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Research Article

FORMULATION AND EVALUATION OF FAST DISSOLVING TABLET USING LOCUST BEAN GUM AS A NATURAL SUPERDISINTEGRANT AND COMPARISON WITH THE MARKETED PREPARATION

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ABSTRACT

The aim was to formulate and evaluate fast dissolving tablets of diclofenac sodium to improve the bioavailability of the drug and patient compliance. Fast dissolving tablets of diclofenac sodium were prepared by direct compression method by using superdisintegrants (locust bean gum) in 2%, 3%, 4% 5% & 6% concentration respectively. Tablets were formulated by using natural superdisintegrants locust bean gum (LBG). This formulated mixture i.e., drug and LBG was mixed with other excipients and the tablets were compressed by direct compression. Formulated tablets were characterized by FTIR, pre-compression and post- compression parameters. The *In vitro* drug release studies were performed in pH 6.8 phosphate buffer. Formulated tablets were characterized by FTIR, the results of IR study showed that there was no interaction between superdisintegrant and pure drug, the results of FTIR study showed that drug was stable in the final formulated tablet. The drug content was evaluated with the help of assay. Five (F1-F5) formulations were evaluated for pre-compression and post-compression parameters and all the results were in the standard limits. Formulated dosage form may be an effective alternative to conventional dosage form which can be effectively used in the treatment of inflammation specially in cases of acute pain.

Keywords: Superdisintegrants, Fast dissolving tablets, Diclofenac sodium, Disintegration time

INTRODUCTION

Oral route of drug administration is perhaps the most appealing route for the delivery of the drugs. The concept of fast dissolving drug delivery system emerged from the desire to provide patient with more conventional means of taking their medication. It is difficult for many patients to swallow tablets and hard gelatin capsules. Hence, they do not comply with prescription, which results in high incidence of non-compliance and ineffective therapy[1]. In some cases, such as motion sickness, sudden episodes of allergic attacks or coughing and unavailability of water, swallowing conventional tablets may be difficult. Particularly the difficulty is experienced by pediatric and geriatric patients. Such problems can be resolved by means of fast dissolving tablet. When put on tongue, this tablet disintegrates instantaneously, releasing the drug which dissolves or disperses in the saliva.

Ideal characteristics of fast dissolving tablets[2,3]

- They should not require water or other liquid at the time of administration.
- Should easily disintegrate and dissolve.
- Mask or overcome unacceptable taste of drug.
- They should have high drug loading.
- They should have pleasant feel in the mouth.
- They should have negligible or no residue in oral cavity after administration.
- They should have low sensitivity against environmental conditions like moisture, temperature etc. Ease of administration for patients who are mentally ill, disabled, and uncooperative. Should be portable without fragility concern. They should be manufactured using conventional tablet processing and packing equipment at low cost.

Superdisintegrants [4,5]

Both natural & synthetic superdisintegrants are used for the formulation of fast dissolving tablet. Examples of natural superdisintegrants are

- Gum karaya
- Okra gum
- Lepidium sativum
- *Plantago ovata*
- Guar gum
- Agar
- Locust bean gum etc.

Similarly, examples of synthetic superdisintegrant are

- Sodium starch glycolate
- Cross povidone
- Crosscarmellose sodium
- Primogel etc

Advantages of natural superdisintegrant over synthetic superdisintegrant are as follows; [6,7]

- Biodegradable.
- Biocompatible & nontoxic.
- Low cost.
- Local availability.
- Better patient tolerance.

