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Formulation and Evaluation of Fast Dissolving tablet of Naproxen Sodium by Using Solid Dispersion Technique

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ABSTRACT

The main aim of current research is to enhance the aqueous solubility of poorly watersoluble drug naproxen sodium by formulating the fast dissolving tablet using solid dispersion technique. The direct compression method was used to formulate and evaluate fast dissolving tablet of Naproxen Sodium. The sodium starch glycolate and croscarmellose sodium was used as the superdisintegrants in theformulation at different concentrations (10, 20, & 30mg) respectively. And inclusion complex of Drug: β-cyclodextrin was used in the formulation F1, F2, F3, F4, F5 and F6. Various formulations of fast dissolving tablets of naproxen sodium F1, F2, F3, F4, F5 and F6 was prepared. The prepared granules was evaluated for different parameters like Bulk density, Tapped density, Angle of repose, Carr's index, Hausner's ratio. The evaluation of granules showed excellent flow properties. The compressed tablets were evaluated for various parameters viz. appearance, thickness, diameter, hardness, friability, weight variation, drug content, disintegration time, wetting time, water absorption, In vitro drug release studies and Stability studies. The disintegration times was found between 43 to 60 sec, Drug content was found between 91 to 99%, wetting time to be in the range of 29 sec to 31 sec and water absorption ratio was found between 98 to 111%. Fast dissolving tablets of Naproxen Sodium showed a significant increase in the drug release. Formulation F5 shows the highest drug release 96.70% within 10 minutes. As the concentration of superdisintegrant that significant effect on disintegration characteristics as well as drug release. Addition of Drug: β-cyclodextrin inclusion complex leads to improve the dissolution characteristics and solubility of drug at optimum concentration. So, considering the above results it was found that the formulation F5 was found to be optimized formulation from the data obtained. It is observed from the formulation F5 which shown disintegration time 55 sec. and percentage cumulative drug release shown 96.70% within 10 minutes. The best formulations F5 was analyzed for stability testing. The formulations were found to be stable.

Keywords: - Fast Dissolving Tablets, Naproxen sodium, Solid Dispersion Technique, Solubility Enhancement, β-cyclodextrin, Superdisintegrant and In-vitro drug release.

1. INTRODUCTION

Naproxen is an NSAID used to treat rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, polyarticular juvenile idiopathic arthritis, tendinitis, bursitis, acute gout, primary dysmenorrhea, and mild to moderate pain. Naproxen is a nonselective COX inhibitor. It is in the propionic acid class of medications. As an NSAID, naproxen appears to exert its anti-inflammatory action by reducing the production of inflammatory mediators called prostaglandins It is metabolized by the liver to inactive metabolites[1].

Naproxen is indicated for the management of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, polyarticular juvenile idiopathic arthritis, tendinitis, bursitis, acute gout, primary dysmenorrhea, and for the relief of mild to moderate pain. Further, it is first-line therapy for osteoarthritis, acute gouty arthritis, dysmenorrhea, and musculoskeletal inflammation and pain.

It belongs to class II under BCS and exhibit low and variable oral bioavailability due to its poor aqueous solubility 0.0159 mg/ml. Hence it is necessary to increase the solubility of drug in order to improve to increase bioavailability to show effective pharmacological action.The drug is having poor aqueous solubility 0.0159 mg/ml [2].

It is used to treat headaches, muscle aches, backaches, dental pain, menstrual cramps, arthritis, or athletic injuries. This medication is also used to reduce fever and to relieve minor aches and pains due to the common cold or flu.But the major drawback is its poor aqueous solubility[3].

SD is now firmly established as a platform technology for the formulation of poorly soluble drugs. Specifically, SD technology has been successfully applied to develop formulations with a high drug and/or containing drugs with a high tendency to crystallize.SD is defined as dispersion of drug in an amorphous polymer matrix where the drug is preferably in the molecularly dispersed state. These systems were defined as the dispersion of one or more active ingredients in an inert matrix in the solid state prepared by melting (fusion), solvent or melting solvent method with the goal of enhancing oral bioavailability[4]

The objective of present research work is to enhance the aqueous solubility of poorly water soluble drug naproxen by formulating the fast dissolving tablet using solid dispersion technique.

MATERIALS AND METHOD

1. MATERIALS

Neproxen Sodiumwas received as a gift sample from Ipca Laboratory(Ratlam). Croscarmellose Sodium was procured from HIMEDIA (NewDelhi).Sodium Starch Glycolate was procured from Qualichem, β-Cyclodextrin, Aspartame, Microcrystaline Cellulose, Magnesium Stearate and talc From SdFine-chem. limited (Mumbai). All other solvent and reagent are used was of analytical grade.

