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Original Article

FORMULATION AND EVALUATION OF ORODISPERSIBLE TABLETS (ODTS) OF DICLOFENAC SODIUM BY USING SUPERDISINTEGRANT FROM NATURAL ORIGIN

SATYAJITH PANDA[1], NODAGALA HEMALATHA[1*], PANCHAGNULA UDAYA SHANKAR[1], SRINIVASA RAO BARATAM[2]

[1]Maharaja's College of Pharmacy, Andhra University, Phoolbaugh, Vizianagaram, Andhra Pradesh, 535002, India, [2]St. Ann's College of Pharmacy, Cantonment, Andhra University, Vizianagaram, Andhra Pradesh, 535003, India
Email: hemalathanodagala@gmail.com

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ABSTRACT

Objective: In this study, a polysaccharide isolated from the seeds of *Cajanus cajan* (pigeon pea) was investigated as a super disintegrant in the orodispersible tablets of diclofenac sodium.

Methods: Diclofenac sodium tablets were prepared separately using different concentrations (5%, 7.5%, 10%, and 15% w/w) of isolated *Cajanus cajan* seed polysaccharide (natural) and sodium starch glycolate (synthetic) as super disintegrant by the direct compression method. Evaluation of tablets was done for various pre-and post-compression parameters. The stability studies were performed on optimized formulation F5. The disintegration time and *in vitro* drug release of the formulation F5 was compared with pregelatinized starch and synthetic super disintegrant (sodium starch glycolate).

Results: The drug-excipient interactions were characterized by Fourier transform infrared studies. The Optimized formulation F5 containing 15% polysaccharide showed wetting time of 118.7 seconds with 105.3 seconds of disintegration time and 95.61% dissolved in 3 min.

Conclusion: The present work revealed that *Cajanus cajan* seed polysaccharide has a good disintegrating agent in the formulation of orodispersible tablets.

Keywords: Diclofenac sodium, Pigeon starch, Sodium starch glycolate, Orodispersible tablets (ODTs)

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INTRODUCTION

Orodispersible tablets (ODTs) are solid dosage forms containing medicinal substances which disintegrate rapidly, usually in a matter of seconds, when placed on a tongue. ODTs taken without administration of water, it shows better patient compliance [1, 2].

The technologies utilized for the preparation of ODTs include lyophilization, direct compression, moulding, cotton candy process, spray drying, sublimation, mass extraction, and quick dissolving film formation. These techniques are based upon the principles of increasing porosity and the addition of super disintegrants and water soluble excipients in the tablets [2-4]. Natural polymers are ubiquitous material in the plant world and most useful to humans as food preparations, binding agent, disintegrating agent, and thickener [5]. They act as vehicles which transport the incorporated drug to the site of absorption and are expected to guarantee the stability of the incorporated drug, the precision, and accuracy of the dosage, and also improve the organoleptic properties of the drugs [6]. Native starch can be modified, causing a change in its physical and chemical parameters. These changes may be achieved by altering starch properties such as pasting temperature, viscosity, surface charge and hydrophilic/hydrophobic nature [7].

Excipients from natural sources have an advantage over synthetic excipients in that they are eco-friendly, biocompatible, local accessibility, low price, nontoxic, nonirritating when compared to synthetic excipients. Examples of natural excipients are *Lepidus sativum*, locust bean gum, isapghula husk, hibiscus, fenugreek [8]. *Cajanus cajan* common names are red gram, congo pea, gungo pea, arhar, pigeon pea. Chemically *C. cajan* containing cajanin, pinostrobin, longistylin, vitexin, orientin. *C. cajan* has several medicinal uses mostly used as relief of pain in traditional Chinese medicine and as a sedative [9]. Diclofenac Sodium is a phenyl-acetic acid derivative, Analgesic and anti-inflammatory drug belonging to the category of a preferential COX-2 inhibitor. The molecular weight of diclofenac sodium is 318.13 g/mol, and its half-life is 1-2 h. It is mainly used as a sodium salt for the relief of pain and inflammation in various conditions [10]. The present research work was aimed at the formulation and evaluation of ODTs of diclofenac sodium by direct compression method using a natural super disintegrant to produce a rapid onset of action and better patient compliance.

MATERIALS AND METHODS

Materials

Diclofenac sodium, Aspartame, Sodium starch glycolate was obtained from Yarrow Chem. Products of Mumbai, India. Lactose monohydrate was obtained from Finar Chemicals Ltd, Ahmedabad, India. Talc was obtained from Loba Chemie Pvt. Ltd., Mumbai. Magnesium stearates were obtained from Moly Chem, Mumbai. *Cajanus cajan* seeds (Pigeon Pea) were collected from the local market. All reagents used were of analytical grade.

