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Fabrication Of Diclofenac SR Tablets

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ABSTRACT

SR (Sustained Release) tablets of Diclofenac Sodium was prepared by using HPMC and Ethyl cellulose. The Evaluation of tablets is involved the Prefabrication studies such as compressibility index, bulk density, angle of repose, and physical characteristics like hardness, weight variation friability, and drug content. In-vitro release of drug was performed in Phosphate Buffer System having pH 7.2 for 10 hours. All the physical characters of the fabricated tablet were within acceptable limits. Dissolution profile of Diclofenac sodium from matrix tablets prepared using different polymers were indicated an increase in the polymer ratio retarded the drug release to a greater extent.

Keywords: *Diclofenac sodium, HPMC, Ethylcellulose, Sustained release*

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1. Introduction

Oral drug delivery is the most liked and helpful alternative as the oral route gives greatest dynamic surface zone among all drug delivery frameworks for organization of different drugs. The engaging quality of these measurements structures is because of attention to toxicity and inadequacy of drugs when controlled by oral traditional technique as tablets and cases. These components just as elements, for example, dreary dosing and unusual assimilation lead to the idea of oral controlled discharge drug delivery frameworks. The controlled release drug delivery framework deals with a wide range of instruments to control the discharge rate of drugs. Different components like osmotic weight, network framework, repository framework, modified thickness framework and so forth have been used as Detailing approaches. The present article contains brief audition of different detailing approaches for controlled discharge drug delivery framework.[1]

An oral drug delivery system giving a uniform drug delivery can just not entirely satisfy supportive and biopharmaceutical needs, as it doesn't consider the site express ingestion rates inside the gastrointestinal tract (GIT). Thus there is a need to make drug delivery system that releases the drug at the helpful time, at the specific site and with the perfect rate.

Any drug or dosage structure modification that drugs out the restorative action of the drug.

1.1 SR Drug Delivery System

Sustained discharge plan keeps up a uniform blood dimension of drug with better patient consistence just as expanded adequacy of drug. Sustained discharge tablets are commonly taken more than once per day during a course of treatment while in conventional dosage forms there is have to take 3-4 times dosage in multi day to accomplish a similar helpful activity.[2]

1.2 Merits of SR drug delivery system

- Reduces the frequency of dose administration.
- Provide increase patient compliance.
- Reduces irritation in the GIT and decreases chances of side effects.
- Drug cost is reduced which increases more patient acceptability.
- Health care cost is reduced by improved therapy.
- Bioavailability of many drugs is improved by formulating them into SR Fabrications.[2]

1.3 Disadvantages of SR Drug Delivery System

- Drugs having short t1/2 require frequent administration of drugs, which increases the chances of missing the dose.

- If the drug is administered at an undefined interval, it provides sun steady peak plasma concentration
- There are more chances of fluctuation in drug plasma concentration.
- Patient compliance is very poor due to frequent administration of drugs.[2]

1.4 Rationale of SR drug delivery system

- To expand the duration of activity of medication.
- To diminish the dose recurrence.
- To limit the variances in plasma level.
- Improved drug usage.
- Less adverse impacts.[2]

1.5 Properties of sustained release Fabrication

Detailing of SR drug conveyance frameworks, consider the a few criteria, for example, the course of organization, kind of drug conveyance framework, what ailment to be dealt with, the patient, the length of treatment and the normal for the drug those previously mentioned factor ought to be considered. The pharmaceutical enthusiasm to inquire about researcher for planning of the conveyance framework the accompanying properties could be considered in the improvement of dose structure. These properties can be delegated pursues.

- Physicochemical properties
- Biological properties

Physio chemical factors considered for designing of oral sustained-release dosage form design

2 Drug Dose

In general, a single dose containing 0.5 to 1.0gm is considered as maximum dose for Conventional dosage for holds SR dosage form.

2.1 Ionization, aqueous solubility and pka

Most drugs having nature of Weak acids or bases, since the unaltered type of Drug enters crosswise over lipid layers which are advantageous for medication retention. Mixes with low solubility (< 0.01 mg/ml) are naturally continued, since their discharge over the time course of a measurements structure in the GI tract will be restricted by dissolution of the medication. So clearly the solubility of the compound will be poor decisions for somewhat dissolvable drugs, since the main thrust for diffusion, which is the medication's concentration in matrix, will be showing low.

2.2 Partition Coefficient

At the point when a drug is administered to the GI tract, it must cross an assortment of biological membranes to create a helpful impact in another part of the body. It isn't unexpected to think about that these membranes are lipidic; consequently the partition coefficient of oil-dissolvable drugs ends up significant in deciding the viability of membrane obstruction infiltration. Compounds which are lipophilic in nature having high partition coefficient is inadequately watery solvent and it hold in the lipophilic tissue for the more extended time. If there should arise an occurrence of mixes with low partition coefficient, it is hard for them to penetrate the membrane, bringing about poor bioavailability. Moreover, partitioning impacts apply similarly to diffusion through polymer membranes. The decision of diffusion-limiting membranes should to a great extent rely upon the partitioning qualities of the drug.

