

## Design and Evaluation of Fast Dissolving Tablet Containing Diclofenac Sodium using *Caesalpinia pulcherrima* Galactomannan as A Natural Superdisintegrant

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**ABSTRACT:** An oral dosage form containing diclofenac sodium prepared by using *Caesalpinia pulcherrima* galactomannan (CPG) as a natural superdisintegrant. In order to prepare the diclofenac sodium tablet, the direct compression method was used. Superdisintegrant property of this polymer is not yet discovered. Trial batches were taken and by that the final formulation were prepared. Superdisintegrant property 3<sup>2</sup> factorial design applied at MET with quantity of drug, CPG and lactose as dependent variables. CPG were used as superdisintegrant and lactose were used as directly compressible excipient. The developed tablets underwent testing for hardness, friability, DT, and in vitro drug release. Design Expert 13 described adequately impact of selected variables (CPG and lactose) at various levels for response under study of disintegration and drug release. The optimized batch showed disintegration time 94±2.00 sec and in vitro drug release between 90.64±0.0023 % The current experimental design study showed that CPG and lactose were effective in developing optimised formulations at low concentrations. It can be inferred from the experimental findings that CPG exhibited superdisintegrant action.

**Keywords:** Diclofenac sodium, *Caesalpinia pulcherrima* galactomannan (CPG), Superdisintegrant, Lactose, Direct compression.

### INTRODUCTION

*Caesalpinia pulcherrima* (CP) belongs to Leguminosae (family: Fabaceae and subfamily: Caesalpinioideae) is a traditional medicine plant with thorny bushy legume locally known as Dwarf Poinciana, Dwarf Flamboyant, Pride of Barbados, Barbados Pride, Barbados Flower-fence, Peacock Flower, Paradise Poinciana, Red Bird-of Paradise is widely distributed in tropical and sub-tropical regions like India, Myanmar, Vietnam, Sri Lanka, and Malay Peninsula. Various pharmacological activities of *C. pulcherrima* L. have been reported such as analgesic and anti-inflammatory, antiulcer, antimicrobial, antibacterial and antifungal activity (Thombre *et al.*, 2013).

Leguminosae, in particular, those with (1-4) are natural polymers like CPG that are extracted from the endosperm of *C. pulcherrima* seeds. a-D-

galactopyranosyl residues linked in pairs of 1–6 with b-D-mannopyranosyl residues, with an M/G ratio of 2.80 (Thombre *et al.*, 2016; Suryawanshi *et al.*, 2015).

Oral administration is the most popular route, because of the simplicity of consumption, the lack of pain, the variety (to accept a wide range of drug candidates), and, most significantly, patient compliance. Furthermore, because solid oral delivery methods do not require sterile conditions, they are less expensive to produce. A wide range of pharmaceutical research is focused on finding new dosage formulations for oral administration. The majority of these initiatives have centered on either developing new drugs or improving existing ones and also increasing patient compliance or improving delivery methods. Orally disintegrating systems have been a favorite of product development scientists among the dosage forms produced to make treatment easier.

The fast-dissolving tablet (FDT) has exceptional disintegration capabilities and may dissolve in a matter of seconds in the mouth without water. Saliva immediately enters the pores of an FDT once it is inserted into the mouth, producing fast disintegration (Puttewaret *et al.*, 2010). Environmentally friendly, economical, and non-toxic (Goksen *et al.*, 2023). Absolute bioavailability of diclofenac sodium was about 50-60% and half-life was 2 hours which was very protein bound (>99%). Due to its high permeability and poor water solubility, it was classified under class II drug. In the absence of a disintegrant, superdisintegrants are typically added to the formulation to speed up the drug's dissolution. The formulations contain a number of superdisintegrants, including sodium starch glycolate (SSC), croscarmellose sodium, and croscarmellose sodium. It was suggested in the current study to develop an oral medication delivery system using the direct compression approach (Sona and Muthulingam 2011). The current study's goals included the extraction of the CPG, evaluation of the powder's flow quantity to properties (bulk density, tapped density, angle of repose, Carr's index, and Hausner ratio), loss on drying, and comparison of the effectiveness of disintegration with that of two commonly used synthetic superdisintegrants, SSG and croscarmellose sodium. Many physical tests were used to examine the tablets.