Extraction of Pigeon pea starch

Pigeon pea grains were washed repeatedly and milled into a fine paste using a laboratory blender. The slurry was strained through a fine muslin cloth and the filtrate was allowed to settle. The supernatant was decanted at 12 h intervals and the starch sediment was washed with distilled water. The starch sediment was spread on trays and placed in a hot air oven at 60 °C for 2 d. The dried mass pulverized using a mortar and pestle and a laboratory blender and the fine powder obtained was sieved using a sieve with the mesh size of 60 mm. The obtained starch was weighed and stored in an airtight container.

Pregelatinization of pigeon pea starch

15 g of pigeon pea starch was weighed and 5 ml of water added and placed over boiling water-bath. The mixture was continuously stirred over the water bath and 30 ml of water was added again with continuous stirring. This process was continued until the starch was well prepared using 73 ml of water in all. The prepared Pregelatinized starch was dried in a hot air oven at 60 °C for 24 h shown in fig. 1d.

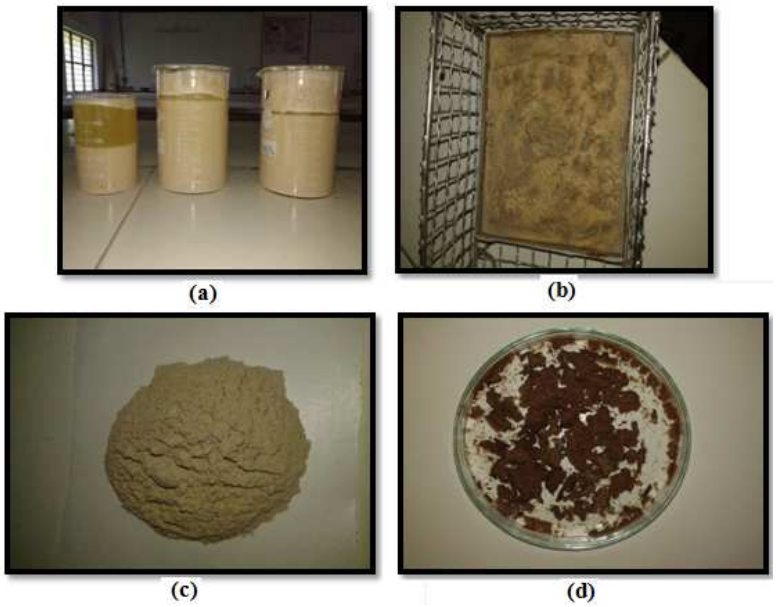

Fig. 1: (a). Sedimentation of Pigeon pea starch; (b). Separation of pigeon pea starch; (c). After drying the Pigeon pea starch; (d) Pregelatinized starch

Formulation of ODTs

ODTs of diclofenac sodium were prepared by direct compression method using natural super disintegrant at the concentrations of 5%, 7.5%, 10%, and 15% w/w. All the ingredients are passed through the 60 mesh sieve. A weighed quantity of each ingredient was taken, and the powder blend was uniformly mixed and compressed into tablets of 200 mg using 8-mm round flat punches on a rotary punching machine (Rimek Tabletting Machine (Karnavti Engg, Ahmedabad)). The composition of each formulation is given in table 1.

Table 1: Formulation of tablets by direct compression method

Ingredients	Formulation code									
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Diclofenac Sodium	100	100	100	100	100	100	100	100	100	100
Pigeon pea starch	-	10	15	20	30	-	-	-	-	-
Pregelatinized Starch	-	-	-	-	-	10	15	20	30	-
Sodium starch glycolate	-	-	-	-	-	-	-	-	-	30
Lactose monohydrate	95	85	80	75	65	85	80	75	65	65
Aspartame	1	1	1	1	1	1	1	1	1	1
Talc	2	2	2	2	2	2	2	2	2	2
Magnesium stearate	2	2	2	2	2	2	2	2	2	2
Total weight (mg)	200	200	200	200	200	200	200	200	200	200

Swelling capacity

10 g of pigeon pea starch was weighed and put in a 100 ml of measuring cylinder. The tapped volume (Vx) occupied by the powder was determined and recorded. About 20 ml of distilled water was added to form a dispersion of the starch. The dispersion was made up of the 100 ml of water and allowed to settle [10]. The dispersion was allowed to stand for 24 h before the sedimentation volume (Vv) was measured and the swelling capacity was calculated using the formula:

$$\text{Swelling capacity} = \frac{Vx}{Vv}$$

Vx=Tapped volume

Vv=Sedimentation volume

Angle of repose

The angle of repose (θ) was carried out by using the fixed funnel method. Accurately weighed required quantity of powder mixture was taken in a funnel. The height of the funnel was adjusted in such a way that the tip of the funnel just touched the apex of the heap of the pile. The powder was allowed to flow through the funnel without any resistance on to the surface. Finally, the diameter and height of the powder were measured [11]. The angle of repose was calculated using the following equation:

$$\theta = \tan{-1}\left(\frac{h}{r}\right)$$

Where h and r are the height and radius of the powder cone respectively.

