FORMULATION AND EVALUATION OF SWELLABLE MATRIX TABLET OF NSAID USING NATURAL POLYMER

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ABSTRACT

The objective of the present study was to formulate sustained release matrix tablets by using Chia seed powder and to compare the formulation by using HPMC at different concentration and thereby to investigate sustained release behaviour of the fabricated tablets. The Chia seed powder was prepared by blending and its physio-chemical properties were assessed. To observe the sustained release character, Diclofenac Sodium was selected as a model drug. FTIR studies have shown that there was no interaction between drug and polymers. Swellable matrix tablets were prepared by wet granulation technique using different concentration of Salvia hispanica Linn powder as natural polymer and PVP 10% as granulating agent. The prepared tablets were evaluated for pre-compression and post-compression parameters .A quantity of 75mg Chia seed powder was used in formulation F2 and was found to be the best one .The formulations were optimized on the basis of acceptable weight variation, thickness, hardness, % friability, % drug content and *in vitro* drug release. The *in vitro* release studies were performed with the aid of USP type II apparatus using phosphate buffer 6.8 as a dissolution medium and it was found that the optimized formulation F2 showed sustained release of Diclofenac over a period of 12hrs.

Keywords: Matrix tablet, Salvia hispanica Linn, sustained release, HPMC, *in vitro* release studies.

INTRODUCTION

The oral route of drug delivery is the most chosen route for administration of drugs. Among them, tablets are the most popular oral formulation available in the market and preferred by the patients and physician alike. For the treatment of chronic disease conditions, conventional formulations are required to be administered in multiple doses and therefore have many demerits. The main reason for the development of a sustained release formulation of a drug is to improve its therapeutic advantages and reducing its side effect while improving the management of the diseased condition.

Sustained release formulations can offer many pharmacokinetic and pharmacodynamic advantages over conventional dosage forms which include maintenance of constant therapeutic levels for a longer period of time and reduction of fluctuations in plasma drug concentrations. Furthermore, sustained release formulations can reduce the risk of treatment failure due to inadequate dosing of antibiotics. Moreover it significantly enhances the therapeutic efficacy of drugs. In such systems, the key performers are drug-release-retarding polymers.

Sustained release delivery systems can acquire an extended duration of activity for drugs with half-life 2-4 hrs, decreased toxicity, reduction of required dose, optimized therapy, and better patient compliance. These new drug delivery systems become popular for maximizing the bioavailability of conventional drugs with minimum side effects. Recently, considerable attention has been focused on hydrophilic polymers within the design of oral controlled drug delivery systems due to their flexibility to get a desirable drug release profile, cost-effectiveness and broad regulatory acceptance. Among the hydrophilic polymers, cellulose derivatives such as methylcellulose, hydroxy propyl, and sodium carboxy methyl cellulose are generally considered to be stable and safe as release retardant excipients in the development of oral controlled release dosage forms. These semi-synthetic polymers are comparatively expensive than natural polymers.

The use of natural polymers for pharmaceutical application is extremely attractive because they're economical, readily available, non toxic, and bio compatible. Many natural polymers from various plant sources are successfully used and a few others are being investigated as excipient in design of dosage form for effective sustained release drug delivery. The plant sources used for the synthesis of polymers are Tamarind gum, Okra gum, Hakea gum, Karaya gum, Fenugreek mucilage, Chia seed powder. The above plant based polymers are used in various pharmaceutical dosage forms like matrix controlled system, film coating agents, buccal films, microspheres, nanoparticles, viscous liquid formulations like ophthalmic solutions, suspensions, implants. These have also been utilized as viscosity enhancers, stabilizers, disintegrants, solubilizers, emulsifiers, suspending agents, gelling agents and bio adhesives, binders etc.

Preparation of sustained release formulation by matrix technique is a commonly used method due to its convenience of preparation, flexibility and low cost. Matrix tablets are widely recognized for oral sustained release (SR) as they're very simple and easy to formulate.

Matrix system is the release system, which prolongs and controls the rate of drug release, which is dissolved or dispersed.

Aim of the proposed work was intended to formulate and evaluate swellable matrix tablet of NSAID using natural polymer, Chia seed powder, with a view to minimize the dosing frequency and side effects. The major objective of the present work was to formulate and evaluate sustained release matrix tablet of Diclofenac using natural polymers.

For the study of effectiveness of its ability to control drug release, Non Steroidal Anti Inflammatory Drug Diclofenac sodium is chosen as a model drug. Diclofenac Sodium is the sodium salt form of Diclofenac, which is a phenyl acetic acid derivative and a non-steroidal anti-inflammatory drug (NSAID) with analgesic, antipyretic and anti-inflammatory property. Diclofenac has a half-life of two hrs.

MATERIALS AND METHODS

MATERIALS: The Chia seed required for the study was purchased from Amazon. Diclofenac Sodium and PVP K30 were obtained from Yarrow chem. Products, Mumbai. Lactose was purchased from Molychem, Mumbai. Talc was picked up from Vikash Pharma, Mumbai and Magnesium stearate was obtained from Ozone international, Mumbai.

Preparation of Chia Seed Powder

The Chia seeds were collected from Amazon. Then it was dried in sunlight and blended using a blender. The blended seed powder was passed through sieve no.40,then it was dried in a hot air oven at 50˚C.The dried Chia seed powder was stored carefully in desiccators to prevent further moisture uptake or degradation.