2.3 Protein binding

Its properties the drugs are authoritative to blood protein. The drug-Protein complex it can go about as a station for drug particle and to discharge a drug for delayed period and prompts display a very official to plasma. The appealing forces are basically relevant for restricting are vanderwaals forces, hydrogen bonding and electrostatic forces. In the event that a drug particle having hydrophobic in nature its can likewise expanding the coupling limit. Drugs binding to mucin it might increase absorption, for example quaternary ammonium compounds bound to mucin in the gastro intestinal tract.

Biological factors responsible for influence over oral sustained-release dosage form design

2.4 Biological half life

When a drug is reaches to the GI tract, it must cross an path of biological membranes to create a helpful another part of the body is also imparted. It isn't unexpected to think about that these membranes are lipid; consequently the partition coefficient of oil-dissolvable drugs ends up significant in deciding the viability of membrane obstruction infiltration. Compounds which are lipophilic in nature having high partition coefficient is inadequately watery solvent and it hold in the lipophilic tissue for the more extended time. If there should arise an occurrence of mixes with low partition coefficient, it is hard for them to penetrate the membrane, bringing about poor bioavailability. Moreover, partitioning impacts apply similarly to diffusion through polymer membranes. The decision of diffusion-limiting membranes should to a great extent rely upon the partitioning qualities of the drug.

2.5 Absorption

It is known that the rate of release is much slower than the rate of absorption. On the off chance that we accept that the transit time of most drugs in the absorptive zones present in GI tract is around 8-12 hours, the greatest half-life for absorption to be approx 3-4 hours; generally, the gadget will go out of the potential absorptive locales before medication discharge is complete. Accordingly corresponds to a base apparent retention rate constant of 0.17-0.23 h-1 to give 80-95% over this period. Henceforth, it accepts that the absorption of the medication ought to happen at a moderately uniform rate over the whole length of small intestine. For some compounds this isn't valid. If a medication is absorbed by active transport or transport is restricted to a particular locale of intestine, SR preparation might be disadvantageous to assimilation.

2.6 Metabolism

Drugs that are essentially metabolized before absorption, either in the lumen or the tissue of the intestine, can show diminished bioavailability from a slower-discharging measurement structure.

Henceforth criteria for the medication to be utilized for planning the Sustained-Release measurements structure is,

- Drug should to have low half-life (<5 hrs)
- Drug should to be freely solvent in water
- Drug should to have bigger therapeutic window
- Drug should to be absorbed all through the GIT.

Indeed, even a medication that is ineffectively water solvent can be defined in SR measurement structure. For the Same, the solvency of the medication ought to be expanded by the reasonable system and later on that is defined in the SR dosage form. Be that as it may, during this the crystallization of the Medication, that occurs as the medication enters the systemic circulation, should to be counteracted and one should be careful for the resistance of the equivalent.[3]

2.7 Distribution

After medication administration it is experiencing for distribution into different body tissues and additional vascular spaces in the body, is a significant parameter for medication elimination kinetic model.

A few parameters are utilized to give thought regarding distribution of medication. Apparent volume of distribution of active component is high it will impact the elimination of measurement structure and not reasonable for making sustained discharge tablet. The term apparent volume

of distribution of a medication is for the most part used to clarify the distribution, including bound to the body system. The complete loft volume of distribution for a medication at enduring state will be calculated by given equation.

Where,		$V_{dss}=[(K_{12}+K_{21}) / K_{21}]V_P$
Vdss	=	Apparent volume of distribution at study state level
K12	=	Drug from central to peripheral compartment
K21	=	Drug from peripheral to central Compartment
V_P	=	Volume of central compartment

2.8 Side effects

The frequency of reaction of a drug is depends upon its therapeutic concentration level in blood. It very well may be cure by the drug concentration level is controlled at which timing that dug exists in blood after administration. toxic impact of a drug is normal over the most extreme effective range level and fall in the therapeutic impact if a medication underneath the dimension of least effective range. So the above issues can be illuminated by making sustained discharge preparation.

2.9 Margin of safety

Therapeutic index of a medication is significant for either sustained or controlled release delivery system. Its value only desired the margin of safety. Therapeutic index value it has been longer methods phenomenal for preparation of sustained discharge tablet. Narrow therapeutic index of some medication exact to discharge the active content in therapeutic sheltered and effective range. Some medication like Cardiac glycosides that therapeutic index worth is extremely small, so it's not utilized for SR delivery system.

3. Non steroidal anti-inflammatory drugs

NSAIDs are drugs having analgesic, antipyretic and anti-inflammatory properties that are used to reduce pain, fever and show anti-inflammatory action.
These drugs are different from steroids drugs, which have a wide range of effects different from NSAID’s have a similar eiconoside depressing, anti-inflammatory action.