Determination of bulk and tapped densities

Approximately 10 g of powder was weighed and transferred into a 100 ml measuring cylinder. The cylinder was gently twisted to obtain a levelled surface of the powder. The initial volume occupied in the cylinder was noted as the Bulk density. The powder in the cylinder was then tapped 100 times at a time and the new volume occupied after each round of tappings noted as the Tapped density. The tapping was continued until no further change in volume was noted [11]. Bulk density and Tapped density were calculated using the following formula:

$$\text{Bulk density} = \frac{\text{Weight of the powder}}{\text{bulk volume}}$$

$$\text{Tapped density} = \frac{\text{Weight of the powder}}{\text{Tapped volume}}$$

Compressibility index and Hausner's ratio

The compressibility index and the Hausner's ratio have become the simple, fast and popular methods of predicting powder flow characteristics [12]. The compressibility index and Hausner's ratio were determined by measuring both the bulk density and tapped density of granules:

$$\text{ompressibility index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100$$

$$\text{Hausner}^{'}\text{sratio} = \frac{\text{Tapped density}}{\text{bulk density}}$$

Tablet hardness

Hardness is an important parameter that prevents breakage of tablets during storage, transportation, and handling. Hardness can be measured by using Monsanto hardness tester and was expressed in terms of kg/cm^2 [13].

Tablet thickness

The tablet was placed between the two arms of the vernier callipers, and the thickness was measured. Five measurements were taken [14].

Weight variation

20 tablets were selected randomly from each formulated batch and weighed individually. The individual weights were compared with the average weight for the weight variation [15].

Friability

Friability is a measure of mechanical strength of the tablet. If a tablet has more friability it may not remain intact during packaging, transport, and handling. 5 tablets were measured and placed in a USP type Roche friabilator. The friability was checked at 25 rpm that is 100 revolutions for 4 min. Then the tablets were dusted and reweighed. The weight loss should not be more than one per cent [16]. The percentage weight loss (friability) was calculated as:

$$\text{Friability} = \frac{\text{Initial weight of the tablet} - \text{Final weight of the tablet}}{\text{Initial weight of tablet}} \times 100$$

Drug content

10 tablets were randomly weighed and crushed to fine powder, and a quantity of powder equivalent to 50 mg of diclofenac sodium was put in a 100 ml of volumetric flask and diluted with methanol. Then the solution was filtered finally made up to 100 ml using PH 6.8 phosphate buffer. The diclofenac sodium content was determined by measuring the absorbance at 280 nm using a UV-Visible Spectrometer (Aligent technology, Malaysia). The drug content was determined using the standard calibration curve. The mean per cent drug content was calculated as an average of three determinations [11, 23].

Wetting time

Wetting time is an important parameter. It helps in studying the effect of different excipients in the disintegration of the tablet. A piece of tissue paper folded twice was placed in a small Petri dish containing 6 ml of pH 6.8 phosphate buffer and add one millilitre of water containing amaranth (water soluble dye), a tablet was put on the paper, and the time for complete wetting was measured. Three trials for each batch were performed and the standard deviation was also determined [17].

Water absorption ratio (R)

The weight of the tablet before keeping in the Petri dish was noted (W_b). Fully wetted tablet from the Petri dish was taken and reweighed (W_a) [17]. Water absorption ratio(R) was determined by using the following equation:

$$R = 100 \times \frac{Wa - Wb}{Wb}$$

Where W_b and W_a denote the tablet weights before and after water absorption respectively.

***In vitro* disintegration time**

Disintegrating apparatus is used. It consisting of a wire basket of 3 cm height and 2 cm diameter and mesh size of # 10 is placed above a beaker containing 900 ml of pH 6.8 phosphate buffer. The assembly is supported with a heater to maintain the temperature at 37 °C and a magnetic stirrer. Orodispersible tablets should be disintegrating within seconds [18].

***In vitro* dispersion time**

In vitro dispersion time was done as an assessment of the grittiness which arises due to the disintegration of the tablet into coarse particles. The test was performed by placing two tablets in 100 ml water and stirring gently until the tablets get completely disintegrated. The formulation is considered to form a smooth dispersion if the complete dispersion passes through a sieve screen with a nominal mesh aperture of 710µm without leaving any residue on the mesh [19].

***In vitro* dissolution**

Paddle type dissolution apparatus containing 900 ml of pH 6.8 phosphate buffer as dissolution medium, maintained at 37±0.5 °C and with a stirring speed of 100 rpm was employed to assess the *in vitro* drug release characteristics of the tablet. Orodispersible tablets from each formulated batch containing an equivalent of 100 mg of the drug were weighed accurately and placed inside the dissolution medium. The whole process was carried out under sink condition for 15 min. At predetermined time intervals, sample (5 ml dissolution medium) were collected and passed through filter paper. Immediately an equal volume of fresh medium (maintained at 37±0.5 °C) was used as replenishment. Withdrawn samples were diluted suitably and assayed spectrophotometrically at the detected λ_{max} values of the respective drug in the same medium. At this wavelength, the tablet interferes with the absorption of the drug in the medium. For each batch, the experiment was followed for six times [15].