Mechanism of tablet disintegration[8,9]

Disintegrants, an important excipient of the tablet formulation, are always added to tablet to induce breakup of tablet when it meets aqueous fluid and this process of desegregation of constituent particles before the drug dissolution occurs, is known as disintegration process and excipients which induce this process are known as disintegrants. The objectives behind addition of disintegrants are to increase surface area of the tablet fragments and to overcome cohesive forces that keep particles together in a tablet. Disintegrants expand and dissolve when wet causing the tablet to break apart in the digestive, releasing the active ingredients for absorption. They ensure that when the tablet is in contact with water, it rapidly breaks down into smaller fragments thereby facilitating dissolution.
There are four major mechanisms for disintegration of fast dissolving tablets as follow:

Swelling
Perhaps the most widely accepted general mechanism of action for tablet disintegration is swelling. Tablets with high porosity show poor disintegration due to lack of adequate swelling force. On the other hand, sufficient swelling force is exerted in the tablet with low porosity. It is worthwhile to note that if the packing fraction is very high, fluid is unable to penetrate in the tablet and disintegration is again slows down.

Porosity and capillary action (Wicking)
Disintegration by capillary action is always the first step. When we put the tablet into suitable aqueous medium, the medium penetrates the tablet and replaces the air adsorbed on the particles, which weakens the intermolecular bond and breaks the tablet into fine particles. Water uptake by tablet depends upon hydrophilicity of the drug /excipient and on tableting conditions.

For these types of disintegrants maintenance of porous structure and low interfacial tension towards aqueous fluid is necessary which helps in disintegration by creating a hydrophilic network around the drug particles.

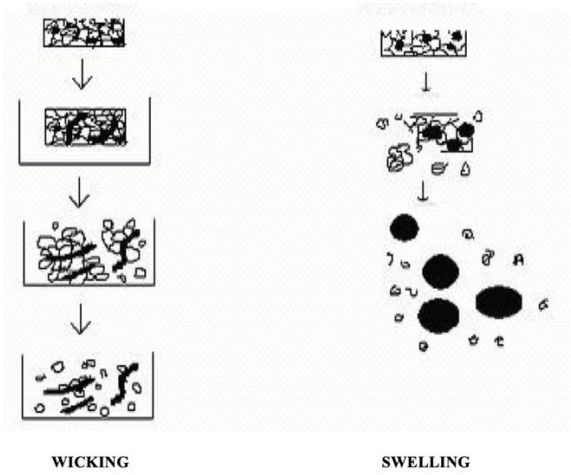


Figure 1: Steps involved in tablet disintegration by wicking and swelling

Due to disintegrating particle/particle repulsive forces
Another mechanism of disintegration attempts to explain the swelling of tablet made with 'non swellable' disintegrants. Guyot-Hermann has proposed a particle repulsion theory based on the observation that non swelling particle also cause disintegration of tablets, the electric repulsive forces between particles are the mechanism of disintegration and water is required for it.

Due to deformation
During tablet compression, disintegrated particles get deformed, and these deformed particles get into their normal structure when they meet aqueous media or water. Occasionally, the swelling capacity of starch was improved when granules were extensively deformed during compression. This increase in size of the deformed particles produces a breakup of the tablet. This may be a mechanism of starch and has only recently begun to be studied.

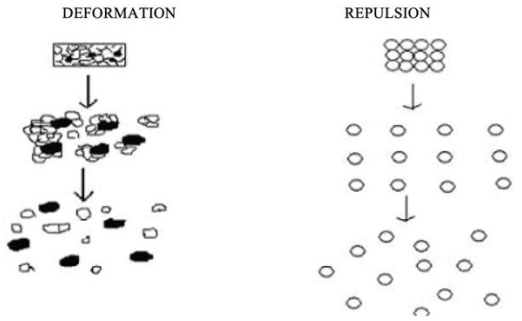


Figure 2: Steps involved in tablet disintegration by repulsion and deformation

The aim of this study was to formulate a fast-dissolving tablet. Advantages of a fast-dissolving tablet include[6]

- Ease of administration,
- Enhanced patient compliance to geriatric, pediatric and psychiatric patient
- Faster therapeutic effect.