**Table 1: Formula for different formulations of Diclofenac sodium tablet.**

Composition	F1	F2	F3	F4	F5	F6	F7	F8	F9
Diclofenac sodium	50	50	50	50	50	50	50	50	50
CPG	0.5	1	1.5	0.5	1	1.5	0.5	1	1.5
Lactose	30	30	30	40	40	40	50	50	50
Magnesium stearate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Talc	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5

**Experimental design.** A combined optimal design was crafted using Design Expert 13.0 comprising two mixture (variable fraction) components CPG and lactose. The main aim was to use disintegrant and binder variable concentration for tablet composition. Thus, two variable fraction components were each set to range from 0.5-1.5% and 30-50% of the tablet composition. The screening was done using a  $3^2$  fractional factorial design, with the two independent factors being CPG and lactose, and the dependent variables being disintegration and dissolution, with the intention of choosing a few crucial variables. For the examination of predictive variables, the CPG was employed as an optimization tool, and it was determined that it was appropriate for the ongoing research (Mishra *et al.*, 2018).

CPG and lactose concentrations have an impact on the disintegration and dissolution profile. There was no statistical evidence apart from that of uncertain variables have an impact on important responses. There was a chance that uncontrollable variables have little impact on response and can be checked without screening. Screening in this research was done for CPG and lactose. For dependent variables like disintegration and dissolution profile, these two variables were

## MATERIALS AND METHODS

**Materials.** The seeds of *C. pulcherrima* plant were obtained from Nasik, Maharashtra, India. diclofenac sodium, lactose, magnesium separate, talc, and all other ingredients used throughout the study were of analytical grade.

### Methods.

**Extraction and Purification of *C. pulcherrima* galactomannan.** CPG was isolated and evaluated for various parameters like moisture content, ash value, swelling index. The polymer was also evaluated for biocompatibility study in previous study (Thombre and Gide 2013; Suryawanshi *et al.*, 2014).

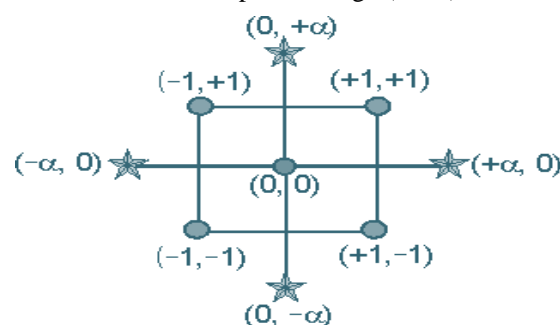
**Formulation of Fast Dissolving Tablet.** The formula utilised in the study is presented in Table 1 along with the preparation of the 50 mg diclofenac sodium tablet utilising the direct compression method. The formulation includes lactose as a directly compressible excipient and CPG in various ratios (for optimization). To achieve homogeneity, each ingredient was run through Sieve No. 60 individually before being fully combined. Using a rotary tablet punching machine, the combined material was immediately compressed into a tablet with a 6.3mm punch (MiniPress I, Karnavati, India).

assessed as independent variables (Thombre *et al.*, 2021).

Based on the results of the trial batches, CPG and lactose were used in additional studies at concentrations of 0.5-1.5% and 30-50%, respectively. Two level fractional factorial design represent in terms of  $2^{k-p}$  Where p was fraction of full and  $2^k$  was factorial.

The methodology, which is based on the design of experiments (DoE) principle, consists of different types of polynomial equation generating, experimental designs, and mapping of the response over the experimental domain.

It includes, central composite design (CCD).



**Fig. 1.** Central composite design for two factors.

**Table 2: 3<sup>2</sup> CCD Central Composite Design Matrix.**

Experiment batch	Lactose (mg)	CPG (mg)	DT (Sec.)	Dissolution (%)
F1	30	0.5	170	80.4±0.0033
F2	30	1.5	173	60.23±0.0008
F3	30	1	164	73.58±0.0078
F4	40	1	94	90.64±0.0023
F5	40	0.5	135	77.23±0.0044
F6	40	1	93	88.64±0.0067
F7	40	1	98	90.12±0.0023
F8	40	1	99	90.32±0.0023
F9	40	1.5	140	72.69±0.0023
F10	40	1	99	90.32±0.0023
F11	50	1.5	150	70.00±0.0084
F12	50	1	150	77.34±0.0078
F13	50	0.5	140	78.83±0.0013

For Central Composite Design two experimental variables were selected. 13 batches were prepared accordingly and dissolution profile and disintegration profile of batches done and optimized formulation batch were selected for further formulation process.