3.1 Mechanism of action

NSAID’s are act by inhibiting he enzyme Cyclooxygenaseive inhibitors of the enzyme

cyclooxygenase, inhibiting both the cyclooxygenase-1 (COX-1) and cyclooxygenase-2(COX-2) isoenzymes.

There is overwhelming evidence pointing to the inhibition of cyclooxygenase enzyme as the main mechanism of NSAIDs' analgesic, antipyretic, and anti-inflammatory properties. Inhibition of Cyclooxygenase (COX) results in the inhibition prostaglandin synthesis and other eicosanoid thereby reducing, fever, and inflammation. The cyclooxygenase (COX) enzyme also known as prostaglandin endoperoxide H synthase (PGHS) which exists in two isoforms: PGHS-1 or COX-1 and PGHS-2 or COX-2. Both isoforms can membrane glycoprotein's catalyzing the formation of prostaglandin from arachidonic acid.[4]

3.2 Classification of NSAIDs

Table1: Classification of NSAIDs

Sr. No.	Category	Drug
1.	**Nonselective COX inhibitors (traditional NSAIDs)**	
	Salicylates	Aspirin
	Propionic acid erivatives	Diclofenac Sodium, Naproxen, Ketoprofen, Flurbiprofen.
	Fenamate	Mephenamic acid [5]
	Enolic acid derivatives	Piroxicam, Tenoxicam
	Pyrazolone derivatives	Phenylbutazone, Oxyphenbutazone
	Acetic acid derivatives	Ketorolac, Indomethacin, Nabumetone
2.	PreferentialCOX-2 inhibitors	Nimesulide, Diclofenac, Aceclofenac, Meloxicam,Etodolac
3.	SelectiveCOX-2inhibitors	Celecoxib, Etoricoxib, Parecoxib.
	Analgesic-antipyretics with poor antiinflammatory action	

4.	Para amino phenol derivative	Paracetamol (Acetaminophen).
	Pyrazolone derivatives	Metamizol (Dipyrone), Propiphenazone.
	Benzoxazocine derivative	Nefopam [6-7]

4. MATERIALS AND METHOD

4.1 Material Source

The following materials were collected from different sources.

4.2 Characterization of Powdered Blend

4.2.1 Bulk density

It is characterized as the angle of heapto the horizontal plane. Angle of repose was controlled by utilizing fixed funnel technique. Specific amount of powder medication was moved to the funnel keeping the opening of the funnel hindered by thumb. Powder was cleared from funnel at that point estimated its angle of repose. Obvious bulk density (pb) was dictated by pouring the mix in to a graduated cylinder.
The bulk volume (vb) and weight of the powder (M) was calculated utilizing the formula.
Pb=M/Vb

4.2.2 Tapped density

Tapped density was calculated by Tapping the known amount of powdered drug for a specific time by using a graduated measuring cylinder. The tapped density (Pt) was calculated by using formula:
Pt=M/Vt

Where,
Vt=minimum volume occupied in the cylinder

M= weight of the blend was measured.[8]

2.4.3 Carr's index

It is also known as compressibility index, it is simple method to measure the compressibility index, indicating easiness of material free flowing, it is calculated by.

I=(Vo-Vt/Vo)×100

Where,

Vo is the bulk volume Vt=tapped volume.

Table 2: Car's Index

Carr'sindex%	Flowability
5-15	Excellent
12-16	Good
18-21	Fairly acceptable
23-35	Poor
33-38	Very poor
<40	Very very poor

2.4.4 Hausner'sratio

Hausner's ratio was ease of indirect index of powder flow measurement. Hausner's ration is indirectly proportional to flow properties of powder means if Lower is Hausner's ratio (<1.25) indicates better flow properties than higher Hausner's ratio (>1.25).[9]

It was calculated by. Hausnerratio=Pt/Pd Where,

Pt=tapped density

Pd=bulk density lower hausner'sratio

(<1.25) indicates better flow properties than higher ones(> 1.25)

2.4.5 Angle of repose

Angle of repose (θ) is defined as the angle between surface of a pile formed by powder and horizontal plane. It is measured by using a funnel method.

The powder blend was poured through a funnel that can be raised vertically until a maximum cone height (h) was formed. After passing of poured powder from funnel the maximum height of cone is obtained and radius of the heap (r) was measured and angle of repose (θ)was calculated by use of the following formula.[10,11]

θ=tan-1(h/r)

Table 3: Angle of Repose.

Sr. No.	Flowability	Angle of repose
1	Excellent	<25

2	Good	25-30
3	Passable	30-40
4	Poor	37-45
5	Very poor	>45

2.5 Fabrication of Sustained Release Tablet of Diclofenac

Tablet Fabrication was prepared by wet granulation technique.

Table 4: Fabrication Batches details of Diclofenac sodium sustained release tablets.

Ingredients(mg)	F1	F2	F3	F4	F5
Diclofenac sodium	50	50	50	50	50
HPMC(K40)	12	20	-	-	-
Ethyl Cellulose	-	-	28	12	20
Lactose	328	320	312	328	320
Talc	5	5	5	5	5
Magnesiumstearate	5	5	5	5	5
IsoPropyl alcohol	qs.	qs.	qs.	qs.	qs.