Fast dissolving tablet needs superdisintegrants in its formulation for rapid dispersion. There are two types of superdisintegrants natural & synthetic. Till now many fast-dissolving tablets are available in market which are prepared by using synthetic superdisintegrants like sodium starch glycolate, cross povidone & crosscarmellose sodium. But now a day's new superdisintegrants are introduced i.e., natural one like gum karaya, okra gum, *Lepidium sativum*, *Plantago ovata*, guar gum, Agar, & locust bean gum,[10] etc.

These natural superdisintegrants have several advantages over synthetic superdisintegrants like [11]

- Biodegradable.
- Biocompatible & nontoxic.
- Low cost.
- Local availability.
- Better patient tolerance.

Locust bean gum has one of the natural superdisintegrant properties. It is called as carob bean gum. It is a vegetable gum extracted from the seeds of the carob tree (*Ceratonia siliqua)*, mostly found in the Mediterranean regions. Locust bean gum has been widely used in food industry as a thickening and gelling agent Locust bean gum has also been reported to have extensive swelling, bio adhesive and solubility enhancement properties. [12,13]

Diclofenac sodium is an anti-inflammatory drug which undergoes extensive hepatic degradation (96%) which have poor bioavailability (26%). For overcoming this problem, fast dissolving tablet of diclofenac sodium can be formulated which avoids extensive first pass comparison improvement in bioavailability. This formulation can be effectively used in case

of pain during travelling & in situation where there is no access of water. [14]

Therefore, the main objective of the present work is to develop fast dissolving tablet of diclofenac sodium to improve bioavailability, dissolution time, dissolution efficacy & patient compliance Also from the literature survey it was seen that not much work has been done on fast dissolving tablet using locust bean gum as natural superdisintegrants.

Hence the proposed work include: -

- Evaluation of natural superdisintegrants (locust bean gum)
- Formulation of fast dissolving tablet of a diclofenac sodium using natural superdisintegrant (locust bean gum).
- Evaluation of prepared tablet.

MATERIALS AND METHODS [15,16-19]

Selection & procurement of drug and excipients.

Evaluation of natural superdisintegrant [20]

- Swelling Index
- Viscosity
- pH
- Loss on drying
- Flow properties
    - Angle of repose.
    - Bulk density.
    - Tapped density.
    - Hausner's ratio.
    - Carr's compressibility index.

Pre-formulation parameters

- Solubility
- Melting point
- λ max
- Standard calibration curve of drug
- Drug-excipient compatibility studies by F.T.I.R.

Formulation of fast dissolving tablet.[21]

Pre-compression parameters.

- Angle of repose.
- Bulk density.
- Tapped density.
- Hausner's ratio.
- Carr's compressibility index.

Post-compression parameters: -[22,23,24]

- Thickness.
- Hardness.
- Friability.
- Weight variation.
- Wetting time.
- Water absorption ratio.
- Drug content.
- *In vitro* dispersion time.
- *In vitro* dissolution study.

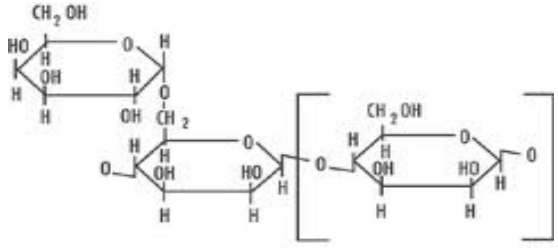
Stability studies

Comparison with marketed formulation

LOCUST BEAN GUM [25,26,27]

Botanical name: *Ceratonia siliqua* (L)
Family: *Leguminosae*
Synonyms: Carob bean gum, carob gum
Vernacular Name: Hindi: Tiddi sema gum, Eng: Carobin

Chemical structure



Distribution: This elegant tree grows throughout world like India, European Union, United States of America, Japan and Australia.