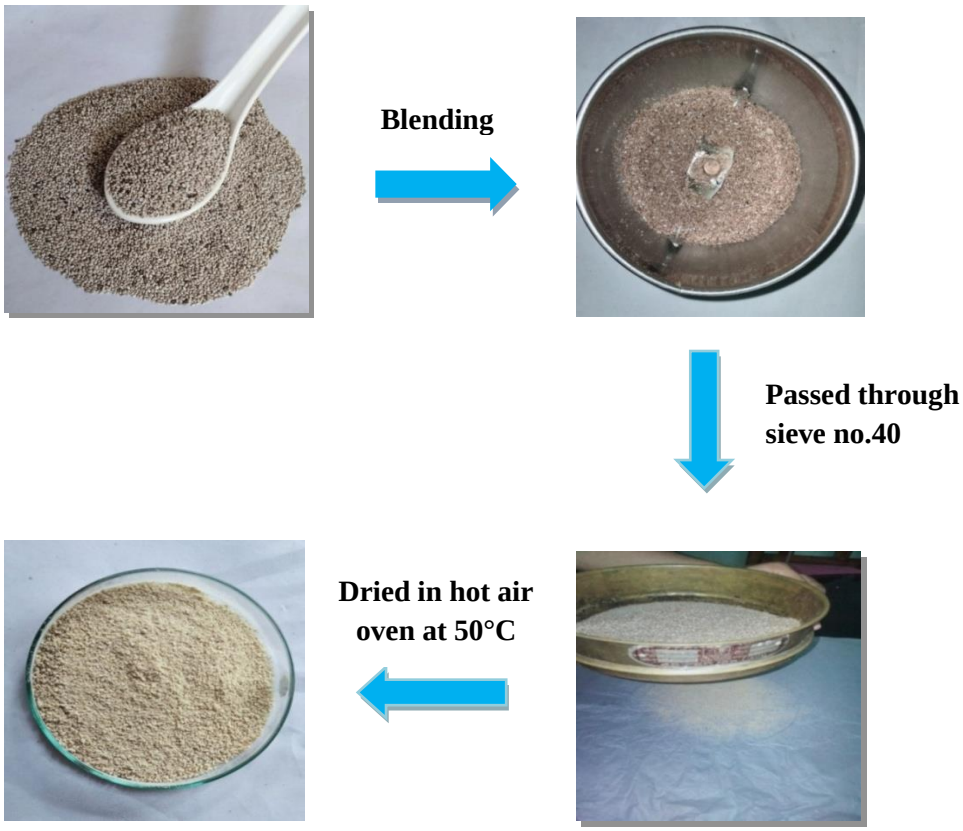


Figure 1: Steps involved in the preparation of Chia seed powder

Preformulation Studies

Preformulation study is the initial step in the rational development of a dosage form of the drug substance. The main objective of the study is to develop information that is useful in formulating stable dosage forms.

Compatibility studies using FT-IR Spectroscopy

The FT-IR spectrum of the given sample of drug and drug + polymer mixture were compared with the standard functional group frequencies of Diclofenac, Chia seed powder, HPMC K100M, respectively. The compatibility between the drug and polymer were evaluated using FT-IR peak matching method and also the spectrum was scanned in the wavelength range of 400-4000cm^{-1}.

Preparation of Calibration Curve of Diclofenac

Preparation of stock solutions for Calibration curve

Stock solution 1: Stock solution of drug (1mg/ml) is prepared by dissolving 100 mg of drug in 100 ml phosphate buffer pH 6.8 in a 100 ml volumetric flask with vigorous shaking and then sonicated for about 10 minutes.

Stock solution 2: 10 ml of this (stock solution 1) is again diluted to 100ml with phosphate buffer pH 6.8 and it was filtered through Whatmann filter paper No.41.

Take the specific samples (0.2ml, 0.4ml, 0.6ml, 0.8ml, 1ml, 1.2ml, 1.4ml) in each test tube, add phosphate buffer pH 6.8 and prepared up to 10 ml to produce (2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24µg/ml) respectively.

Preparation of Calibration curve

The standard solutions for the drug having concentration were prepared with phosphate buffer pH 6.8 from the stock solution. The absorbance of solutions was measured at 276 λ max and a calibration curve was plotted between concentration of drug (µg/ml) on x-axis v/s absorbance (nm) on y-axis.

Physiochemical Evaluation of Chia seed Powder

Organoleptic properties of the Chia seed powder

The physical characteristics such as color and odour of excipient were observed.

Melting point determination

The melting point of Chia seed powder was measured by capillary method using melting point apparatus.

Solubility study

Solubility study of Chia seed powder was assessed by adding 1g of Chia seed powder to 10ml of solvent (Distilled water, methanol,ethanol,acetone,and phosphate buffer pH 6.8) in a 25ml stoppered standard flask with vigorous shaking.

Loss on drying

The loss on drying test is employed to calculate the quantity of water and volatile matters in a sample, when the sample is dried under specified conditions.

$$\text{Loss on drying} = [(W1 - W2) / W1] \times 100$$

Where; W1=initial weight

W2=final weight

pH determination

1%w/v of the Chia seed powder in water was stirred continuously for 5 minutes and pH was determined using a digital pH meter.

Swelling characteristics

Swelling characteristics of Chia seed powder were examined in distilled water, and phosphate buffer (pH 6.8). The Swelling index is the volume in ml occupied by part 1g of the substance. The test was performed by taking 1g of the powder in a 100ml ground glass stoppered graduated cylinder. To this 100ml of distilled water, phosphate buffer (pH 6.8) was added and this was shaken vigorously for 10min and then allowed to rest for 24 hrs. The volume occupied by the Chia seed powder was measured. The following equation was used to calculate the swelling index of powder.

$$SI = (V2-V1) /V1$$

Where, V1 is volume occupied by the mucilage powder before hydration

V_2 is volume occupied by the mucilage powder after hydration.

Pre-Formulation Studies of Powder Blend

- Bulk density
- Tapped density
- Compressibility index or Carr's index(CI)
- Hausner's ratio
- Angle of repose

Preparation of sustained release matrix tablet of Diclofenac by wet granulation method

Different tablet batch formulations (F1-F6) were prepared by wet granulation method. Pure drug and polymers (Chia seed powder, HPMC K 100) were mixed well in a mortar. The above mix was triturated so as to cause an even distribution of mixture. Now added 10% PVP drop by drop and so as to obtain a particular consistency in such a way that it could withstand the stress when it was moulded. The coherent mass was passed through sieve no:

10 to get wet granules and then dried in hot air oven at 50˚C for a particular time. After drying, the granules were passed through sieve no: 20 (dry screening) which is then placed over sieve no: 40. The overs and fines were separated.15% of fines were added to the weight of overs and finally required quantity of Magnesium stearate and Talc were added. The granules were then compressed into tablets using a single punch rotary tablet punching machine.