Drug excipients interaction study

The drug and excipient interactions were studied using Fourier transform infrared spectroscopy (IR-Prestige 21, Shimatzu make, Japan). The pure drug, the mixture of the drug with the polymer (1:1), and the optimized formula (a mixture of the drug with various excipients used in the preparation of ODT formulation) were characterized by Fourier transform infrared spectroscopy so the compatibility can be determined. The scanning range was 400-4000 cm^{-1} and IR spectra of samples were obtained using the KBr disc method. Differential scanning calorimetry (DSC) was performed using PerkinElmer instruments, Singapore. The thermograms of pure diclofenac sodium and physical mixture of drug and excipients were obtained at a scanning range of 10 °C/minute conducted over a temperature range of 30-300 °C. ODT tablets were subjected to XRD (Ultima111 instrument, Rigaku make Japan), with Cu-Kα radiation (400KV, 30Ma, and scan speed 1/minute) to investigate the physical state of diclofenac sodium [20, 22].

RESULTS

FTIR spectrum of pure diclofenac sodium by KBr pellet method was shown in fig. 2. The FTIR of the pure drug was characterized peak at around 1602.85 cm^{-1} C=C and COOH-Carboxylic acid group stretching at 3203.76 cm^{-1}and N-H (amine) group stretching at 3387.00 cm^{-1}were observed. Before the formulation of the dosage form, drug-excipients studies were done through visual inspection and FTIR. The drug alone and combination with other polymers are placed in vials for 3 to 4 mo. There is no significant difference in the colour of preparation during this period which means that there might not be any incompatibility present. The obtained FTIR spectra for the physical mixture are studied at 4000 cm^{-1}to 400 cm^{-1}and shown in the fig. 3. FTIR result showed no major shift in the peaks which adds up to the conclusion that there might not be any incompatibility between the drug and the excipients.