2. EXPERIEMENTALS

2.1 Identification of drug

2.1.1 By UV Spectroscopy

Identification of the drug, Naproxen was done by UV Spectrophotometric method using Shimadzu Spectrophotometer UV-1800 (Shimadzu Corp. Japan). About 100mg of drug was weighed and was dissolved in 100ml of methanol (1000 µg/ml). 10ml of this solution was withdrawn and volume was made up to 100 ml. Appropriate dilutions were made with methanol to give concentration of 100 µg/ml, scanned in UV range from 200- 400nm, which could be utilized for analysis and spectrum was recorded. The UV spectra of naproxen drug are shown in fig1.

2.1.2 By melting point determination

Melting point determination of drug was performed using melting point apparatus (BTI-34) Melting point apparatus, Mumbai, India). In this method small amount of drug was filled in capillary tube open from both ends and it was placed along with thermometer in melting point apparatus. The temperature in the heating stand is ramped at user programmable fixed rate until the sample in the tube transition into the liquid state[6]. Melting point of drug sample was recorded in table 2.

2.1.3 By Fourier transform infrared spectroscopy analysis

Identification of Aceclofenac was done by FTIR Spectroscopy. The sample was analyzed by FTIR instrument (IR Affinity-1,(Shimadzu, Japan) was scanned and recorded. The obtained IR spectrum is shown in fig 3,and 4.

2.2 Preparation of standard Calibration curve of Naproxen: Standard stock solution of Naproxen was prepared by dissolving 100 mg of drug in 100 ml of methanol (1000 µg/ml) from the above stock solution 10 ml was taken and diluted to 100 ml in methanol (100 µg/ml). From the above solution 1.0, 2.0, 3.0, 4.0, 5.0 and 6.0 ml was taken and diluted upto 10 ml with methanol to get series of 10-60 µg/ml solutions in concentration. Absorbance was noted using UV-VIS Spectrophotometer at nm against blank (methanol) [6]. The calibration curves of naproxen are shown in fig.5.

2.3 Solubility study

Solubility of Naproxen was determined in distilled water and various non-aqueous solvents like phosphate buffer 6.8, methanol, ethanol, Hcl, chloroform.

Qualitative solubility analysis for naproxen was determined in distilled water and various non-aqueous solvents like phosphate buffer 6.8, methanol, ethanol, Hcl and chloroform. Ten mg of drug was dissolved in 10 ml of solvent taken in conical flask. For the determination of solute dissolved in each solvent. The solvents were shaken at 25^{o}C for 24 hrs. After shaking, the samples were examined for the presence of any dissolved, suspended particles and clarity[7]. Results are disclosed in the table 6.

3. FORMULATION AND OPTIMIZATION OF FAST DISSOLVING TABLET OF NAPROXEN SODIUM BY SOLID DISPERSION TECHNIQUE:

3.1 EXPERIMENTALDESIGNFOROPTIMIZATION:

The formulation optimization of fast dissolving tablet of Naproxen and experimental trials are performed at all 6 possible formulation. In which the amount of β-cyclodextrin (X_1), Sodium starch glycolate (X_2) and Croscarmellose sodium(X_3) were selected as independent variables (factor) varied at three different level: low(-1), medium(0), and high(+1) levels. The drug release and disintegration time used as dependent variables (response) [7].

3.2 FORMULATIONDEVELOPMENTFAST DISSOLVINGTABLET:

Table No. 7 : Composition of Fast Dissolving tablet:

S.No	Name ofingredients	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)	F6 (mg)
1.	Drug (Naproxen Sodium)	275	275	275	275	275	275
2.	β-cyclodextrin	10	10	20	20	30	30
3.	Microcrystalline Cellulose	90	80	70	90	80	70
3.	Sodium Starch Glycolate	15	25	35	-	-	-
4.	Croscarmellose Sodium	-	-	-	15	25	35
5.	Aspartame	2	2	2	2	2	2
6.	Magnesium Stearate	3	4	4	4	4	4
7.	Talc	4	4	4	4	4	4
Total		400	400	400	400	400	400

3.3 PREPARATION OFINCLUSION COMPLEXBYKNEADINGMETHOD:

275 mg of Naproxen with β-CD in different concentration. β-cyclodextrin and drug were taken in mortar-pestle and triturated. The trituration was continued for one hour and passed the complex through sieve no. #60.