INGREDIENTS	F1	F2	F3	F4	F5	F6
Diclofenac(mg)	100	100	100	100	100	100
Chia seed powder(mg)	50	75	100	150	-	75
PVP10%	q.s	q.s	q.s	q.s	q.s	q.s
HPMCK100M(mg)	_	_	_	_	100	75
Lactose(mg)	150	125	100	50	100	50
Talc (mg)	1%	1%	1%	1%	1%	1%
Magnesium Stearate(mg)	2%	2%	2%	2%	2%	2%
Total weight of tablet(mg)	**300**	**300**	**300**	**300**	**300**	**300**

Table 1: Formulation trials of Diclofenac 300 mg

Evaluation of prepared formulation

Organoleptic properties: The physical characteristics such as color and odour of tablet were observed.

Thickness: The thickness of the prepared matrix tablets was measured using vernier calliper and the results were expressed as mean values of three determinations, with standard deviations. It is expressed in mm

Weight uniformity test: Twenty tablets from each batch were weighed using an electronic balance together and individually, and calculated the average weight and percentage deviation.

Average weight of tablet	% deviation
80mg or less	±10
More than 80mg but less than 250mg	±7.5

250mg or more	±5

Table 2: Weight variation specification as per IP

Hardness measurement: To determine the hardness of tablet Pfizer hardness tester was used. It was defined as the force applied across the diameter of the tablet in order to break the tablet. The test was carried out in triplicate for all formulation.

Friability: Ten tablets were randomly picked from each batch and weighed. The tablets were then set to rotate for 100 revolutions in a Roche Friabilator with triplicate readings. The friability was calculated by the given formula:

$$\% \text{ Friability} = [(\text{Initial weight} - \text{Final weight})/\text{Initial weight}] \times 100$$

Swelling Index of Tablet

The swelling of tablet is the capacity to absorb a liquid to increase its weight and volume. Tablets from each batch were weighed and placed in a Petri-dish containing 25ml of phosphate buffer 6.8 to assess the extent of matrix swelling .Tablets were removed from media, wiped off by using filter paper and reweighed in every 1 hr up to 12hr. The swelling index was calculated using following formula.

$$\text{Swelling Index S.I.} = (W_t - W_0)/W_0) * 100$$

W_t = weight of tablet at time‘t’

W_0 = weight of tablet at time t = 0

Drug content

Five tablets were selected randomly and powdered. A quantity of powder corresponding to 100 mg of Diclofenac sodium was dissolved in 100 ml of pH 6.8 phosphate buffer, stirred for 60 min and filtered. 1 ml of the filtrate was diluted to 100ml with pH 6.8 phosphate buffer. Absorbance of this solution was determined at 276 nm using phosphate buffer pH 6.8 as blank and content of Diclofenac sodium was assessed.

In vitro release studies

The release rate of Diclofenac from tablets was examined using United States Pharmacopeia (USP) Dissolution Testing Apparatus type 2 (paddle method). The dissolution test was performed using 900ml of 6.8 pH phosphate buffer, at 37 ± 0.5 0C and 50rpm. A sample (1ml) of the solution was withdrawn from the dissolution apparatus hourly and the samples were replaced with fresh dissolution medium. The samples were diluted to a suitable concentration with 6.8 pH phosphate buffer. Absorbance of these solutions was measured at 276 nm using a Thermospectronic-1 UV/Vis double-beam spectrophotometer. Cumulative percentage of drug release was computed using an equation obtained from a standard curve. The results are shown in figure 10.

Dissolution test parameters

Dissolution test apparatus: USP Dissolution testing apparatus type II (paddle)
Dissolution medium: Phosphate buffer pH 6.8
Temperature of medium: 37 ± 0.5oC
Speed of rotating paddle: 50 rpm

Sampling volume: 1 ml

RESULTS

COLLECTION AND PREPARATION OF CHIA SEED

The Chia seeds required for the study were purchased from Amazon. The seeds were blended and approximately 50 gm powder was obtained from 150 gm of Chia seeds.

PREFORMULATION STUDIES

Organoleptic properties of the drug

Table 3: Organoleptic properties of drug

SI.No:	Tests	Observation
1	Character	white or slightly yellowish, slightly hygroscopic crystalline powder
2	Color	White
3	Taste	Tasteless
4	Odor	No characteristic odor

Determination of melting point

Table 4: Melting point of Diclofenac Sodium

Property	Specification(BP)	Observation
Melting point	275^0C-280^0C	280^0C

Solubility study

Table 5: Solubility of drug

SI.No	Solvent	Solubility
1	Water	Sparingly soluble
2	Acetone	Slightly soluble
3	Methanol	Freely soluble
4	Ethanol	Soluble
5	Phosphate buffer 6.8	Soluble

Solubility of Diclofenac Sodium in various solvents such as water, acetone, methanol, ethanol, and phosphate buffer 6.8 were studied and found that it was sparingly soluble in

water, slightly soluble in acetone, freely soluble in methanol and soluble in ethanol and phosphate buffer 6.8.

FT-IR Spectroscopy of Diclofenac

The FT-IR spectrum of Diclofenac complies with standard functional group frequencies.

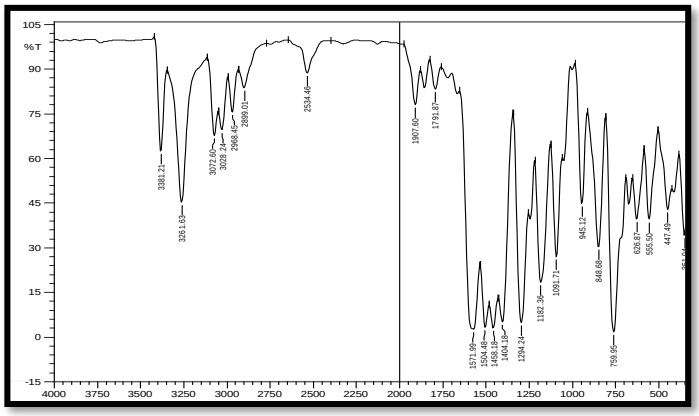


Figure 2: FT-IR spectrum of Diclofenac

Compatibility between drug and polymer

The FT-IR spectrum of Diclofenac is shown in figure 3 and combination of Diclofenac with excipients are shown in figure 4.