Figure 3: Photograph showing pod, seed, and powder of Locust bean gum

Description

Carob bean gum, also known as locust bean gum, carubin or algaroba, is obtained from the endosperm of seed of the carob (locust) tree, *Ceratonia siliqua* (L.) Taub (Fam. *Leguminosae)*. The carob tree is a large seed of the carob (locust) tree, *Ceratonia siliqua* (L.) Taub (Fam. *Leguminosae).* The carob tree is a large evergreen tree, and its fruit is a long brown pod containing very hard brown seeds, the kernels. The seeds are dehusked by treating the kernels with dilute sulfuric acid or with thermal mechanical treatment. The gum may be washed with ethanol or isopropanol to control the microbiological load (washed carob bean gum). It may also be further clarified (purified, extracted) by dispersing in hot water, recovery with isopropanol or ethanol, filtering, drying, and milling, which is called as clarified (purified, extracted) carob bean gum. The gum is a white to yellowish white, nearly odorless powder.

Carob bean gum is insoluble in most organic solvents including ethanol. It is partially soluble in water at ambient temperature and soluble in hot water. Carob bean gum typically needs heating to above 85ºC for 10 minutes for complete solubility.

Chemical constituents

Carob bean gum is mainly consisting of the high molecular weight (approximately 50,000-3,000,000) polysaccharides composed of galactomannans. The clarified gum has higher galactomannans content The mannose: galactose ratio of carob bean gum is approximately 4:1. The mannose and galactose content has been reported as 73-86% and 27-14% respectively.

Purification of locust bean gum [25]

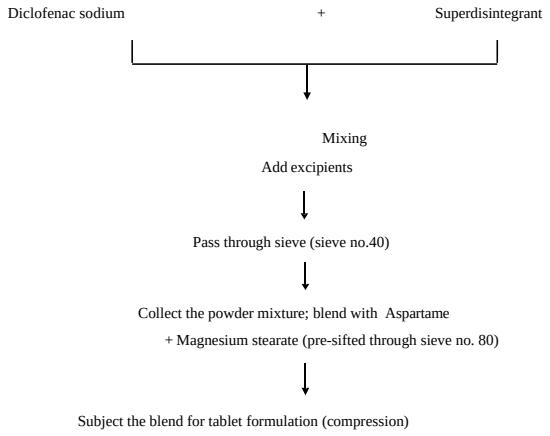
Locust Bean Gum was dispersed in water and dissolved by heating. This solution was filtered (with a filter aid) to remove insoluble material. From this clear solution, the carob bean gum is precipitated with isopropanol or ethanol, the precipitate was filtered off. The white fibrous precipitate formed was collected by filtration under vacuum and washed twice with isopropanol and successively

with acetone and diethyl ether, after drying overnight in oven at 30 ºC, the precipitate was ground to fine powder.

Evaluation of powder properties of locust bean gum [26,27]
The locust bean powder was evaluated for flow properties including bulk density, tapped density, angle of repose, Carr's compressibility index and Hausner ratio.

Formulation of tablets
Five batches of tablets (F1 to F5) were prepared with the help of natural superdisintegrants i.e., Locust bean gum by direct compression method. Each superdisintegrant was used in the concentration of 2%, 3%, 4% ,5% & 6%. Diclofenac sodium fast dissolving tablets were manufactured in ten formulations F1 to F5 using the ingredients mentioned in the Table 5.3. Diclofenac sodium was used with Locust bean gum to formulate the fast-dissolving tablet. All the ingredients with drug except magnesium stearate were taken in the mortar. The powder blend was then mixed well by using mortar and pestle for 15 to 30 minutes, and then each mixture was passed through # 80 sieve.

Finally, magnesium stearate was added as a lubricant and mixed thoroughly. The powder blend was compressed using tablet compression machine to produce tablets of diclofenac sodium weighing 200 mg having diameter of 8 mm. The steps involved are shown in fig .8 (flow chart).