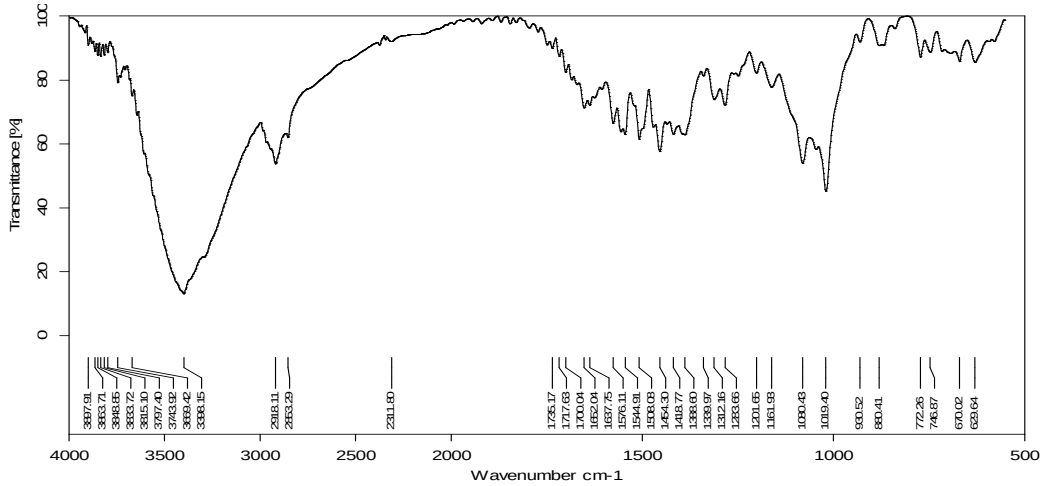

Fig. 2: Fourier transform infrared spectrum of pure diclofenac sodium

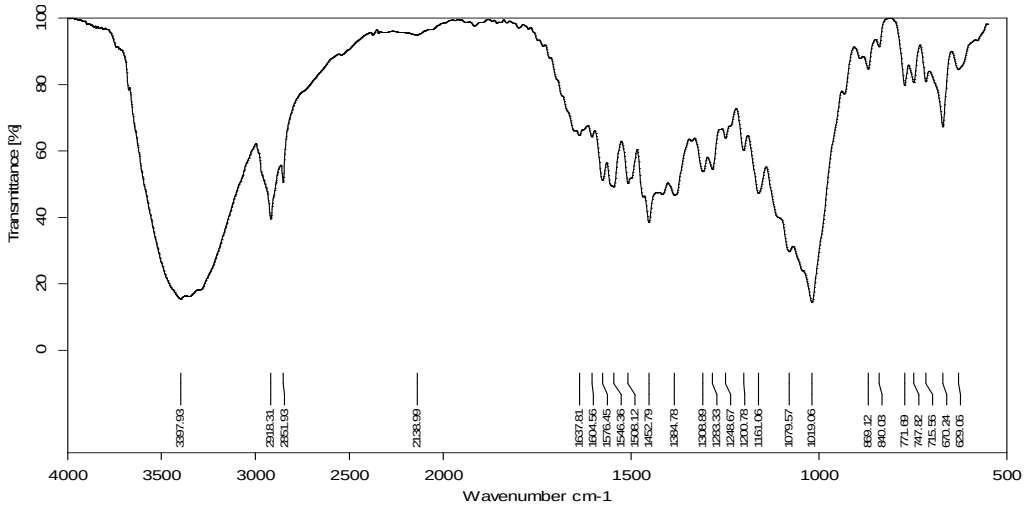

Fig. 3: Fourier transform infrared spectra for the physical mixture of drug and excipients

The melting point of the pure drug (Diclofenac sodium) was determined using melting point and found to be in between 250-300 °C. DSC curve obtained also shows the melting point temperature at 283.38 °C as shown in fig. 4. DSC thermogram of the physical mixture formulation containing diclofenac sodium and pigeon pea seed starch was shown endothermic peak 273.42 shown in fig. 4. Thus DSC analysis confirmed that both drug and pigeon pea seed starch were compatible with each other.

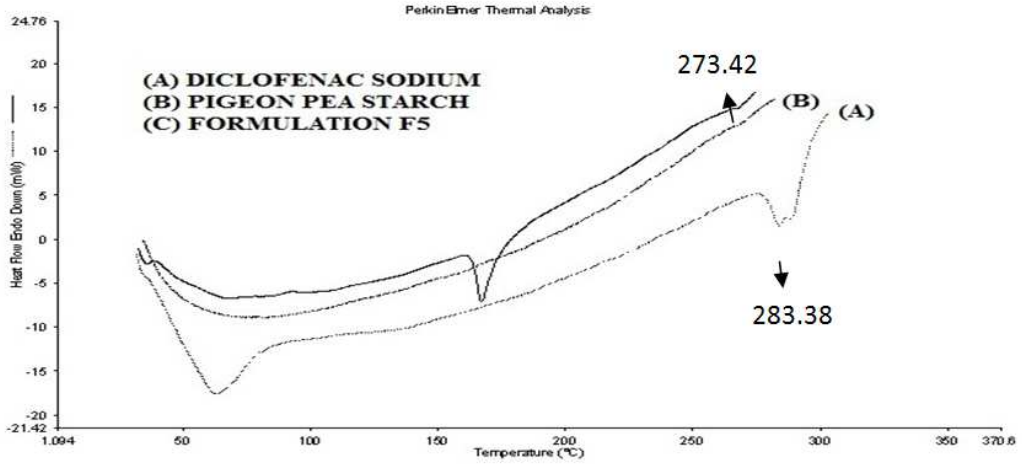

Fig. 4: Differential scanning calorimetry (DSC) of pure diclofenac sodium, pigeon pea starch, and formulation F5

The crystalline structure of pure diclofenac sodium was confirmed from the diffractogram obtained during the X-ray crystallographic study shown in fig. 5. The diffractogram of the physical mixture of drug and excipients displayed an identical pattern, but with a minor reduction in peak intensities shown in fig. 5. It demonstrates the homogeneous distribution of drug inside the tablet and the drug from crystalline to an amorphous state and it doesn't affect the therapeutic efficacy of the drug as all the functional groups were present.

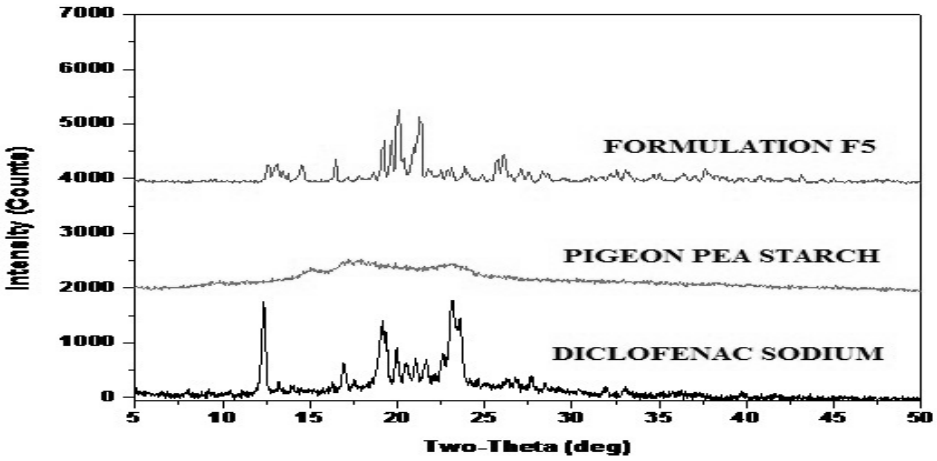

Fig. 5: X-Ray analysis of formulation F5, pigeon pea starch and diclofenac sodium