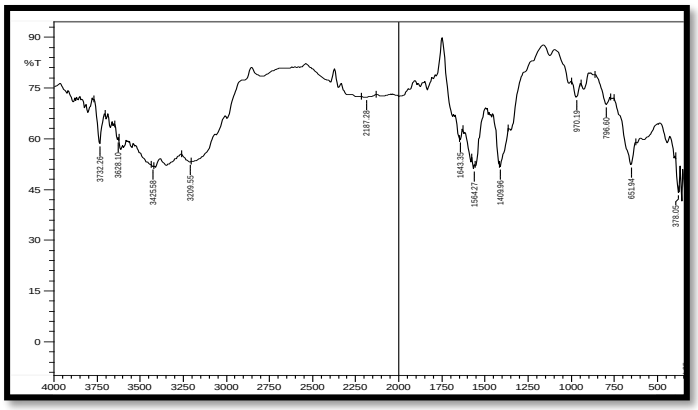


Fig 3: FT-IR spectrum of physical mixture of Diclofenac with polymers

The compatibility between drug-polymers was carried out using FT-IR peak matching method. All major peaks present in the spectrum of pure drug were observed in the spectrum of drug-polymer mixture. This suggests the absence of any chemical interaction and concluded that there was no incompatibility between drug and polymers.

PREPARATION OF CALIBRATION CURVE OF DICLOFENAC

Preparation of phosphate buffer solution pH 6.8

Place 50ml of 0.2 M Potassium di-hydrogen phosphate, 22.4 ml of 0.2 M sodium hydroxide and then add distilled water to make up the volume 200ml.

a. Preparation of 0.2 M Potassium di-hydrogen phosphate solution

Dissolve 27.218g of potassium di-hydrogen phosphate in sufficient distilled water and make up the volume 1000ml in a 1000ml volumetric flask.

b. Preparation of 0.2 N NaOH

Dissolved 8g NaOH pellets in 1000ml standard flask and make up with distilled water. Table 8 shows the absorbance of standard solution containing 2-14 µg/ml of drug in phosphate buffer pH 6.8.

Figure 4: UV Spectrum of Diclofenac sodium

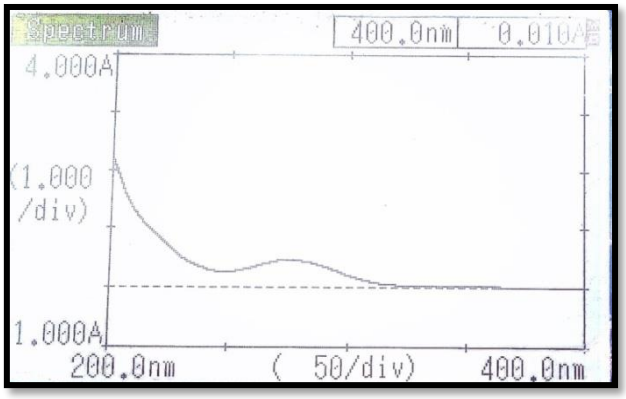
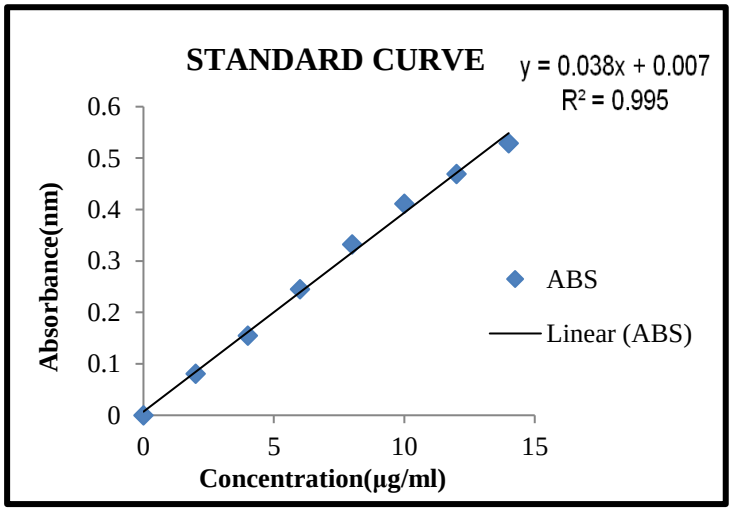


Figure 5: Standard graph of Diclofenac in phosphate buffer 6.8



Plotted calibration curve was found to be straight line with a slope of 0.038. Calibration curve could be used to determine the unknown concentration of drug, for the further studies of drug content, release profiling etc.

Physiochemical Evaluation of Chia Seed Powder

Organoleptic properties of the Chia seed powder

Figure 6: Chia seed powder

Table 6: **Organoleptic properties of Chia seed powder**

SI.No	Tests	Observation
1	Character	Colored powder
2	Color	Off –white
3	Taste	Tasteless
4	Odor	Odorless

Melting point determination

Table 7: Melting point of Chia seed powder

Property	Observation
Melting point	60^0C

Solubility study

Table 8: Solubility of Chia seed powder

Sl. No	Solvent	Solubility
1	Cold water	Swells to form gel
2	Ethanol	Insoluble
3	Acetone	Insoluble
4	Methanol	Insoluble
5	Phosphate buffer 6.8	Insoluble

Loss on drying

Table 9: Loss on drying of Chia seed powder

Property	Observation
Loss on drying	0.30%w/w

The value obtained in loss on drying was less, it indicates that it contain less moisture content so it was found to be stable.

pH Determination

Table 10: pH of Chia seed powder

Property	Observation
pH	7.0

pH of Chia seed powder is satisfactory for uncoated tablet because of its less irritancy.

Swelling Characteristics of Chia seed powder

Table 11: Swelling Characteristics of Chia seed power

Medium	V1 (volume occupied before hydration)	V2(volume occupied after hydration)	Swelling Index
Distilled water	2.5	11	3.40
Phosphate buffer pH 6.8	2.4	11.2	3.66

Swelling index of Chia seed powder was tested both in water and phosphate buffer 6.8 and found that swelling of Chia seed powder was high at phosphate buffer pH 6.8 than distilled water.