Flow chart showing steps involved in formulation of tablets

RESULTS

Purification of locust bean gum
The % yield of locust bean gum was found to be **20%**

Evaluation of Locust bean gum

Table 1: Powder evaluation of locust bean gum

Parameter	Result
Bulk Density(g/cm^3) (±SD) (n=3)	0.50 ± 0.001
Tapped density(g/cm^3) (±SD) (n=3)	0.62 ± 0.001
Angle of repose(θ)	20.52
Carr's compressibility index (%)	19.85
Hausner ratio	1.14
Swelling index	14
Loss on drying (%)	7
pH	5.9
Viscosity (cps) at 50 rpm (1%)	6

SD=standard deviation, n=3 all parameters shown above are based on 3 replicate and expressed as mean

Preformulation studies
Melting point determination
The melting point of diclofenac sodium was found to be 280-282ºC.

Solubility studies
The solubility of diclofenac sodium in various solvents reveals that it was sparingly soluble in water, soluble in alcohol and slightly soluble in acetone

Estimation of diclofenac sodium by UV spectroscopy

Determination of λ max

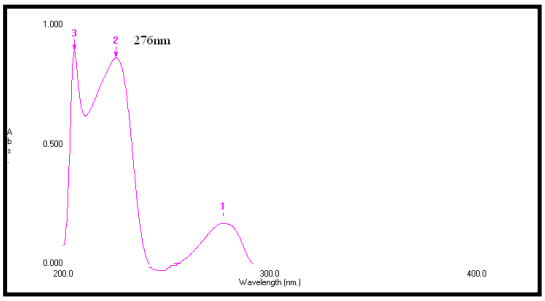


Figure 4: UV Spectra of diclofenac sodium
λ max of diclofenac sodium in pH6.8 buffer solution was found to be 276 nm

Calibration curve

Table 2: Absorbance data for the calibration curve of diclofenac sodium in pH 6.8 buffer

Concentration(µg/ml)	Absorbance
0	0
10	0.311
20	0.609
30	0.837
40	1.092
50	1.361

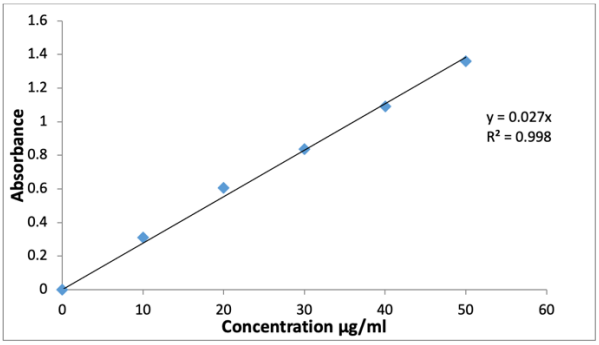


Figure 5: Standard calibration curve of diclofenac sodium in pH6.8 buffer.

Compatibility studies
FTIR Spectroscopy

Identification of diclofenac sodium
The IR spectrum of pure drug was found to be similar to the standard spectrum of diclofenac sodium