#### Physicochemical characterization of galactomannan

**1. Moisture content.** Moisture content was used to check if a sample contained significant amount of moisture or solvents. The material sample was weighed (W<sub>1</sub>) and weighed sample was placed in an oven for two hours. It was then eventually weighed after cooling in a desiccator's dry environment (W<sub>2</sub>).

$$\% \text{ Moisture content} = [(W_1 - W_2) / W_1] * 100$$

Where, W<sub>1</sub>= Initial weight of powder; W<sub>2</sub>= Final weight of powder.

**Swelling index-** Swelling index of CPG was determined using 100 mL graduated cylinder. 1 g of CPG was added in water and make up the volume upto 25 mL. Shaked the graduated cylinder every after 10 min for 1 hours. Allowed it to stand for 24 hours. The swollen mass was measured after 24 hours (Omidian *et al.*, 2008).

Swelling index was determined by

$$\text{Swelling index} = 100 * (V_2 - V_1) / V_1$$

Where V<sub>1</sub>= Initial volume of material before hydration;

V<sub>2</sub>= Volume of hydrated material.

**Viscosity-** 5 mL of distilled water were used to suspend 1 g of CPG powder for 4 hours. To create the 1% concentration, up to 100 mL of distilled water was used. The mixture was homogenised using a mechanical stirrer for 2 hours, and the viscosity was assessed using a Brookfield viscometer, spindle SC4-18 (Brookfield Viscometer, DV-2+LV), operating at 5 revolutions per minute (Babu *et al.*, 2011).

**Ash value-** Two grams of drug powder were taken into the crucible. Warm up the powdered until the carbon is burnt out in muffle furnace. Calculate the ash value after cooling in a desiccator (Khandelwal *et al.*, 2008).

$$\text{Total ash value} = 100(a-b)/c$$

Where, a= weight of empty dish; b= weight of drug taken; c= weight of dish+ ash.

**Evaluation of tablets.** The physical characteristics of each tablet, including weight variation, hardness, friability, disintegration time, wetting time, drug content, and in vitro dissolution studies, were all assessed (Rangole *et al.*, 2008; Taylor *et al.*, 2018).

**2. Thickness.** Vernier callipers (Dial Cappiler/Advance) were used to measure the thickness of the tablets that had been developed. 5 tablets from formulation were used and average value were calculated. It was expressed in mm.

**3. Weight variation.** The homogeneity of the weight of the prepared tablet were examined. 20 tablets were weighed both collectively and separately for this purpose. The average weight was determined from the total weight. The weight of each tablet was then compared to the average weight, to determine whether it was within the allowed range or not.

$$\frac{\text{Average weight of tablet} - \text{Individual weight of tablet}}{\text{Average weight of tablet}} \times 100$$

**3. Hardness.** Hardness of tablet was measured using Monsanto hardness tester (Dolphin). Five tablets were selected randomly and their hardness was measured. Hardness value mean and standard deviations were determined.

**4. Friability.** Roche friabilator (META LAB) was used to determine the tablet friability. The initial weight of 20 tablets was incorporated through a friabilator for 100 revolutions. The tablets were then dedusted, and percentage loss was then calculated. The following formula can be used to determine friability:

$$\% \text{ Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} * 100$$

**5. Wetting time and water absorption ratio.** A petri dish contained a folded piece of tissue paper. 6 mL of water containing the water-soluble dye (eosin) were added to the Petri dish. Tablets that had already been weighed were placed on tissue paper. The amount of time required for water to contact the tablet's upper surface was used to compute the wetting time. The following equation was used to compute the water absorption ratio (R).

$$R = 100 (W_b - W_a) / W_b$$

Where W<sub>a</sub> and W<sub>b</sub> are the weight of tablet before (dry weight) and after water absorption (weight weight) respectively.

**6. Drug content.** Twenty tablets were weighed and powdered. The powdered tablets were dissolved in 100 mL of phosphate buffer, pH 6.8. The solution was filtered, and the amount of drugs was found. The UV spectroscopic technique at 276 nm was used to determine the amount of drug present (Kumar and Babu, 2014).

**7. In vitro disintegration test.** The *in vitro* disintegration time was calculated by using (Electrolab, USP type ED- 2L, Bombay) disintegration test apparatus without disc for six tablets. 900 mL of distilled water kept at  $(37.0 \pm 0.5)^\circ\text{C}$  and stirred at a rate of  $(30 \pm 2)$  r/min were used to calculate the *in vitro* disintegration time. The amount of time in seconds required for the tablet to completely dissolve until no mass was left inside the device.

**Differential scanning calorimetry (DSC).** The thermal behaviour of the pure drug and formulation was assessed using a Shimadzu DSC-60 plus thermal analyzer and differential scanning calorimetry. Weighed and sealed in common aluminium pans, sample 3 mg were then heated at a rate of  $10^\circ\text{C}$  per minute and scanned over the temperature range of  $10^\circ\text{C}$  to  $350^\circ\text{C}$ .