3. Evaluation of Sustained Release Tablet of Diclofenac

Thickness and diameter of tablet was estimated utilizing calibrated vernier calipers. Ten tablets of every Fabrication were selected randomly and evaluated for thickness and diameter. The tablets were assessed for appearance, thickness, weight variation, hardness and friability.[12]

3.1 Appearance

The tablets were inspected visually for elegance and general appearance. Evaluated tablets was found as round in shape, unstained in color, having smooth texture contains no odor.

3.2 Dimensions (Thickness and Diameter)

Thickness of tablets was measured by using calibrated vernier Calipers. Tablet was Placed in between two jaws vertically and thickness was measured. Thickness was measured in mm.

3.3 Hardness

Monsanto hardness tester was used for determination of hardness. Hardness of tablet was measured by fitting of tablet length wise between plungers and applied the force. The pressure at which tablets was crushed was noted, Called hardness of Tablet. It is measured in Kg/cm2. This study requires 6 tablets were used for this study.[12]

3.4 Percent friability

- Friability is defined as Loss of Tablets during transportation and Storage. Roche friabilator is used for calculation of friability.
- 20 tablets are randomly selected from each Fabrication; tablets are weighed, note down the initial weight.
- Place into drum friabilator, and tested for 4 min. by rotating at 25 RPM.
- After 4min. the tablets was withdrawn from drum and dust was removed,
- Tablets were re-weighed for calculation of % Friability and friability percentage was calculated using the following equation. C It is expressed in percentage (%) and calculated by the following formula:

$$\text{Friability (\%)} = \frac{\text{Initialweight-Finalweight}}{\text{Initial weight}} \times 100$$

0.5-1.0% for compressed tablets that lose less than of their weight was generally considered acceptable.

3.5 Weight variation

Weight of 20 tablets from each Fabrication was taken individually, Average weight of tablets was calculated and the weight of individual tablet was compared with the average weight of tablets.

USP States that the tablets meet the USP test if close to two tablet are outside the percentage limit if no tablet vary by two times of percentage limit. The weight variation resistances for uncoated tablets vary contingent by and large weight. Weight variation of tablets was determined by comparing the of weight of individual tablet average weight.

Table 5: Acceptance criteria for %Deviation.

S. No	Average Weight of tablet	% Deviation
1.	80 mg or less	10
2	More than 80 but less than 250mg	7.5
3	250 mg or more	5

3.6 Drug Content Uniformity (Assay)

The arranged Fabrication of Diclofenac sodium was weight and crushed. Powder identical to 50 mg of diclofenc sodium was gauged and shaken with 10 ml of methanol in 100 ml volumetric flask

and filtered. The aliquot (1 ml) was taken and make up its volume up to 100 ml with methanol and absorbance was taken at 285 nm utilizing UV spectrophotometer. A standard curve of diclofenac sodium is prepared for detrmining he Drug content.

3.7 Drug Release Study

The tablet tests were exposed to in-vitro dissolution studies using USP Type II dissolution apparatus at 37±2°C and 50 rpm speed. According to the official proposal of USFDA, 900 ml of 7.4 Phosphate Buffer was utilized as dissolution medium. Aliquot equal to 10 ml was pulled back at explicit time intervals and, the dissolution media volume was complimented with fresh and equal volume of 7.4 Phosphate Buffer. The aliquots were filtered and checked with suitable weakening and amount of Diclofenac sodium discharged from the tablet tests was determined spectrophotometrically at a wavelength of 276 nm by comparing with the standard calibration curve.

3.8 Stability Studies

Stability studies should include testing of stability-indicating attributes of the API, i.e. those that are susceptible to change during storage and are likely to influence quality, safety and/or efficacy. The testing should cover, as appropriate, the physical, chemical, biological and microbiological attributes. A guide to the potential attributes to be tested in the stability studies is provided in Appendix 1. Validated stability-indicating analytical procedures should be applied. Whether and to what extent replication should be performed will depend on the results from validation studies.[15]

3.9 Procedure

Testing recurrence for long-term studies, the recurrence of testing should to be adequate to set up the stability profile of the API. For APIs with a proposed retest period or shelf life of in any event 12 months, the recurrence of testing at the long-term storage condition ought to typically be like clockwork over the main year, at regular intervals throughout the second year, and every year from that point all through the proposed retest period or shelf life. At the accelerated storage condition, at least three time points, including the initial and final time points (for example 0, 3 and 6 months), from a multi month study is suggested. Where it is normal (in light of improvement experience) that outcomes from accelerated studies are probably going to approach noteworthy change criteria, extra testing ought to be directed either by including samples at the final time point or by including a fourth time point in the study design.[13,14]

4. RESULTS AND DISCUSSION

Table 6: Characterization of powder Blend.