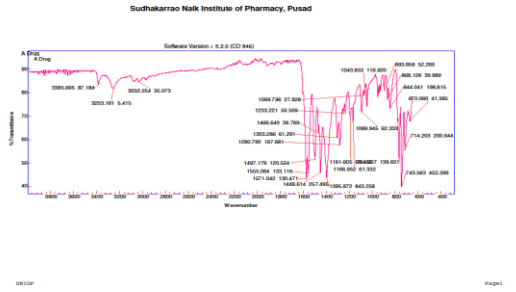


Figure 6: IR spectra of pure diclofenac sodium

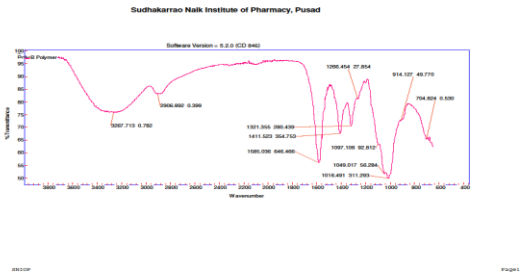


Figure 7: IR spectra of pure polymer locust bean gum

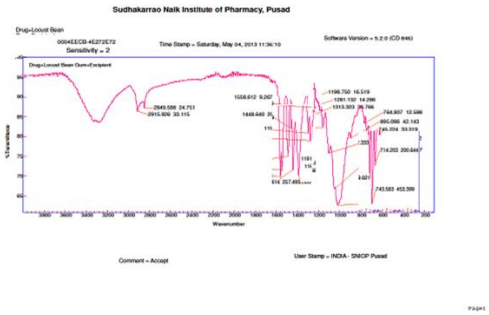


Figure 8: IR spectra of physical mixture of diclofenac sodium, locust bean gum & excipient

It was found that diclofenac sodium was compatible with superdisintegrants used in the formulation, there were no extra peaks observed. Thus, the chosen superdisintegrants for the formulations were found to be compatible with diclofenac sodium and have no physical interaction.

Formulation development [28,29]

Formulation design

Table 3: Composition of diclofenac sodium fast dissolving tablets by direct compression method

Ingredients(mg)	F1	F2	F3	F4	F5
Diclofenac sodium	50	50	50	50	50
Locust bean gum	4	6	8	10	12
Microcrystalline sodium	131	129	127	125	120
Aspartame	10	10	10	10	10
Magnesium stearate	2.5	2.5	2.5	2.5	2.5
Talc	2.5	2.5	2.5	2.5	2.5
Total weight	200	200	200	200	200

Evaluation of fast dissolving tablets of diclofenac sodium

Pre-compression Evaluation

Table 4: Evaluation of powder

Formulation code	Bulk Density g/ml (±SD) (n=3)	Tapped Density g/ml(±SD) (n=3)	Angle of repose (θ) (±SD) (n=3)	Compressibility (±SD) (n=3)	Hausner's ratio (±SD) (n=3)
F1	0.71 ±0.001	0.86± 0.001	21.2 ± 0.15	17.44 ± 0.12	1.15 ± 0.12
F2	0.62± 0.001	0.80± 0.001	21.6 ± 0.18	15.00 ± 0.15	1.21 ± 0.08
F3	0.67± 0.001	0.80± 0.002	20.4 ± 0.09	15.85 ± 0.13	1.17 ± 0.14
F4	0.68± 0.002	0.82± 0.002	22.12± 0.23	17.07 ± 0.11	1.14 ± 0.15
F5	0.66± 0.001	0.81± 0.001	23.3 ± 0.16	17.02 ± 0.08	1.19 ± 0.10

SD=standard deviation, n=3 all parameters shown above are based on 3 replicate and expressed as mean

Post compression evaluation

Table 5: Post compression evaluation of fast dissolving tablets of diclofenac sodium

Formulation code	Thickness (mm) (±S.D),n=3	Hardness) (±S.D),n=3 (kg/cm^2)	Weight variation (mg) (±S.D)	Friability (%) (±SD),n=3
F1	2.60±0.011	3.2 ± 0.12	193±0.01	0.66 ± 0.8
F2	2.66±0.012	3.2 ± 0.12	192±0.01	0.58 ± 1.2
F3	2.62±0.015	3.3 ± 0.13	195±0.01	0.64 ± 0.4
F4	2.70±0.014	3.3 ± 0.14	196±0.01	0.57 ± 0.5
F5	2.68±0,013	3.5 ± 0.11	193±0.01	0.61 ± 0.2

SD=standard deviation, n=3 all parameters shown above are based on 3 replicate and expressed as mean

Table 6: Post compression evaluation of fast dissolving tablets of diclofenac sodium

Formulation code	Dispersion time (sec) (±SD), n=6	Wetting Time (sec)(±SD), n=3	Drug content (%) (±SD),n=1
F1	40±0.9	28.14 ± 1.6	99.86 ± 0.4
F2	36±0.	20.07 ± 1.4	99.28 ± 0.2
F3	34±1.2	18.04 ± 1.1	99.49 ± 0.9
F4	31±0.6	18.11 ± 1.8	99.51 ± 0.7
F5	35±0.7	22.16 ± 1.4	99.22 ± 1.0