**X-ray diffraction (XRD).** The crystallinities of CPG and diclofenac sodium were evaluated by XRD measurement recorded for CPG loaded diclofenac sodium tablet using X-ray diffractometer (BRUKER, Germany D2 Phaser Second generation). Scanning was done up to  $2\theta$  range between  $2^\circ$  and  $90^\circ$  using Ni-filtered (Niknam *et al.*, 2020).

**Fourier transforms infrared spectroscopy.** Physical mixture of Diclofenac sodium and all additives (1:1% w/w) was subjected to FTIR (Shimadzu FTIR 1800 crop, Japan) for the purpose of evaluating the compatibility study was made and scanned at  $4000$  to  $400\text{ cm}^{-1}$ . The resulting spectra were compared to the standard spectra to check for any modification.

**In vitro dissolution test.** In 900 mL of phosphate buffer pH 6.8 at  $(37.0 \pm 0.5)^\circ\text{C}$  at 75 r/min, dissolving rate was investigated using a USP type II paddle dissolution equipment (Electro Lab, India). The same volume of freshly prepared, pre-warmed  $(37.0 \pm 0.5)^\circ\text{C}$  dissolution medium was substituted for the aliquot of dissolution medium that was taken out at regular intervals. Following appropriate dilution, each sample's drug concentration of diclofenac sodium was determined using a Shimadzu UV-spectrophotometer at 276 nm (the Indian pharmacopeia 2014).

**Stability study.** Diclofenac sodium-containing tablets underwent a brief stability trial at  $25 \pm 2^\circ\text{C}$  and  $40 \pm 2^\circ\text{C}$  with a humidity of 75% respectively. The size, friability, hardness, disintegration, and drug release of the tablets were examined.

## RESULT

The physicochemical characterization of the CPG was assessed after it was extracted, as indicated in Table 2. Infrared spectral investigations were used to perform research on the compatibility of diclofenac sodium with CPG, as illustrated in Fig. 1-3. The viscosity and swelling index of CPG were 345% and 392.4 mPa.s. respectively. The percent of loss on drying was observed within limit. Micromeritic investigations revealed that the bulk density was  $0.387\text{ g/cm}^3$  and the tapped density was  $0.405\text{ g/cm}^3$ . The proportion of

Carr's index derived from was 14.57%. A  $23.6^\circ$  angle of repose was discovered. Hausner's ratio was discovered to be under 1.67%, which indicates a well-acceptable limit.

**Statistical analysis.** Statistical analysis involves a series of experiments and ensures that the study's findings, which identify the response variables, are accurately and persuasively interpreted. It also involves carrying out the necessary statistical tests to choose the best model, fitting mathematical models to the data, and figuring out the values of independent formulation variables to produce the best response. In order to improve the formulation and identify interactions between the selected parameters, the current study used a factorial design, one of the most common statistical experimental designs.

To study the effects of independent variables on its attributes and performance, a  $3^2$  fractional factorial design was applied. The independent variables such as concentration of polymer and concentration of other excipient at two levels were evaluated for their effect on % drug release, and disintegration.

The results were listed in Table 2. To obtain model equations for the studied responses that were analysed in this study, the values of the examined responses that were measured for all trial formulations were fitted in the  $3^2$  factorial design. According to the findings of regression analysis and ANOVA, the variables picked had a significant impact on all of the analysed answers.

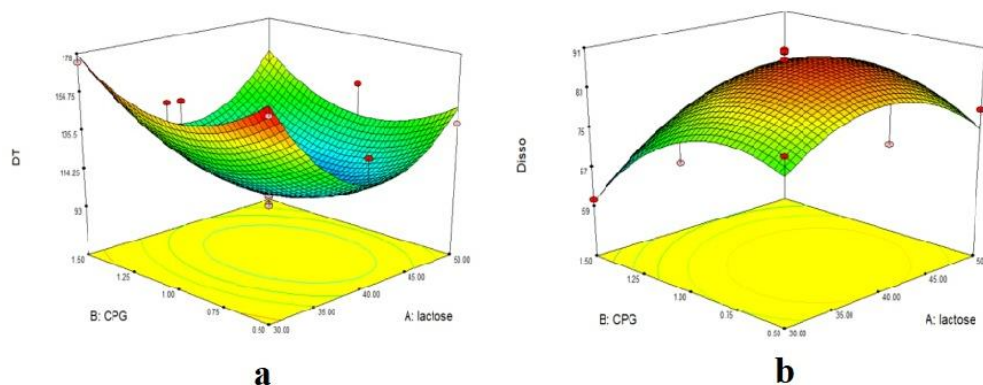
Diclofenac sodium tablet drug release was reported to range from 60.23 to 90.64% (Table 2). Regression analysis showed that the study's factors had a substantial impact on the drug release from the formulation ( $r^2 = 0.8786$ ). The dominating impact of the polymer ratio, drug concentration, is revealed by comparing the magnitudes of the regression coefficient. The results response surface curve (Fig. 2) showed that medication release impact increased as polymer concentration decreased. The model was significant, according to the model F value of 10.14.