Fabrication Code	Bulk density Gm/ml	Tapped density Gm/ml	Hausner's ratio	Car's Index	Angle of repose
F1	0.675	0.740	1.15	11.53 %	34.25
F2	0.640	0.743	1.14	12.19 %	28.23
F3	0.627	0.785	1.22	15.22 %	32.40
F4	0.633	0.743	1.18	14.16 %	34.16
F5	0.610	0.725	1.21	15.02 %	28.45

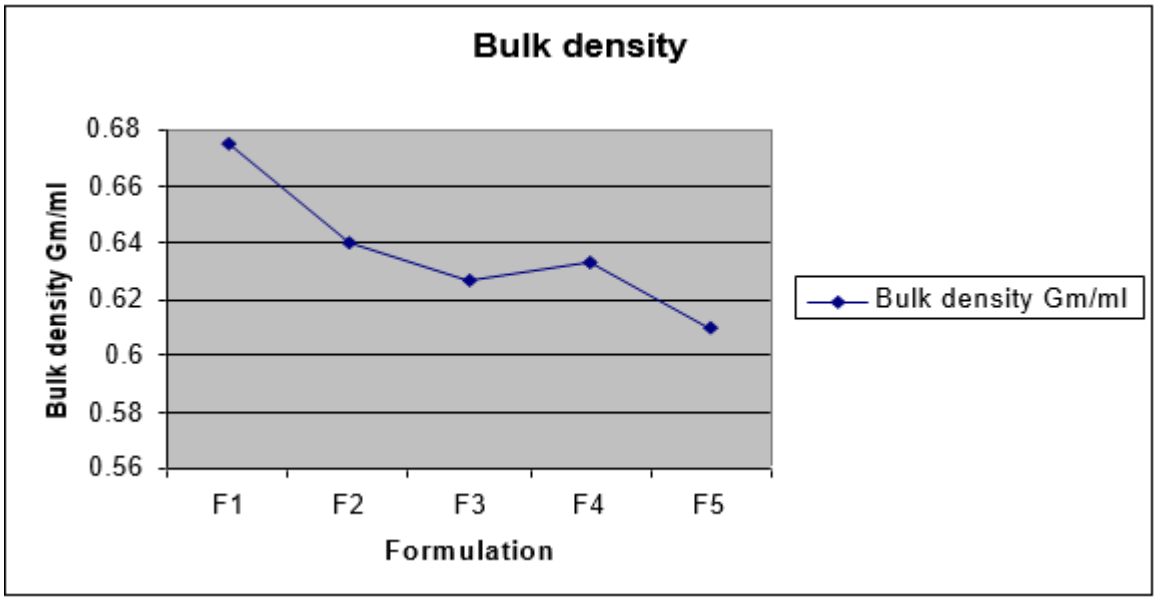

Figure 1: Bulk Density

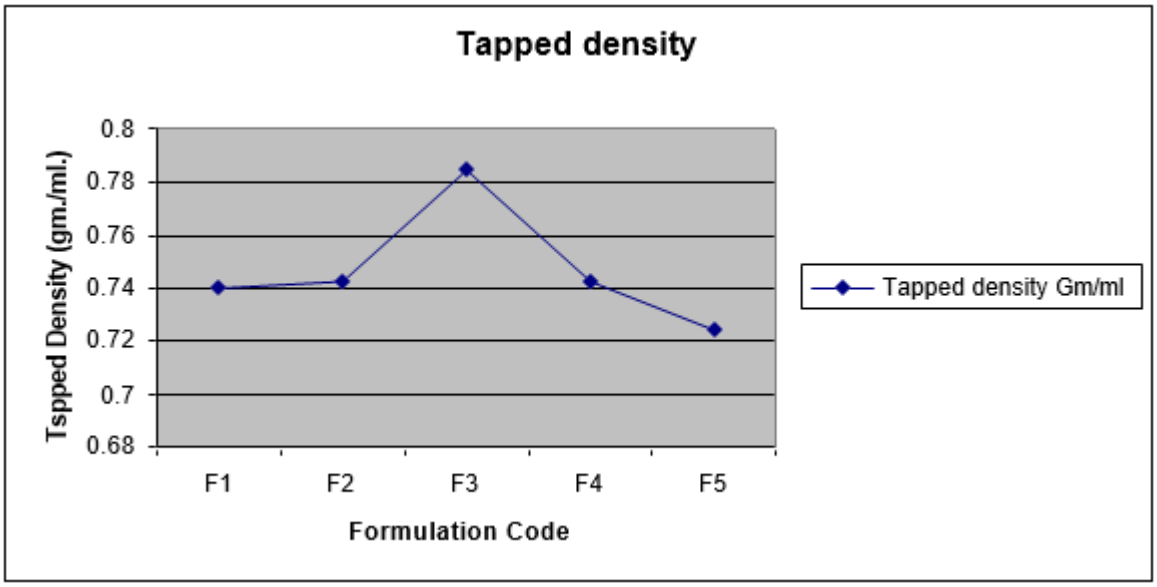

Figure 2: Tapped Density

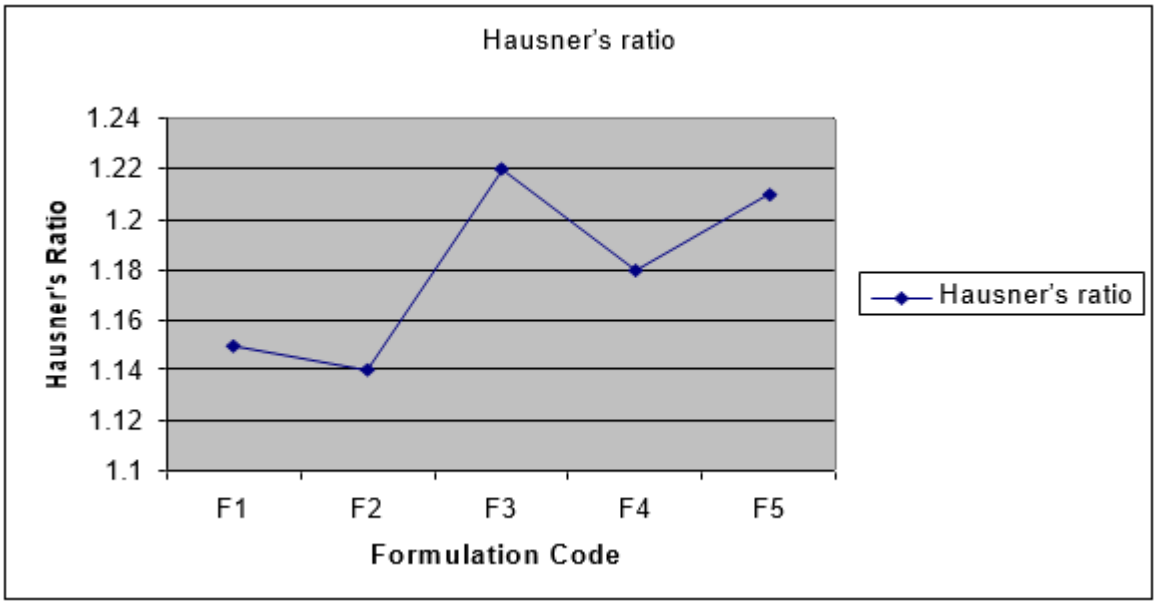

Figure 3: Hausner's Ratio

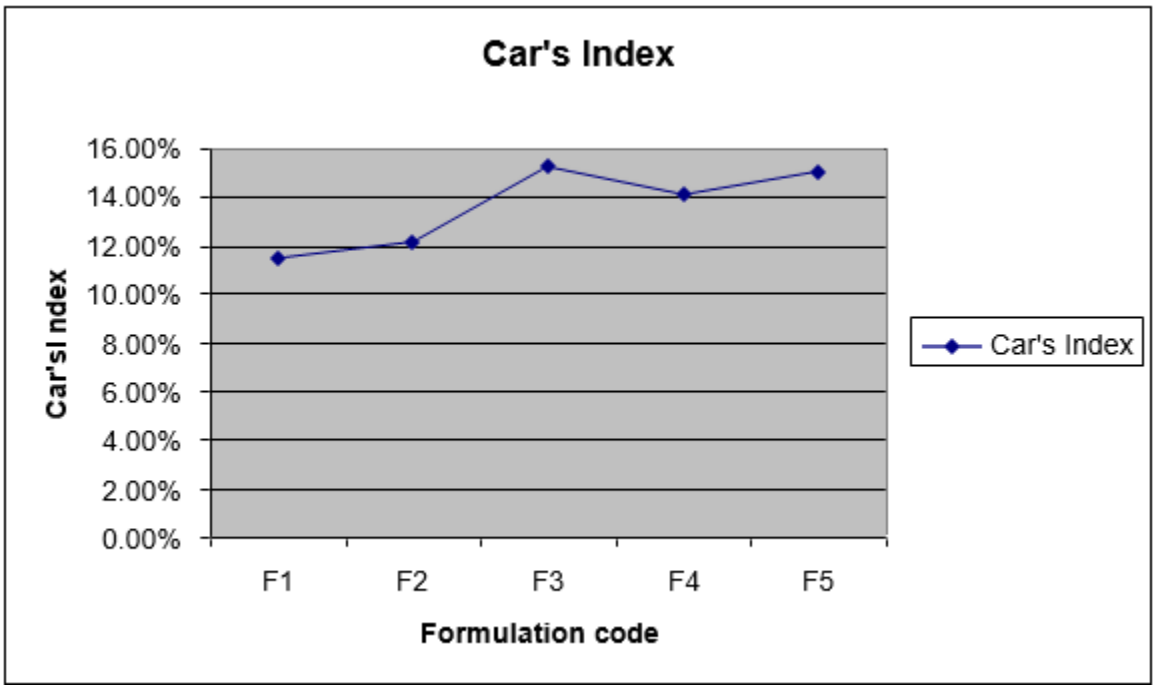

Figure 4: Car's Index

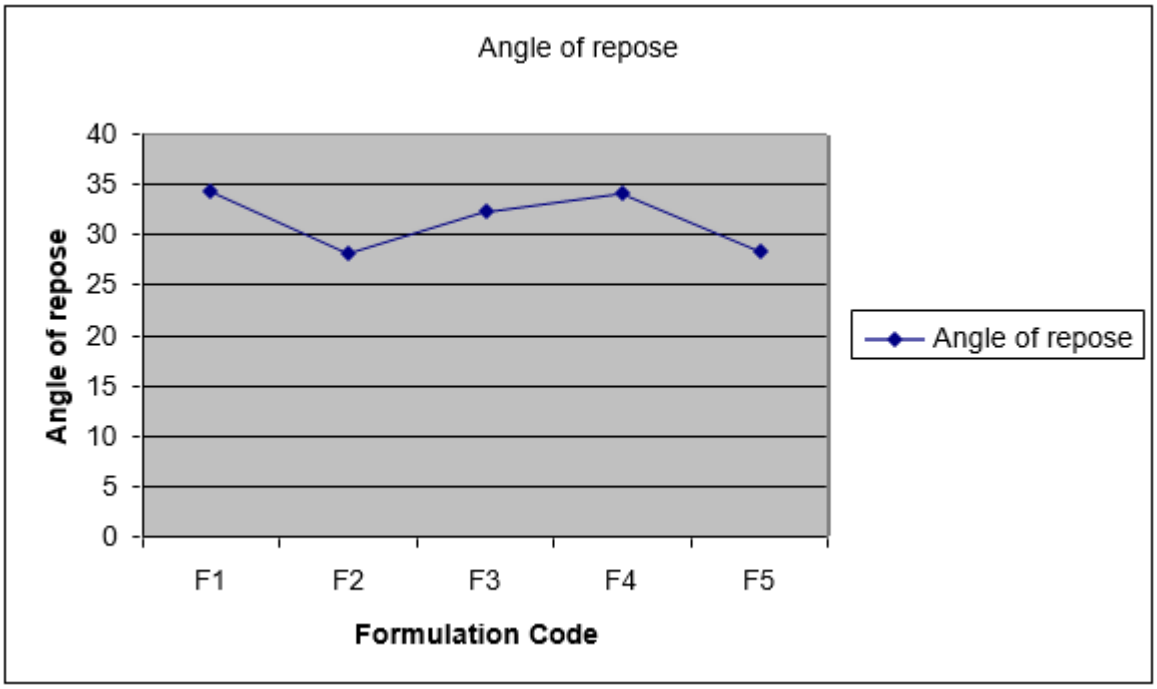