SD=standard deviation, n=3 all parameters shown above are based on 3 replicate and expressed as mean, n=6 all parameters shown above are based on 6 replicate and expressed as mean

Drug release profile

Table 7: In-vitro drug release data of fast dissolving tablets of diclofenac sodium (F1-F5)

Time (min.)	% Cumulative drug release (±SD), n=3				
	F1	**F2**	**F3**	**F4**	**F5**
	0	0	0	0	0
0	28.1±1.04	33.25±1.03	36.18±1.03	42.19±1.02	39.01±1.03
2	38.06±1.03	44.29±1.04	49.19±1.03	60.21±1.05	55.68±1.08
4	51.39±1.05	65.26±1.08	69.56±1.03	78.83±1.09	71.39±1.05
6	68.19±1.07	71.98±1.05	75.98±1.03	87.37±1.06	85.90±1.03
8	79.56±1.04	83.02±1.04	87.03±1.03	97.89±1.05	94.18±1.06
10	79.56±1.04	83.02±1.04	87.03±1.03	97.89±1.05	94.18±1.06

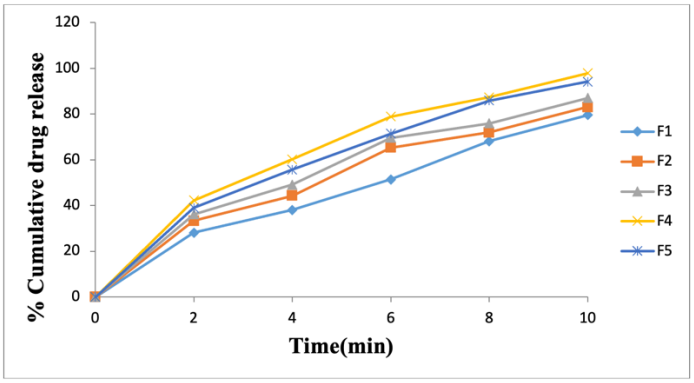


Figure 9: *In-vitro* drug release of fast dissolving tablets of diclofenac sodium (F1-F5) using locust bean gum

Drug release studies were carried out for all formulations (F1-F5) with pH 6.8 buffer used as dissolution medium, formulation F4 showed the highest drug release 97.89%.

Standard for drug release profile of fast dissolving tablets
Fast dissolving tablets shows drug release more than 80% within 10 minutes

Comparison of best formulation with marketed preparation

Comparison with Marketed Product
Labelled claim: Diclofenac sodium 50mg,
Total weight of tablets 200mg

Characterization of the marketed tablets of diclofenac sodium

Table 8: Characterization of the marketed tablets of diclofenac sodium & its comparison with optimized formulation (F4)

Evaluation parameter (±SD), n=3	Observation of marketed formulation	Observation of optimized formulation (F4)
Thickness	2.70±0.05 mm	2.70±0.01 mm
Hardness	4.3 ±1.23 kg/cm2	3.3 ± 0.14 kg/cm2
Friability	0.55±0.03 %	0.57 ± 0.5%
Weight variation	191±0.09 mg	196±0.01 mg
% Drug content	98.20±0.79%	99.51 ± 0.7 %
% Cumulative drug release	96.00±1.04	97.89±1.07
Dispersion time	64 sec	31sec

SD=standard deviation, n=3 all parameters shown above are based on 3 replicate and expressed as mean

% Drug release of marketed tablets of diclofenac sodium

Table 9: % Drug release of marketed tablets of diclofenac sodium & its comparison with optimized formulation (F4)

Time in minutes	%CDR (marketed formulation) (±SD), n=3	%CDR (optimized formulation (F4)) (±SD), n=3
0	0.00	0.00
2	25.19±1.07	42.19±1.02
4	45.84±1.06	60.21±1.05
6	86.40±1.02	78.83±1.09
8	91.55±1.04	87.37±1.06
10	96.00±1.03	97.89±1.05