For coded factor equation was,  
 $\text{Dissolution} = +88.36 + 1.99 * A - 5.59 * B + 2.84 * A * B - 8.78 * A^2 - 9.28 * B^2$

Table 1 shows a substantial correlation between the disintegration time, which ranged from 94 to 170 seconds, and the influence ( $r^2 = 0.8957$ ). With a rise in polymer concentration, the disintegration time lengthens. Fig. 2's reaction surface curve, which was created as a result of the findings, showed that the disintegration time grew as the polymer concentration did. The likelihood of noise producing a "Model F-Value" this large was 0.25% at most. The model was apparently significant because the model F value was 12.03.

For coded factor equation was  
 $\text{DT} = +102.07 - 11.17 * A + 3.00 * B + 1.75 * A * B + 41.26 * A^2 + 21.76 * B^2$ .





**Fig. 2** (a) Central composite design for 3D surface of disintegration (b) Central composite design for 3D surface of dissolution.

**Characterization of Diclofenac sodium.** Developed formulation compared to biological and physicochemical characteristics such as appearance, color, odor, melting point. The appearance of

diclofenac sodium was white powder. Color of drug was white and odorless. Melting point of diclofenac sodium was 282°C. All points meet to the standard range.

**Table 3: Physical evaluation of Diclofenac sodium tablet.**

Formulation	Weight variation (mg ±SD)	Hardness (Kg/cm <sup>2</sup> ±SD)	Thickness (mm±SD)	Friability (%±SD)	Drug content (%)	Wetting time (sec)	Water absorption test (%)	Disintegration time (sec)	In vitro dissolution (%)
F1	100±4.15	3.02±0.25	3.2±0.25	0.63±0.03	95.39±0.33	41±1.00	80.90±0.36	170±1.00	80.4±0.0033
F2	100± 2.23	3.0 ±0.33	3.3±0.15	0.43±0.06	94.39±0.33	39±2.00	79.25±0.25	173±2.00	60.23±0.0008
F3	100± 3.16	3.0±0.29	3.3±0.66	0.63±0.05	93.13±0.41	37±1.00	85.32±0.45	164±1.00	73.58±0.0078
F4	100± 2.17	2.5 ±0.22	3.2±0.36	0.56±0.04	98.25±0.12	35±2.00	89.34±0.40	94±2.00	90.64±0.0023
F5	102± 3.17	2.5 ±0.25	3.2±0.12	0.65±0.07	91.45±0.33	50±1.00	77.23±0.36	135±2.00	77.23±0.0044
F6	104± 4.18	3.0±0.26	3.5±0.52	0.60±0.09	96.32±0.36	56±2.00	85.36±0.14	93±2.00	88.64±0.0067
F7	103± 2.19	2.5 ±0.27	3.2±0.74	0.65±0.05	91.21±0.63	49±1.00	79.32±0.78	98±2.00	90.12±0.0023
F8	100± 1.34	3.0 ±0.24	3.2±0.52	0.65±0.04	92.32±0.14	52±1.00	77.25±0.66	99±1.00	90.32±0.0023
F9	101± 3.22	2.5±0.22	3.1±0.11	0.69±0.09	90.56±0.33	43±1.00	83.25±0.23	140±2.00	72.69±0.0023
F10	100±3.29	3.02±0.29	3.3±0.17	0.65±0.09	92.56±0.39	53±1.00	84.25±0.23	99±2.09	90.32±0.0023
F11	100±3.15	3.06±0.25	3.2±0.15	0.65±0.08	90.96±0.43	56±1.00	83.2±0.23	150±2.10	70.00±0.0084
F12	100±4.36	3.03±0.23	3.4±0.16	0.65±0.02	91.46±0.33	51±1.00	83.25±0.20	150±1.00	77.34±0.0078
F13	100±4.66	3.03±0.24	3.3±0.15	0.65±0.03	90.56±0.30	59±1.00	83.65±0.27	140±3.00	78.83±0.0013

**Hardness.** The tablet's hardness was found to be between 2.5-3.6 Kg/cm<sup>2</sup>, which was within the permissible range.