Figure 5: Angle of Repose

4.1 Post-Compressional Studies of Tablet of Diclofenac Sodium

The weight of Diclofenac loaded matrix tablets was in the range of 0.389 ± 0.004 to 0.399 ± 0.002 gm. Thickness was observed as 1.2 ± 0.1 mm and % friability of various Fabrications was found to be in between 0.06 ± 0.009 to 0.81 ± 0.011. The hardness of tablet was found to be 5.5 ± 0.2 to 7.2 ± 0.2 kg/cm2. The in vitro drug release that was performed for HPMC.

Table 7: Post-compressional studies of Diclofenac loaded matrix tablets

Fabrication code	Weight variation	Hardness (kg/cm^2)	Thickness (mm)	% Friability
F1	0.392 ± 0.003	5.7± 0.2	1.2±0.1	0.21 ± 0.001
F2	0.397 ± 0.005	6.5 ± 0.2	1.2±0.1	0.15 ± 0.09
F3	0.399 ± 0.002	7.0 ± 0.3	1.2±0.1	0.25 ± 0.012
F4	0.396 ± 0.005	6.5 ± 0.3	1.2±0.1	0.35 ± 0.021
F5	0.397 ± 0.004	6.8± 0.2	1.2±0.1	0.22 ± 0.03

Table 8: %Drug Release of Diclofenac Sustained release Tablets

Time(hrs)	% cumulative drug release				
	F1	**F2**	**F3**	**F4**	**F5**
1	19.2	18.5	15.4	16.4	17.4
2	26.5	25.2	22.5	25.3	25.6
3	36.8	37.4	35.2	34.2	35.3
4	46.2	45.4	41.4	42.5	43.6
5	55.7	57.4	54.3	55.4	56.4
6	66.3	68.3	65.3	66.3	66.4
8	78.3	78.6	75.2	76.6	78.1
10	87.5	87.2	88.6	87.7	88.3