Micrometric properties of pre-compressional powder blend

Table 12: Micromeritic properties of formulation blends

Formulation	Angle of repose(ɵ)	Bulk density (g/ml)	Tapped density (g/ml)	Carr's index	Hausner's ratio
F1	28.65±0.46	0.44±0.001	0.51±0.013	13.8±0.169	1.16±0.002
F2	**26.64±0.56**	**0.45±0.002**	**0.52±0.032**	**8.61±0.324**	**1.15±0.001**

F3	27.65±0.32	0.54±0.001	0.62±0.001	11.89±0.14	1.13±0.005
F4	29.99±0.02	0.43±0.003	0.51±0.012	14.75±0.033	1.17±0.023
F5	28.36±0.11	0.42±0.001	0.50±0.013	15.20±0.11	1.17±0.013
F6	27.50±0.46	0.44±0.002	0.51±0.036	14.06±0.089	1.16±0.016

Flow property of powder is determined by using angle of repose. The angle of repose of the prepared powder blends ranges from 26.64^0 to 29.99^0, indicates good flowability.

The bulk density of a powder depends on particle size distribution, particle shape and also the tendency of the particles to stick one another. The blends of different formulations were evaluated for bulk density. The bulk density of the prepared powder blends ranges from 0.424 to 0.548 g/cc.

The blends of different formulations were evaluated for tapped density. The tapped density of the prepared powder blends ranges from 0.500 to 0.622 g/cc.

The compressibility index lies within the range of 8.61 to 15.20%, indicates good compression properties.

The Hausner's ratio of the prepared powder blends ranges from 1.13 to 1.17.Hausner's ratio less than 1.25 show better flow properties.

Based on above observation it showed that formulation F2 comply with all the requirements of powder flow property and shows values within range.

EVALUATION OF TABLET

Organoleptic evaluation

Figure 7: Formulated Tablet (F2)

All the prepared formulations showed specific color without specific odor.

Table 13: Organoleptic properties of Formulations F1-F6

Formulation Code	Color	Odor
F1	Off-white	None
F2	**Off-white**	**None**
F3	Off-white	None
F4	Off-white	None

F5	Off-white	None
F6	Off-white	None

Post compression parameters:

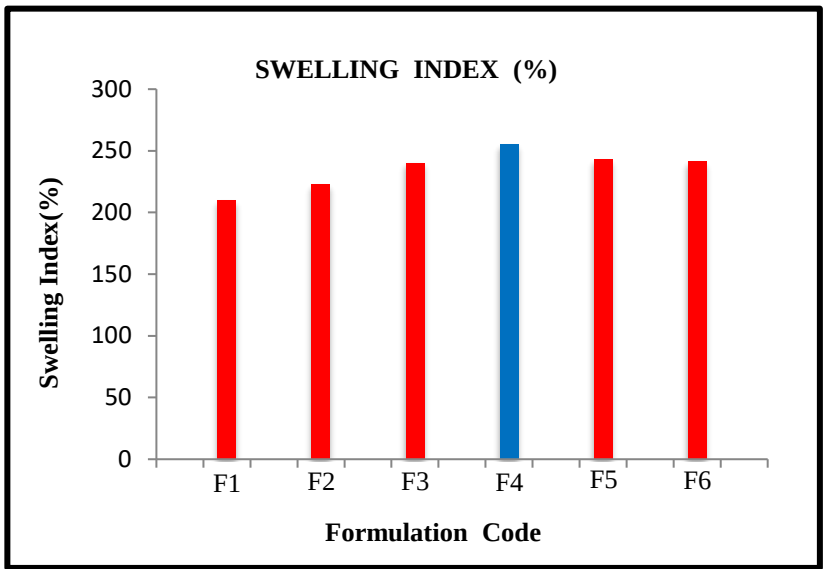
Table 14: **Post compression parameters**

Formulation	Thickness (mm)	Average weight of Tablet	Hardness (kg)	%Friability
F1	2.3	298	3.8	0.800
F2	**2.7**	**300**	**4.3**	**0.524**
F3	2.6	302	5.5	0.491
F4	2.4	302	5.8	0.462
F5	2.8	300	4.5	0.623
F6	2.6	299	4.4	0.573

Twenty tablets were randomly picked from each formulation and evaluated. The values were almost uniform and were within the specification. Hardness, friability, thickness of tablets was evaluated and hardness ranged from 3.80 -5.80 mm and friability ranged from 0.462-0.800, so the tablets of all formulations are within the acceptable limits.

Swelling Index of Tablet

Figure 8: Graphical representation of swelling index

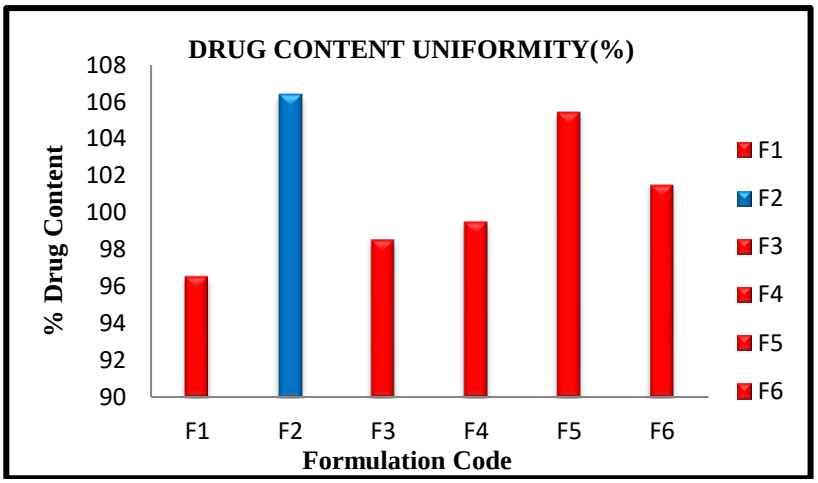


The values swelling index ranged from 210 -255% and the swelling index of F4 formulation was found to be high due to high amount of Chia seed powder.

Drug Content

Drug content estimation of all formulations was carried out by using UV spectrophotometer at 276 nm and was found to be in the range of 96.55– 106.40% which is in the range specified in IP (90-110). The maximum % drug content was found to be 106.40 % in F2.