SD=standard deviation, n=3 all parameters shown above are based on 3 replicate and expressed as mean

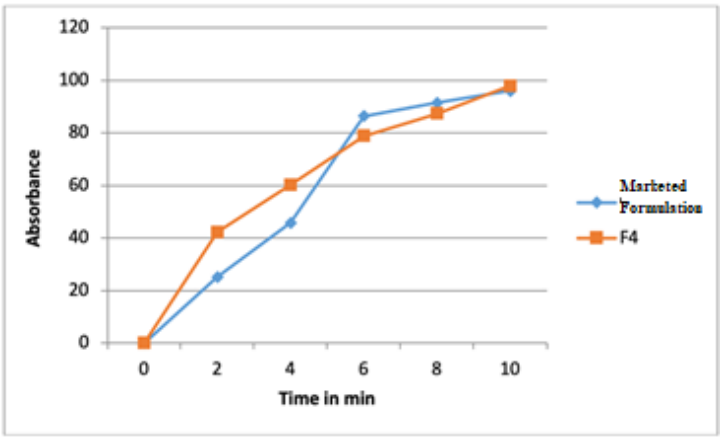


Figure 10: Comparison of *in vitro* drug release profile of diclofenac sodium tablet

Formulation F4 with marketed formulation % Drug release of optimized formulation (F4) is 97.89 as compared to marketed formulation i.e., 96.00%

DISCUSSION

The concept of formulating fast dissolving tablets containing diclofenac sodium offers a suitable, practical approach to achieve fast release of the drug. Absorption of these tablets takes place directly into the systemic circulation which avoids the hepatic first pass metabolism of diclofenac sodium which ultimately results in the improvement in the bioavailability. In present work, fast dissolving tablets of diclofenac sodium were prepared successfully by direct compression method using the different superdisintegrants in different concentrations like locust bean gum in different concentrations. Other excipients used were microcrystalline cellulose as diluent, magnesium stearate as lubricant, talc as glidant. & Aspartame as sweetener. All the pre-compression parameters like angle of repose, bulk density, Carr's index was studied. The compressed tablets were subjected to drug content, hardness, friability, weight variation and *in vitro* dissolution studies.

The drug and excipients compatibility were studied by FTIR which revealed that no chemical or physical interaction took place. Fast dissolving tablet of diclofenac sodium were prepared successfully by direct compression method using the superdisintegrants like locust bean gum in different concentrations and showed the different release patterns. The prepared tablets were found to be good without chipping, capping, and sticking. The drug content was uniform in all the tablet formulations indicating uniform distribution of drug within the formulated tablet. Five formulations were prepared viz. F1-F5 in which F4 formulation showed highest drug release 97.89% and lowest dispersion time 31sec which contained 5% locust bean gum. The optimized formulation F4 was found to be complying with all the properties of tablets and the other formulations were satisfactory. From the results of disintegration time, dissolution profile it was concluded that formulation F4 was found to be the most optimal formulation. Formulation F4 containing 10% locust bean gum can be effectively used in the clinical formulation of Fast dissolving tablets, especially in cases of sudden pain. By studying above results locust bean gum was most suitable superdisintegrant for formulation of fast dissolving tablets of diclofenac sodium.

CONCLUSION

We can conclude that fast dissolving tablets can be prepared by using natural superdisintegrants i.e., locust bean gum which showed the dispersion time less than that prepared by using synthetic superdisintegrants. Also, there are several advantages of natural superdisintegrants over that of synthetic superdisintegrants. Hence, from the results of disintegration time, and dissolution profile study it was concluded that formulation F4 was found to be the most suitable formulation. Formula of formulation F4 (5% locust bean gum) which can be used in future for production of fast dissolving tablets of diclofenac sodium which can be an effectively used in the treatment of inflammation especially in cases of sudden increase in pain.

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