**Thickness.** The tablet's thickness was measured to be between 3.1-3.5 mm. The thickness was uniform, as demonstrated by the minimum standard deviation values.

**Friability.** Friability can be used to study tablet weight loss. It was determined that the tablets percentage of friability ranged from 0.43 to 0.69% which was satisfactory.

**Weight variation.** The uniform distribution of the excipient and drug was demonstrated by the fact that the dosage of the tablets varied from 100 to 104 mg.

**Disintegration time.** Tablets disintegration times were found to be between 94 to 170 seconds, which was within acceptable limits.

**Wetting time.** Tablet wetting time were found to be between 39 to 59 sec which was satisfactory.

**% Drug release-** Drug release found between 60.23-90.64% which was within acceptable limit.

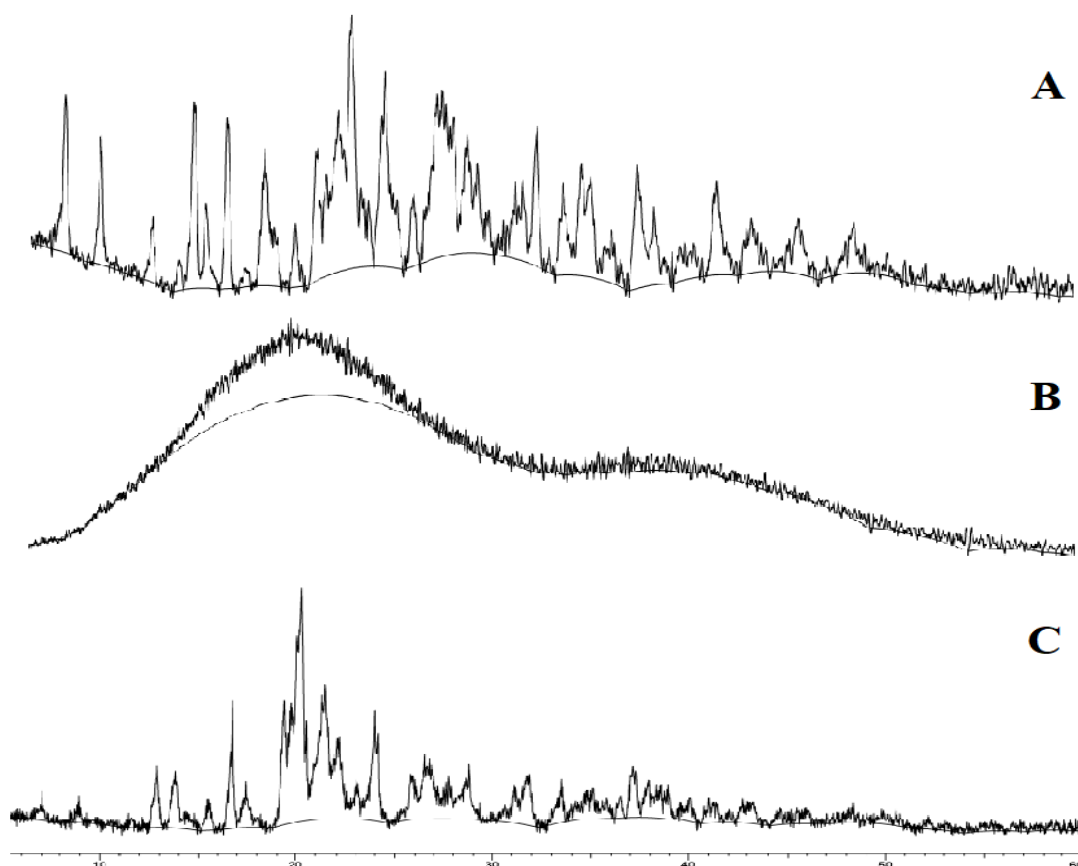
**Differential scanning calorimetry (DSC)-** The DSC thermogram of CPG galactomannan showed a sharp endothermic peak at 123.14°C at 10.11 min and at 276°C drug showed exothermic peak in 25.03 min.

Diclofenac sodium spectra was showed 3 endothermic peak at 56.24, 103.42 and 286.14°C in 1.68, 6.41, 24.62 min. The DSC thermogram of CPG loaded diclofenac sodium tablet showed endothermic peak at 154.64°C in 11.05 min and exothermic peak was observed at 1873.92°C in 13.85 min. The evaluation of the thermograms clearly revealed no physical interaction between the polymer and the drug. The analysis of thermograms revealed no physical interaction between the polymer and the drug in the prepared tablets.