Figure 9: Graphical representation of drug content



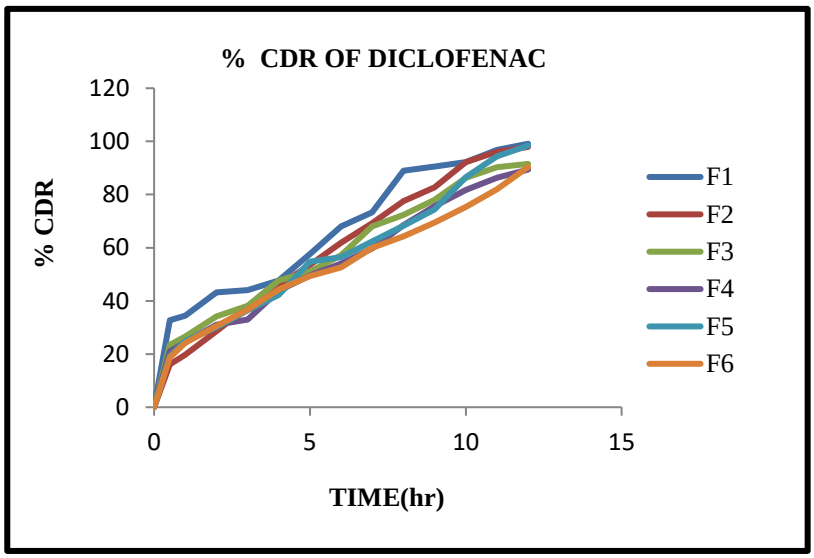
In vitro release studies

In-vitro dissolution studies of all formulations of Diclofenac were carried out in dissolution test apparatus using phosphate buffer pH 6.8 as the dissolution medium for 12 hr. Percentage cumulative drug release at each time interval was shown graphically.

From the *in-vitro* drug release data of sustained matrix tablet of Diclofenac, it was found that the percentage cumulative drug release of Diclofenac decreased as the concentration of Chia seed powder increased.

Also the *in-vitro* drug release of F2 was found closer to that of drug release shown by HPMC in formulation F5.From that it was concluded that Chia seed powder was used as a substitute for HPMC at low cost.F2 released 97.92% of the drug in 12 hrs made the formulation good to sustain the drug release.

Figure 10: *In vitro* drug release profile of formulations F1-F6



Kinetics of *in vitro* drug release

The results obtained from *in vitro* release studies were attempted to be fitted into various mathematical models.

Table 15: Kinetic study of Diclofenac from formulations F1-F6

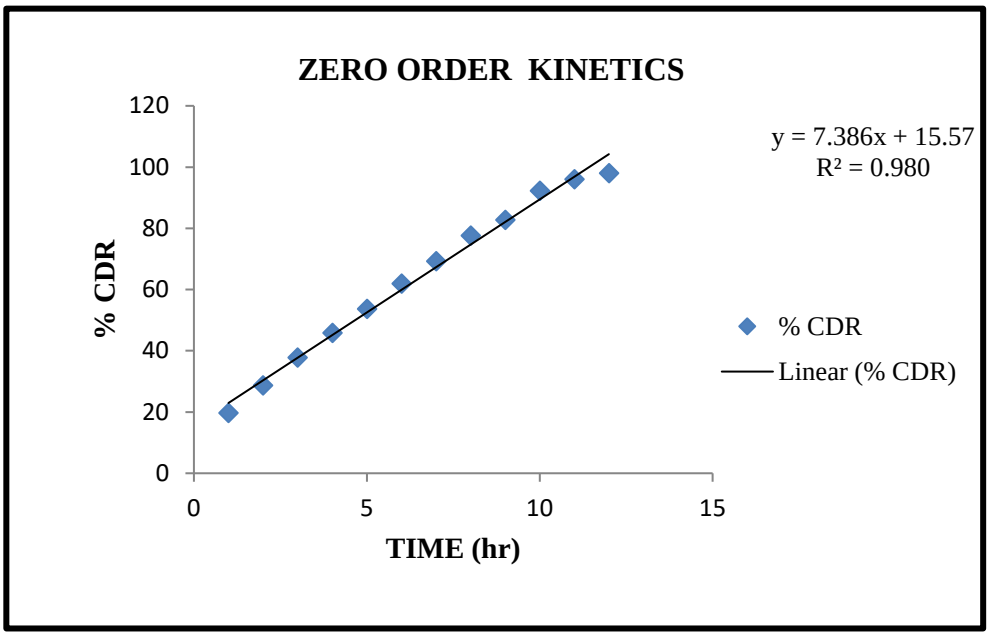
Formulation	Zero order	First order	Higuchi	PEPPAS	
				n values	R^2values

F1	0.889	0.851	0.951	0.473	0.930
F2	**0.980**	**0..889**	**0.978**	**0.678**	**0.996**
F3	0.961	0.947	0.977	0.534	0.973
F4	0.970	0.951	0.975	0.561	0.963
F5	0.976	0.850	0.989	0.582	0.962
F6	0.978	0.918	0.994	0.531	0.979

The *in-vitro* drug release data was subjected to goodness of fit by linear regression analysis, according to zero order, first order kinetic equation, Higuchi and Korsmeyer models to ascertain the mechanism of drug release. The result of linear regression analysis of data including regression coefficient were summarized in table 15.When the regression coefficient 'R^2' values of zero order and first order plots were compared, it was observed that the 'R^2' values of zero order plot was higher than that of first order plots which indicates that the drug release from the formulations were more likely to follow zero order kinetics as the 'R^2' values of zero order kinetics was found to be close to unity.

Based on the values of regression coefficient, it was concluded that the formulation F2 strictly followed zero order kinetics compared to other formulation. Based on physiochemical evaluations and drug release profile, the formulation which is made from the quantity of Chia seed powder as 75 was selected as optimized formulation.