Table 2: Physicochemical characterization of powder blend

Formulation code	Angle of repose (θ)	Bulk density (g/cm³)	Tapped density (g/cm³)	Compressibility index (%)	Hausner's ratio
F1	38±1.01	0.65±0.5	0.81±0.16	22.0±0.05	1.21±0.032
F2	27.4±0.2	0.47±0.02	0.61±0.01	13.43±1.20	1.17±0.026
F3	26.1±0.2	0.46±0.04	0.62±0.02	15.16±1.43	1.19±0.052
F4	25.7±0.5	0.48±0.02	0.56±0.05	14.08±1.60	1.27±0.031
F5	24.8±0.9	0.46±0.03	0.64±0.31	15.23±0.53	1.18±0.025
F6	28.6±0.2	0.48±0.12	0.53±0.02	14.67±0.40	1.26±0.015
F7	27.9±0.6	0.45±0.15	0.61±0.05	14.28±1.56	1.21±0.004
F8	26.4±0.2	0.44±0.01	0.58±0.02	13.56±0.05	1.19±0.021
F9	25.9±0.9	0.42±0.06	0.51±0.01	12.81±0.84	1.15±0.035
F10	28.8±0.1	0.48±0.02	0.56±0.05	14.08±1.35	1.27±0.033

(mean±SD, n=3)

The angle of repose of formulation blend was found to be 24.8 to 28.8, which indicate the good flow of the drug. The Carr's index was found to be in the range of 12.81 to 22.0 indicating good compressibility of the powder. Hausner's ratio was found in the range of 1.15 to 1.27 is good as reported in table 2. The formulation of ODTs of diclofenac sodium using natural super disintegrant and all formulations can be prepared by direct compression method. The natural polymer extracted from *C. Cajan* seeds was a light brown coloured powder. Carr's index and angle of repose indicated that the natural super disintegrant has good flow properties.

Table 3: Post compression parameters of diclofenac sodium orodispersible tablets

Formulation code	Thickness (mm)	Hardness (kg/cm²)	Friability (%)	Weight variation(mg)
F1	2.14±0.02	4.7±0.20	0.6±0.03	200.1±0.51
F2	2.19±0.03	4.6±0.18	0.5±0.01	200.1±0.55
F3	2.32±0.05	4.6±0.17	0.5±0.01	200.2±0.14
F4	2.37±0.08	4.5±0.14	0.5±0.03	200.3±1.46
F5	2.29±0.03	4.1±0.11	0.5±0.03	200.1±1.50
F6	2.17±0.10	4.5±0.17	0.6±0.02	199.8±0.62
F7	2.22±0.08	4.5±0.15	0.6±0.01	200.4±0.57
F8	2.27±0.06	4.3±0.12	0.5±0.01	200.3±0.53
F9	2.31±0.13	3.8±0.12	0.5±0.02	200.1±0.55
F10	2.18±0.04	4.7±0.19	0.5±0.04	200.1±1.45

(mean±SD, n=3)

The hardness of the tablets was determined and was found to be in the range of 3.8-4.7 kg/cm^2. Friability was observed to be between 0.5%-0.6%, which was less than 1% indicating that the tablets had good mechanical resistance. The results of the post-compression parameters are summarized in table 3 and 4.

The wetting time and water absorption ratio are important criteria for understanding the capacity of a disintegrant to swell in the presence of a small amount of water. The wetting time for all formulations was found to be between 58.22±0.46 to 195.12±1.62 s. The *in vitro* disintegration time for the formulations F1 to F10 is summarized in table 4. The *in vitro* drug release rate from the formulations containing natural super disintegrant was found to be rapid when compared to the formulation containing sodium starch glycolate. The *in vitro* drug release profile of the formulations F1 to F10 are represented in fig. 6, 7 and 8.

Table 4: Post compression parameters of Diclofenac sodium orodispersible tablets

Formulation code	*In vitro* disintegration time (s)	*In vitro* dispersion test (s)	Wetting time (s)	Water absorption ratio
F1	237.2±1.35	125±1.32	195.12±1.62	40.02±0.21
F2	167.1±0.24	58.2±0.53	145.10±0.29	42.73±0.25
F3	144.2±0.39	55.7±0.89	141.34±0.25	45.23±0.32
F4	135.5±0.68	50.3±0.62	131.15±0.33	47.08±0.24
F5	105.3±0.57	48.6±0.30	118.17±0.21	48.05±0.28
F6	179.2±0.48	68.8±1.74	90.23±0.35	50.12±0.47
F7	159.4±0.67	60.0±1.52	80.08±0.42	50.73±0.36
F8	153.3±0.63	56.8±1.68	66.47±0.39	51.45±0.59
F9	140.5±0.41	50.4±1.24	58.22±0.46	52.38±1.34
F10	174.3±0.58	70.6±1.67	153.14±0.83	53.27±0.75