3.4 PREPARATIONOFFAST DISSOLVINGTABLET BYDIRECTCOMPRESSION:

Fast dissolving tablet of naproxen sodium were prepared by direct compression method.Weighed all the ingredients accurately according to the table no.6.2. Each tablet (weight 400mg) consisted of super disintegrants such ascroscarmellose sodium, sodium starch glycolate (SSG), microcrystalline cellulose, aspartame were mixed with drug- β-cyclodextrin inclusion complex and triturationwas continued for 15 minute. Then passed through sieve no. #60. All the ingredients are mixed well in the motor.Then mixed with lubricant (2mg) for 3 min in a motor.

The powder was compressed using multi station tablet punching machine (Aidmach Pvt. Ltd.)with 8mm flat punch, B-tooling and corresponding dies.

4. EVALUATIONFAST DISSOLVING TABLET OF NAPROXEN SODIUM

4.1 PRE COMPRESSION PARAMETER OF FAST DISSOLVING TABLET:

Bulk characterizations were estimated by Bulk density, Tapped density, Carr's index, and Hausner'sratio. The flow property was determined by Angle of repose. These properties were determined by using the following equations:[8,9]

Bulk Density = Mass (g)/ bulk volume

Tapped density= Mass (g)/tapped volume

Carr's index= Tapped density- bulk density/ tapped density X 100

Hausner's ratio= tapped density/ bulk density

Angle of repose= Tan0=h/r.

The bulk characterization and flow properties were recorded in table 12.

4.2 EVALUATIONOFINCLUSIONCOMPLEX:

Solubility Determination:

An excess amount of prepared Naproxen-β-cyclodextrin inclusion complex at different concentration were separately dissolved in 5ml distilled water in vials and sealed properly and stirred continuously. The process was repeated until saturation solubility of inclusion complex. The solution was kept for 24 hours at room temperature. Then solution was filtered. The adequately diluted with distilled water. Then solution was analyzed by using UV-visible spectrophotometer at 233 nm[10].

4.3 POST COMPRESSION PARAMETER OF FAST DISSOLVING TABLET::

- **Appearance:**

The tablets were visually observed for capping, chipping, and lamination[10].

- **Dimension (thickness and diameter):**

The thickness and diameter of tablets were important for uniformity of tablet size. The thickness and diameter of the tablets was determined using a vernier caliper. Ten tablets from each type of formulation were used and average values were calculated

- **Weight variation**

For weight variation, 20 tablets of each type of formulation were weighed individually on an electronic balance, average weight was calculated and individual tablet weight was then compared with the average value to find out the deviation in weight[11].

Table 8: Specifications of %Weight variation allowed in tablets as per IP.

S.No.	Average Weight	%difference allowed
1	80 mg or less	±10 %
2	80 mg to 250mg	±7.5%
3	More than 250 mg	±5 %

- **Hardness:**

For each type of formulation, the hardness value of 10 tablets was determined using Monsanto hardness tester[71].

- **Percentage friability:**

Friability is the measure of tablet strength. This test subjects a number of tablets to the combined effect of shock abrasion by utilizing a plastic chamber which revolves at a speed of 25 rpm, dropping the tablets to a distance of 6 inches in each revolution. A sample of pre-weighed tablets was placed in Roche friabilator which was then operated for 100 revolutions. The tablets were then deducted and reweighed. A loss of less than 1 % in weight is generally considered acceptable. Percent friability (% F) was calculated asfollows[11].

$$\%F = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \quad 100$$

- **Disintegration time:**

The test is carried out on the 3 tablets using the apparatus specified in USP distilled water at 37 ^{0} C ± 2 ^{0} C was used as a disintegration media and the time in second taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured in seconds[12].

- **Drug content:**

The drug content was determined by calibration curve method are as follow:

From each batch of prepared tablets, ten tablets were collected randomly and powdered. A quantity of powder equivalent to weight of one tablet was transferred in to a 100 ml volumetric flask, to this 50 ml pH 6.8 buffer of was added and then the solution was subjected to sonication for about 2 hrs. The solution was made up to the mark with pH 6.8 buffer. The solution was filtered and suitable dilutions were prepared with pH 6.8 buffer. Same

concentration of the standard solution was also prepared. The drug content was estimated by recording the absorbance at 233 nm by using UV-Visible spectrophotometer[13]. The drug content of various formulations is recorded in table 7.12.