**Powder X-ray diffraction (PXRD).** PXRD of diclofenac sodium tablet was shown in Fig. 4. The formulations dramatically reduced the intensity of peaks indicative of the crystalline nature of the pure medication, which may have been caused by the impact of the polymer or the formulation process. Pure diclofenac sodium exhibited prominent peaks in its XRD spectra at 20° and 24° (2θ). Peak intensities in the X-ray diffraction pattern of the formulation with pure drug were significantly reduced, and PXRD results for CPG and diclofenac sodium indicated that the drug's crystallinity had decreased.



**Fig. 3** (A) DSC spectra of Diclofenac sodium (B) DSC spectra of *Caesalpinia pulcherrima* galactomannan (C) DSC spectra of CPG loaded diclofenac sodium tablet



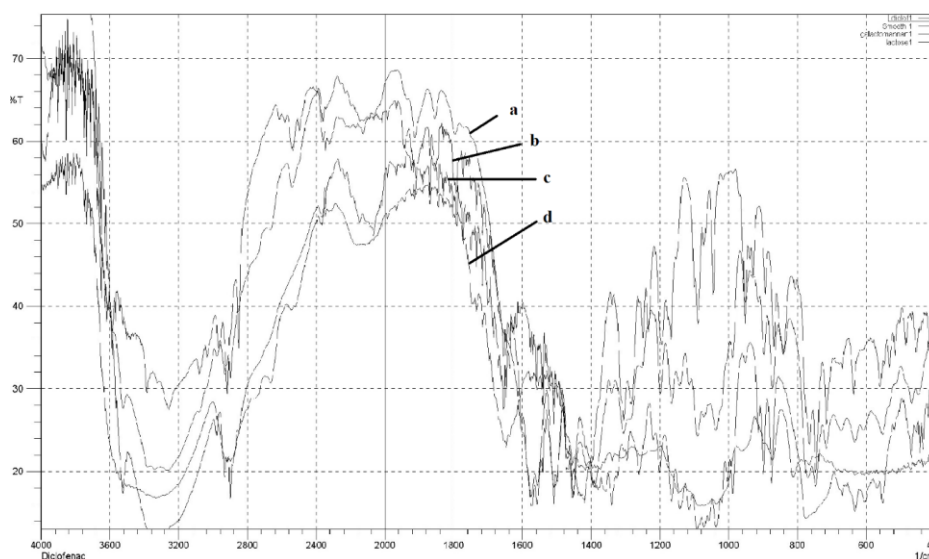
**Fig. 4.** (A) X- ray Diffraction of Diclofenac sodium (B) *Caesalpinia pulcherrima* galactomannan (C) CPG containing Diclofenac sodium tablet formulation.

**Fourier transform infrared analysis.** FTIR spectroscopic analysis was performed to confirm the compatibility of diclofenac sodium with CPG to prepare diclofenac sodium tablet. The FTIR spectra of

CPG, diclofenac sodium, lactose and formulation were shown in Fig. 5. FTIR spectrum of CPG showed characteristic peak at  $1637.56\text{ cm}^{-1}$  (N-H stretching),  $2370.51\text{ cm}^{-1}$  (C=C) and at  $422.41\text{ cm}^{-1}$  (C-

X). Indicating the absence of chemical interactions between medication and polymer after tablet manufacture, characteristic peaks of the drug were also

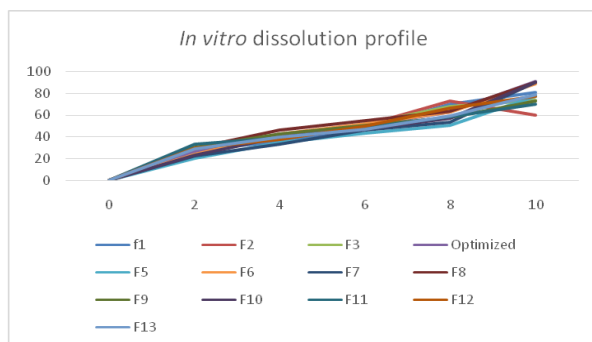
present in the formulation's FTIR spectrum with some broadening and intensity reduction spectrum with some broadening and intensity reduction.



**Fig. 5.** (a) FTIR spectra of diclofenac sodium (b) FTIR spectra of formulation (c) FTIR spectra of crude galactomannan (d) FTIR spectra of lactose.