(mean±SD, n=3)

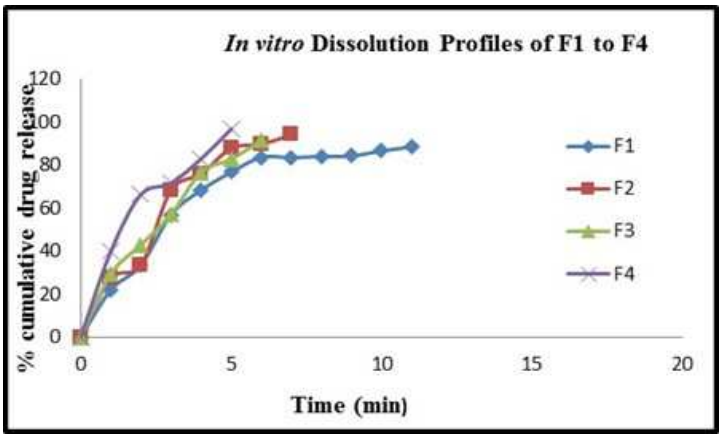

Fig. 6 : In vitro drug release profile of formulations F1,F2,F3 and F4. (Values are expressed as mean±SD, n=3)

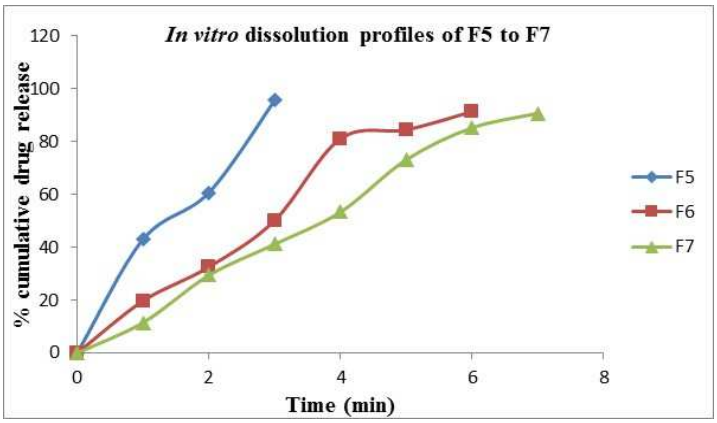

Fig.7: In vitro drug release profile of formulations F5,F6 and F7. (Values are expressed as mean±SD, n=3)

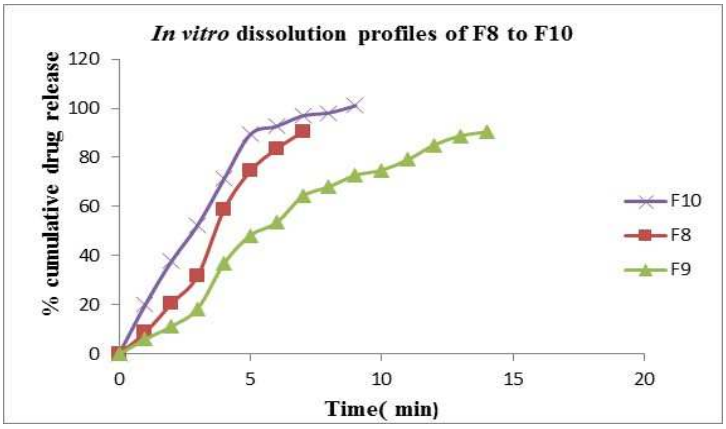

Fig. 8: In vitro drug release profile of formulations of F8,F9, and F10 (Values are expressed as mean±SD, n=3)

Table 5: *In vitro* drug release profile of ODTs of Diclofenac sodium

Time (min)	*In vitro* drug release profile of ODTs of Diclofenac sodium from F1 to F5				
	F1	**F2**	**F3**	**F4**	**F5**
0	0	0	0	0	0
1	21.94±0.54	27.44±0.65	29.24±0.54	39.77±0.86	42.99±0.64
2	33.41±0.43	33.37±0.75	42.90±0.64	66.32±0.43	60.70±0.85
3	56.93±0.74	68.41±0.64	57.02±0.75	71.62±0.75	95.61±0.43
4	68.4±0.21	75.91±0.32	76.68±0.65	82.98±0.43	
5	76.77±0.65	87.95±0.64	82.83±0.32	96.85±0.56	
6	83.7±0.35	89.81±0.68	91.64±0.98		
7	83.57±0.75	94.18±0.84			
8	84.13±0.32				
9	84.38±0.87				
10	86.67±0.97				
11	88.57±0.56				
12	85.64±0.54				
13	82.83±0.77				
14	76.81±0.56				
15	76.59±0.79				

(mean±SD, n=3)