Figure 11: Zero order plot of formulation F2



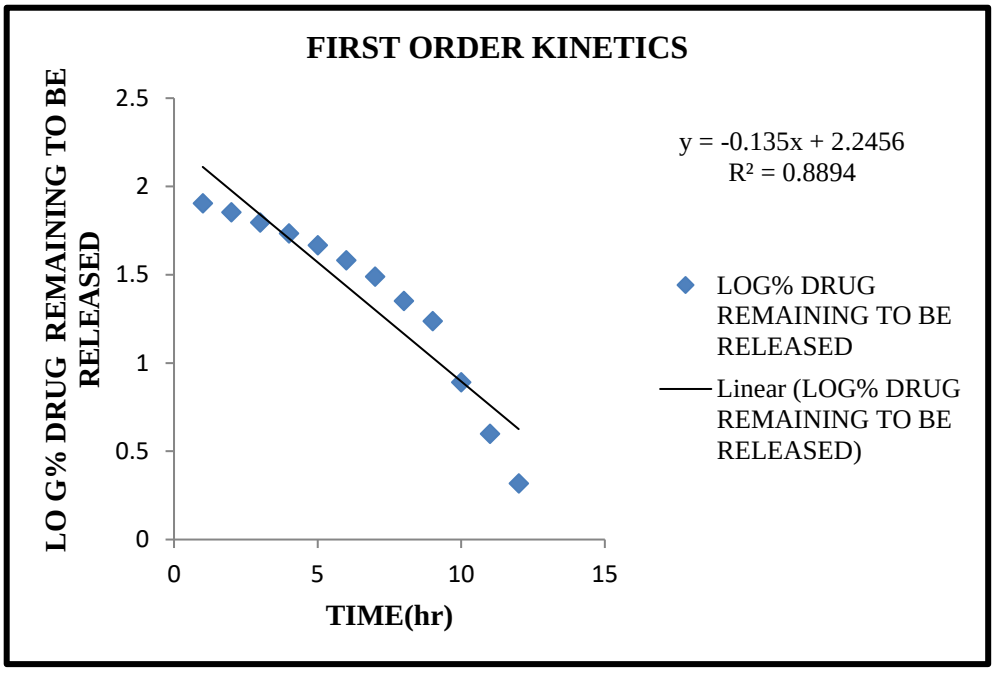
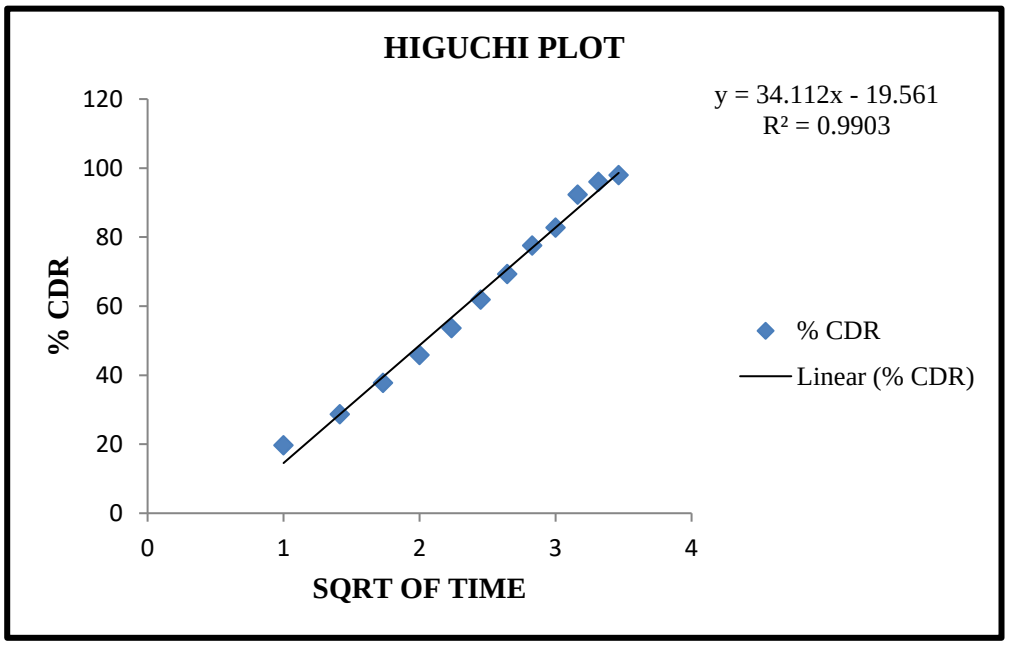


Figure 12: First order plot of formulation F2

Figure 13: Higuchi plot of formulation F2



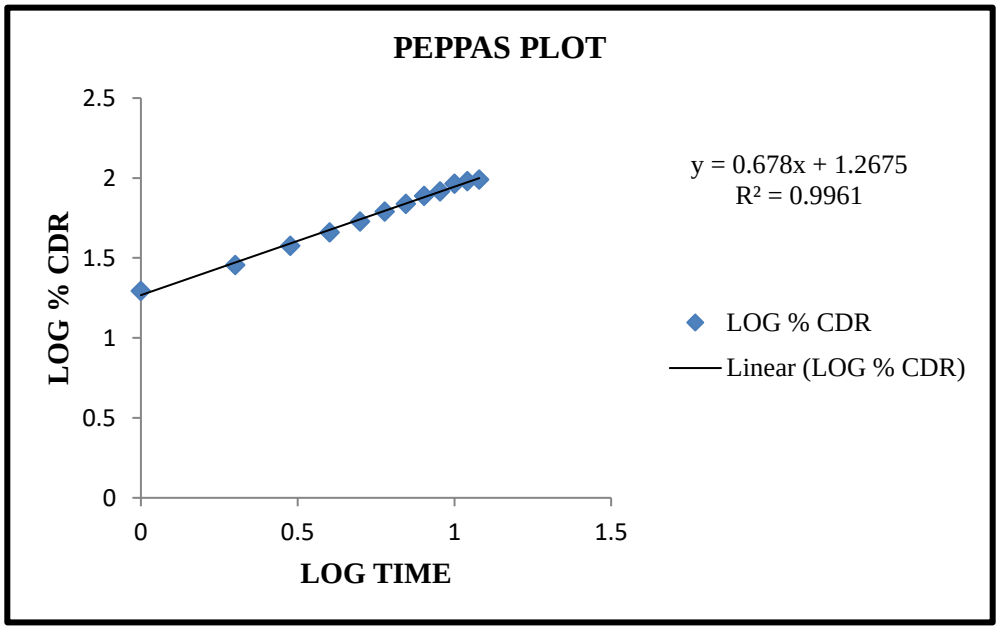


Figure 14: Peppas plot of formulation F4

From the above graphs, it was concluded that the formulation F2 follow zero order kinetics.