**Stability study.** The stability study suggested that the optimized formulation were stable at  $25 \pm 2^\circ\text{C}/75\text{ RH}$  and at  $40 \pm 2^\circ\text{C}/75\text{ RH}$ . For some period as there was no significant change in dimensions, friability, hardness, disintegration and drug release (Eisa *et al.*, 2022).

**In vitro dissolution studies.** The in vitro drug release profiles of diclofenac sodium with different polymer concentrations are shown in Fig. 6. The rate and extent of diclofenac sodium with CPG in low concentration significantly gave higher drug release. The prepared tablet % CDR was plotted against time and the % drug release of prepared tablet was calculated. The batch F4 showed a maximum drug release rate at 10 min which was 90.64% and it was seen a maximum release profile than other prepared batches.



**Fig. 6.** *In vitro* drug release of diclofenac sodium in pH 6.8 phosphate buffer.

## DISCUSSION

A diclofenac sodium tablet was created as a result of this research employing CPG as a natural superdisintegrant. A natural polysaccharide with analgesic, anti-inflammatory, and antibacterial properties is galactomannan. Excipients such as lactose and galactomannan were used to make the diclofenac sodium tablets. The formulation used a  $3^2$  fractional

factorial design. Screening and optimization for various factors were done using DoE. These DoE and RSM are an important tool for checking the effect at different concentrations. To determine whether all of the parameters for tablet formulation are within range, pre-compression and post-compression parameters were used. The main focus of the current research was the disintegration and dissolution time of tablet. Testing for dissolution and disintegration is crucial in final formulation. The effectiveness of the biopharmaceutical excipients on the product was examined using dissolution. The compatibility study and impact of galactomannan and lactose in this research played a significant role and had a favourable impact on dissolution and disintegration. Data from *in vitro* dissolution demonstrates that change in concentration of excipient and medication solubility cause these changes. Anova software was used to check 3D surface of disintegration and dissolution. Swelling index of galactomannan had a favourable swelling index in distilled water. Galactomannan had a pseudoplastic behaviour and having gel-like consistency. The DSC spectra show that drug and tablet was identical and FTIR spectra showed that drug was stable. The *in-vitro* dissolution study was performed for all batches.

Prior to compression of tablets, the consistent mass of the tablets is crucial, and the flow properties of the powder contribute to this. The powder micromeritic features, such as its bulk density and tapped density, suggested that it had good precompression properties. It was discovered that the Carr's index, Hausner's ratio, and angle of repose were, respectively, 14.57%, 1.67%, and  $23.6^\circ$  showing the desired flow properties. Evaluation of the formulated tablet was done. All tablet formulations weight variation meet with pharmacopeial restrictions. The FDT ranged in hardness from 2.5 to 3.06  $\text{Kg}/\text{cm}^2$  and the thickness was 3.2 to 3.4 mm. Studies on the tablet hardness and thickness revealed its

mechanical strength. The percentage of friability was well within allowed ranges, demonstrating the tablet structural strength. All of the tablets were uniformly dosed since the drug content percentage ranged from 90.56% to 98.25% in all of the manufactured tablets. All of the formed tablet wetting times (F1 to F13) were discovered to be between 35 to 59 seconds. The tablets made with CPG (F4) showed the least amount of wetting time, with a wetting time of only 35 seconds. These results suggested that the wetting process of the tablets was closely related to the inner structure of the tablets, particularly pore size. It was shown that the decreased CPG concentration had speed up drug release and increased disintegration. The tablet dissolves in 94 seconds was the outstanding super disintegrant properties of CPG at a concentration of 1 mg, meeting the IP requirements. Furthermore, the F4 formulation's greater dissolve rate of 90.64% after 10 min showed that CPG was a superior alternative to well-known synthetic super disintegrating agents as SSG and croscarmellose sodium. Hence, it may be said that CPG works well as a super-disintegrating agent.

## CONCLUSIONS

The present work involves to formulate diclofenac sodium as fast dissolving tablets (FDT) using *Caesalpinia pulcherrima* galactomannan as a natural superdisintegrant. FDTs containing various incorporating active ingredients were evaluated for effect of various excipients FDTs containing various excipients were evaluated for disintegration and dissolution. The current study claimed as an ideal tool for development of product as per ideal limits.

## FUTURE SCOPE

Pre-clinical and clinical studies should be carried out for pharmacokinetic and pharmacodynamics analysis. Also, comparative Study with marketed formulation can be done.

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**Conflict of Interest.** None.

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