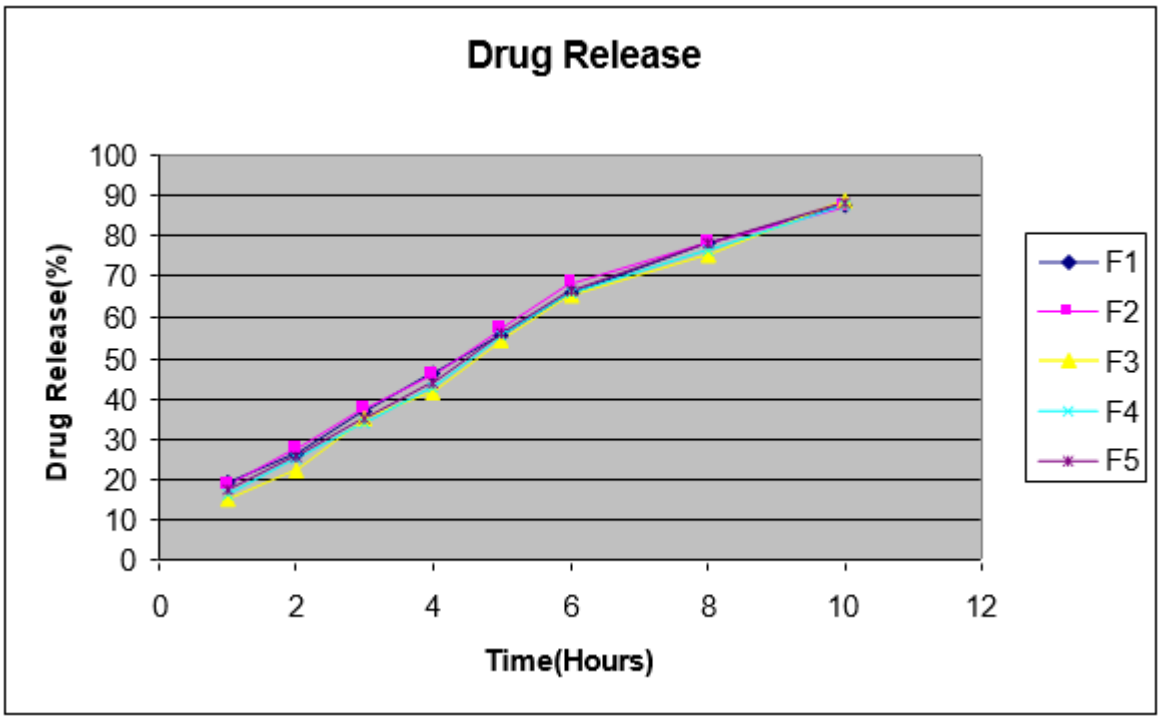

Figure 6: Drug Release from Diclofenac Sustained-release Tablets

4.2 In-vitro Drug Release Study

The *in vitro* drug release was carried out in phosphate buffer of pH 6.8. The initial drug release was depending upon the water penetration in to the polymeric matrix. The Fabrications F1 to F5 were given sustained drug release profile for 10h study as 79.2±0.013 to 88.5±0.010.

Polymer has more release retardant property than natural polymer. Availability of sufficient time for swelling and gelling was responsible for the slow release of drug.[15] The viscosity of HPMC K4M was more than the acacia so; it was showing better result in matrix tablet. And the hydration rate of HPMC depends on the nature of the substituents like hydroxypropyl group content. Hence, HPMC K4M was formed a strong viscous gel in contact with aqueous media which may be useful in controlled delivery of drug than natural polymer.

4.3 Stability Studies

After keeping the tablet batches for 60 days at 40±2°C/ 75± 5%RH, they were first examined visually for their appearance and it was found that there was no significant difference observed in color, surface and drug content of Fabrications. However, the hardness of the tablets appears to get

increased due to the fluffy particles of the polymer gets settle down on stabilization and thus resulted in slight increase in hardness.

5. Conclusion

From the above study, it was estimated that the synthetic polymer exhibit release over a long period of in present investigation an attempt has been made to design and develop Diclofenac Sodium SR matrix tablets using HPMC K100M, and ethyl cellulose, as release retarding polymers. Diclofenac Sodium is widely used as a centrally acting muscle relaxant, herefore have been selected to prepare SR dosage forms.

The granules were prepared by wet granulation method. The prepared granules were evaluated for Angle of repose, Bulk density, Tapped density and Carr's index. The results obtained were found to be satisfactory and within the specified limits.

After compression parameters like Thickness, Hardness, Weight variation, Friability, content uniformity and In-Vitro release studies were evaluated.

Result of the present study demonstrated that hydrophilic polymers could be successfully employed for formulating SRmatrix tablets of Diclofenac Sodium.

In the present study the effect of types and concentration of polymer were studied on In-Vitro drug release. It shows that increase in concentration of polymer results in the sustained drug release for 10 hours. The study has revealed that by increasing the concentration of polymer, release rate of drug was retarded and results confirmed that the release rate from hydrophilic matrix tablets depends on type and concentration of polymer.

According to stability study it was found that there was no significant change in hardness, drug content and in vitro dissolution of optimized Fabrication.

In the present work the sustained release matrix tablets of Diclofenac Sodium were formulated using hydrophilic polymers such as HPMC, ethyl cellulose.

6. Conflict of interest

The authors have no conflict of interest.

7. Acknowledgement

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