The *in-vitro* drug release data as log % CDR versus time were fitted to Korsmeyer-Peppas equation in order to understand the mechanism by which Diclofenac was released from this formulation. The value of exponent 'n' was found to be 0.473 – 0.678. The Korsmeyer-Peppas model yields 'n' values >0.45 indicating that the diffusion mechanism from the formulation followed Non-Fickian (Anomalous) diffusion. The 'n' value of optimized formulation F2 was found to be 0.678 which indicated that the drug was released by zero order kinetics with anomalous (Non-Fickian) release.

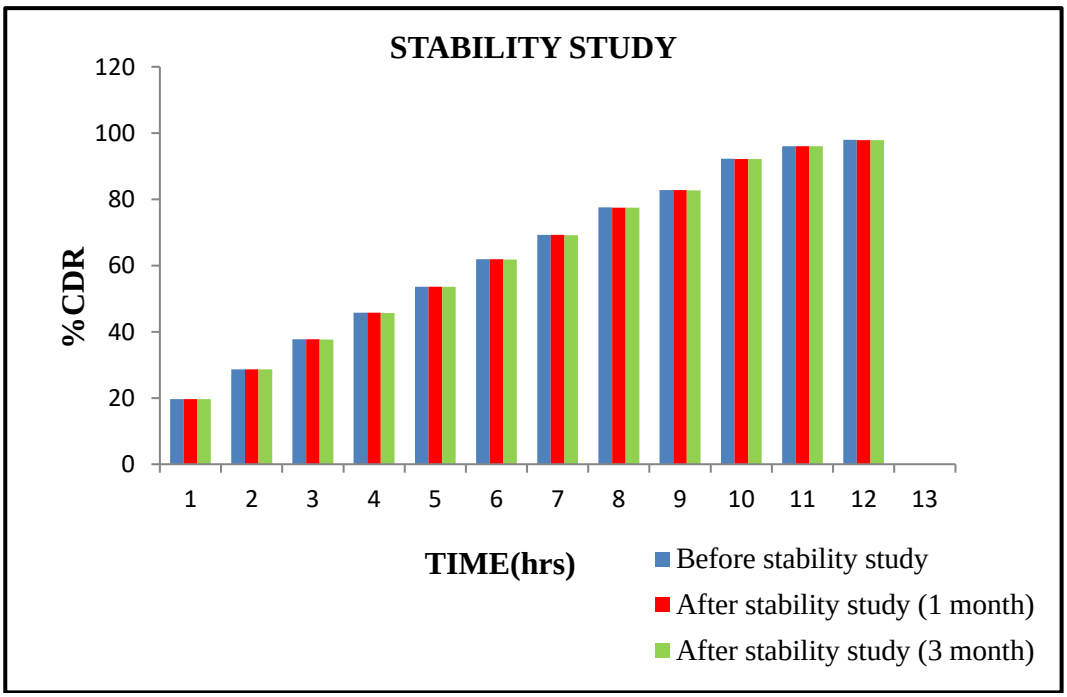
Stability studies

Stability studies were carried out on formulations F2 for a period of 3 month and comparison of the parameters before and after stability studies were represented in table 16.

Table 16: Comparison of physical parameters before and after stability studies

PARAMETERS	BEFORE STABILITY STUDIES	AFTER STABILITY STUDIES (1 MONTH)	AFTER STABILITY STUDIES (3 MONTH)
Physical Changes	Off-white, Round, Standard convex	No changes	No changes
%CDR	97.92	97.90	97.87
Hardness	4.3	4.1	4.0
% Drug Content	106.40	106.35	106.33

Figure 15: Graphical representation of %CDR before and after stability studies



The stability of the optimized formulation was known by performing stability studies for 3 month at accelerated conditions of 40°C ± 75 % RH. The formulation was found to be stable with no physical changes and also shows comparable results in hardness, % drug content and in-vitro drug release studies after the stability period. From the stability studies, it was confirmed that the formulation was stable.

DISCUSSION

The results of the present study demonstrates that Chia seed powder have comparable effect with the synthetic polymer HPMC K100M and it has better efficiency in sustaining the drug release. So Chia seed powder was used as a substitute for HPMC K 100 at low cost. A total of six formulations were prepared by wet granulation technique using PVP 10% in alcohol as granulating agent. The Preformulation studies such as bulk density, tapped density, angle of repose and Carr's compressibility index demonstrates good flow property. The melting point of Diclofenac shows it was absolutely pure. Typical tablet defects, like capping, chipping & picking were not observed. Results of other physical evaluation were found to be within the acceptable limits. The drug content was also within the range specified in IP. Formulation was optimized on the basis of acceptable properties and *in-vitro* drug release. *In-vitro* drug release was performed using USP Type II apparatus at 50 rpm in 900 ml of phosphate buffer (pH 6.8) for 12hrs. Standard curve and withdrawal samples were analyzed in UV-VI spectrophotometry at 276 nm.

CONCLUSION

The present study is meant to formulate matrix tablets of Diclofenac as sustained release tablets using Chia seed powder & the formulations were compared using HPMC at different concentration and thereby investigate sustained release behaviour of the fabricated tablets.It has been observed that Chia seed powder retarded the drug release up to 24 hours satisfactorily. The FTIR spectral data indicates there was no incompatibility between the drug and polymers. All the polymers are compatible with the drug .The drug release process involves anomalous transport (Non-Fickian) diffusion, as indicated by the n value for all the formulations were ranged from 0.473 to 0.678 ($0.43<n<0.85$) in Korsmeyer's plot. The results of the present study demonstrated that Chia seed powder can be used as an appropriate matrix forming agent by wet granulation technique for sustained release of Diclofenac over a period of 12 hr by providing reduced dosing frequency and side effects with low cost.

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