Table 6: *In vitro* drug release profile of ODTs of Diclofenac sodium

Time (min)	*In vitro* drug release profile of ODTs of Diclofenac sodium from F1 to F5				
	F6	**F7**	**F8**	**F9**	**F10**
0	0	0	0	0	0
1	19.71±0.21	11.51±0.35	8.83±0.35	6.12±0.35	20.02±0.35
2	32.56±0.35	29.46±0.24	20.55±0.54	11.33±0.46	37.74±0.52
3	50.18±0.51	41.18±0.65	31.96±0.36	18.58±0.31	52.46±0.35
4	81.18±0.54	53.36±0.45	58.69±0.45	36.82±0.65	71.19±0.69
5	84.53±0.25	73.17±0.57	74.42±0.36	48.30±0.95	89.31±0.36
6	91.48±0.74	85.22±0.64	83.48±0.64	53.48±0.5	92.63±0.52
7		90.74±0.22	90.37±0.32	64.21±0.36	96.92±0.35
8				68.08±0.51	98.13±0.38
9				72.77±0.69	101.01±0.25
10				74.82±0.32	
11				79.07±0.21	
12				85.09±0.25	
13				88.75±0.65	
14				90.34±0.45	
15					

mean±SD, n=3

DISCUSSION

The formulation of ODTs was made by diclofenac sodium using natural super disintegrant (*Cajanus cajan*). It has good swelling property. So, we have observed that the selected natural super disintegrant was found to be suitable in formulating ODTs of diclofenac sodium. ODTs of diclofenac sodium were prepared by direct compression method using different concentrations (5%, 7.5%, 10%, and 15%) of *C. Cajan* as a natural super disintegrant and sodium starch glycolate (15%) as a synthetic super disintegrant.

The physicochemical properties of the starches are presented in table 2. The bulk density of the native starch was significantly different from Pregelatinized Starch. The disintegration time values for all the formulations containing native starch (NAS) had the low disintegration time values, the rank order was native starch (NAS)>pregelatinized starch (PG)>sodium starch glycolate (SSG). The least dissolution values were obtained from the native starch, which can be correlated with the swelling capacity of the starch. The highest disintegration time observed for SSG. The ranking order was NAS>PG>SSG. *In vitro* dispersion and water absorption ratio of native starch shows a better result than that of pregelatinized and sodium starch glycolate. The ranking order was NAS>PG>SSG. Native starch had high wetting time values when compared to other formulations. The ranking order was PG>NAS>SSG, because some quantity of water was added to pregelatinized starch and heated to boiling water bath. So, the prepared gelatinized solution containing hydration capacity. Tablets containing pigeon pea starch 15 % w/w (F5) showed better drug release (95.61 %) at 3 min compared to that of 5 % w/w (F2), 7.5 % w/w (F3), 10 % w/w (F4) as shown in table 5 and 6. Tablets containing Pregelatinized starch 5 % w/w (F6) showed better drug release (91.48 %) at 6 min compared to that of 7.5 % w/w (F7), 10 % w/w (F8), 15 % w/w (F9) as shown in table 5 and 6. Tablets containing sodium starch glycolate 15 % w/w (F10) showed drug release (92.63) at 6 min. In all the ten formulations F5, F6 and F10 formulations containing 15 % w/w, 5 % w/w and 15 % w/w concentrations of pigeon pea starch, pregelatinized starch, sodium starch glycolate showed higher drug release in less time compared to other formulations. Among all the formulations F5 formulation containing 15 % w/w pigeon pea seed starch showed the rapid drug release (95.61 %) within 3 min. It was observed that the % drug release increased within concentration of the disintegrant and decreases in time. In the present research work, the quantity of pigeon pea seed starch used for the designing of the ODTs is less than the above mentioned quantities in ayurvedic system of medicine. So, they are safe to use and also effectively used as a natural super disintegrants [24].

The drug release of the F5 formulation was rapid and better compared to the other formulations. The formulation F5(15%) natural super disintegrants showed a rapid disintegration, dissolution time, *in vitro* dispersion time and water absorption ratio as compared with the formulation prepared using a synthetic super disintegrants at the same concentration level. Hence, batch F5 was considered the optimized formulation.

CONCLUSION

From this work, concluded that the native and modified form of pigeon pea starch (*C. Cajan*) is a potential candidate for use as a disintegrant in the formulation of ODTs. Because *C. cajan* is inexpensive, nontoxic, compatible and easy to manufacture, compared to synthetic super disintegrant. So, it can be used in place of commercially available synthetic super disintegrant. The prepared tablets also offer further advantages in terms of patient compliance, quick onset of action, high bioavailability, and good stability all of which make these tablets a better dosage form for the treatment of inflammation.

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AUTHORS CONTRIBUTIONS

All the author have contributed equally

CONFLICTS OF INTERESTS

All the authors hereby declaring that there are no conflicts of interest.

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