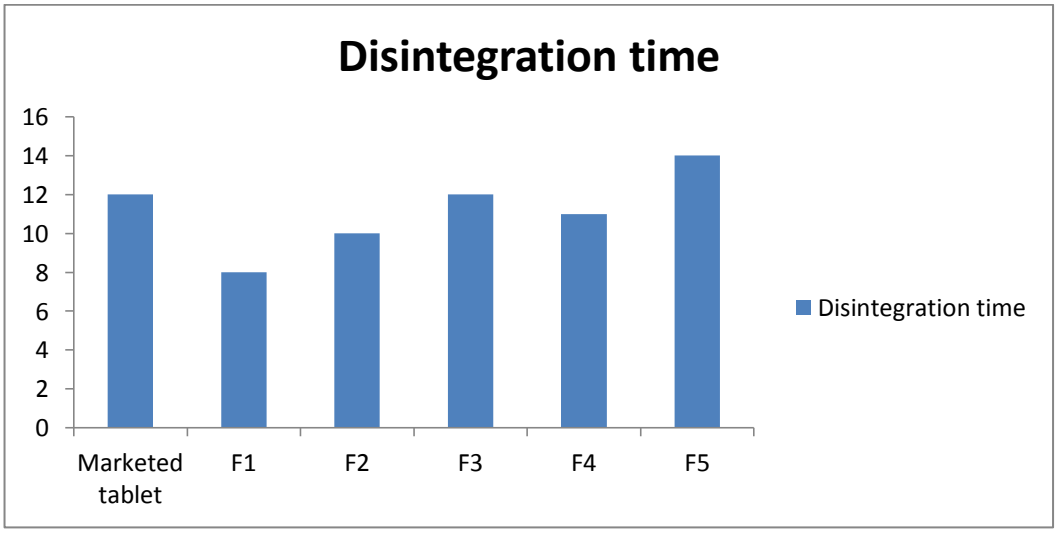

Fig. – 7 Comparative Disintegration time marketed tablet and formulation

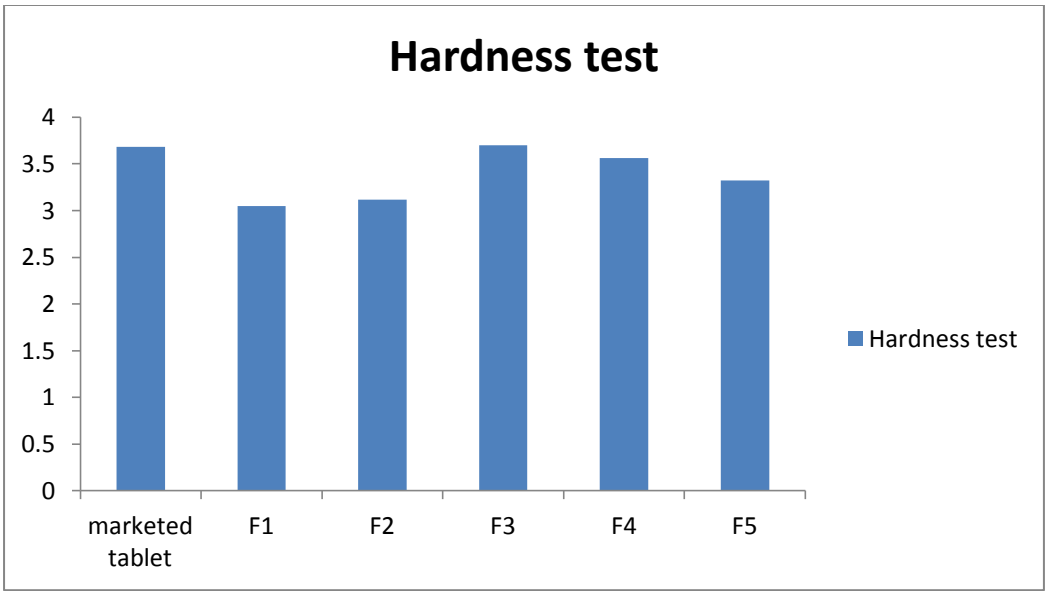

Fig. – 8 Comparative study of hardness test

Disintegration time observed was less with papaya starch at all the concentrations employed compared to those of corn starch which may be due to higher swelling capacity subjected to good disintegration property of Carica papaya. The study of disintegrating property of all the formulations showed that the disintegration time for the tablets prepared with Carica papaya was less than that of Corn starch (**Table 10**) reflecting its good disintegrating characteristic.

Table no. 11 Dissolution of marketed product and Prepared formulation F_1

Sr. no	Time (Min)	Marketed Product	F_1
1	5	75	81
2	10	80.2	84
3	15	82.44	86
4	20	86.21	90
5	25	88	91
6	30	90	92
7	40	92	92

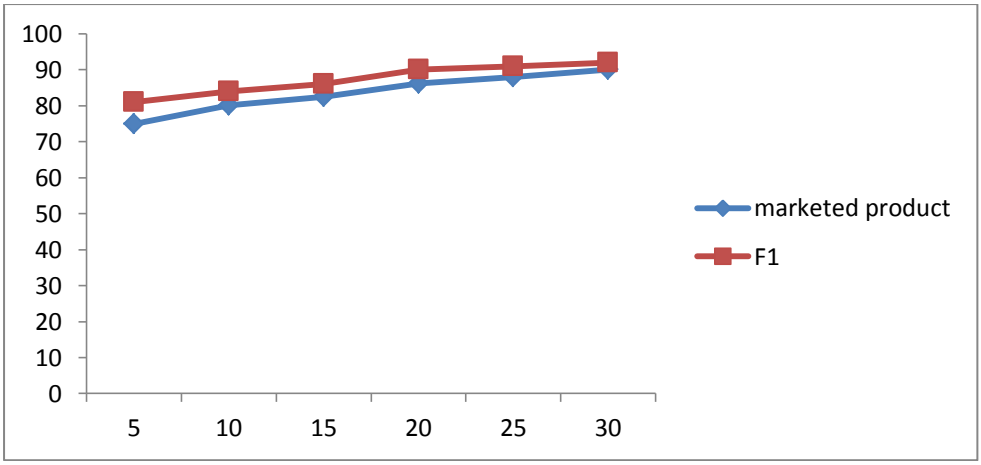

Fig. – 9 compared study of marketed tablet and prepared formulation

Conclusion:-

The study provide some insights into the relative effectiveness of papaya starch as disintegrating agent over corn starch In addition to this it is observed that it maintains mechanical strength of a tablet in terms of friability and hardness. The dissolution studies suggest that tablets (batch F1) containing 10% Carica papayastarch gives 92 % of drug release after specified dissolution test time. Thus it can be concluded that the starch isolated from unripe papaya fruit possesses significant disintegrating properties and will excellent scope as disintegrant in pharmaceutical formulations. Papaya starch can used as a promising pharmaceutical excipient in tablet technology as, it will be show adequate physicochemical and disintegrating properties.

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