- **Wetting time and water absorption ratio:**

A piece of tissue paper folded twice was placed in a small petridish containing10 ml of water. A tablet was put on the tissue paper and the time required for the water to diffuse from the wetted absorbent paper throughout the entire tablet was then recorded using a stopwatch.

For water absorption ratio: The wetted tablets were the reweighed. The water absorption ratio and R was determined using following equation

$R = W_a\text{-}W_b/W_b \times 100$

Where,

Wa = Weight of the tablet after water absorption

Wb = Weight of the tablet before water absorption[14].

- **In vitro Drug release study:**

Freshly prepared phosphate buffer (pH 6.8) of 900 ml was placed in each dissolution vessels of dissolution test apparatus (USP, II paddle method). The tablets were placed in the dissolution medium. The temperature of the dissolution medium was maintained at 37± 0.5^0C and the paddle was rotated at 50 rpm. Five ml samples were withdrawn. The sample volume was immediately replaced with the same volume of fresh media as when a sample was taken. The samples withdrawn were filtered, diluted and estimated spectrophotometrically at 233 nm. Cumulative amount of the drug released at each interval was calculated by using standard graph of Naproxen sodium[15].

- **Stability study:**

The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light, enabling recommended storage conditions, re-test periods and shelf-lives. Generally, the observation of the rate at which the product degrades under normal room temperature requires a long time. To avoid this undesirable delay, the principles of accelerated stability studies are adopted ICH specifies the length of study and storage conditions[62].

- **Long-Term Testing**: 25^0 C ± 2^0 C at 60% RH ± 5% for 12 Months
- **Accelerated Testing:** 40^0 C ± 2^0 C at 75% RH ± 5% for 6 Months

In present study the selected formulation F5 exposure up to 1 months stability studies at accelerated condition (40^0 C ± 2^0 C at 75% RH ± 5% RH) to find out the effect of aging on hardness, drug content and *in vitro* drug release. Stability studies were carried out at accelerated condition (40^0 C ± 2^0 C at 75% RH ± 5% RH) for the optimized formulation F5. The fast dissolving tablets were stored at 40^0 C ± 2^0 C at 75% RH ± 5% RH for accelerated temperature in closely packed with aluminum foil for 3 months. The samples were withdrawn after periods of 1st month. The samples were analyzed for its physical appearance[16].

5. RESULT AND DISCUSSION

5.1 Identification of drug

5.1.1 Determination of wavelength by UV Spectroscopy:

The peak of Naproxen sodium was obtained at 233nm. Which shows that drug is pure as given in the refrence. The UV spectrum of naproxen sodium drug is shown in the fig. 9.

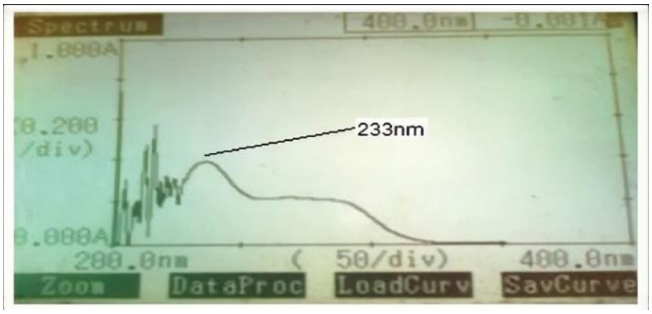

Fig 9: Spectrum of Naproxen sodium by UV Spectroscopy

5.1.2Melting point:

The melting point of drug sample was determined by using melting point apparatus. As given in the reference. The melting point of naproxen Sodium is shown in the table: 10.

Table 10 : Melting Point of Naproxen Sodium

Drug	Observed	Reference
Naproxen Sodium	153-156^{0}C	152–155 ℃

5.1.3 Fourier transform infrared spectroscopy

The IR spectra of pure Naproxen sodium drug showed the characteristic absorptionbands are as follows: COO^- at 1585 cm^{-1}, aromatic CH_3- CH stretching at 2957 cm^{-1},aliphatic CH_3O stretching at 2904 cm^{-1}, C-H stretching of aromatic ring at 3058 cm^{-1},carboxyl keto group showed absorption band at 1631 cm^{-1}, naphthalene stretching at 1500cm^{-1}andstrongbending modeat900-650cm^{-1}.

No drug-polymer interaction was observed in the FTIR spectra of the powder mixtureof optimized formulation since the absorption peaks of the drug still could be detected in themixture.

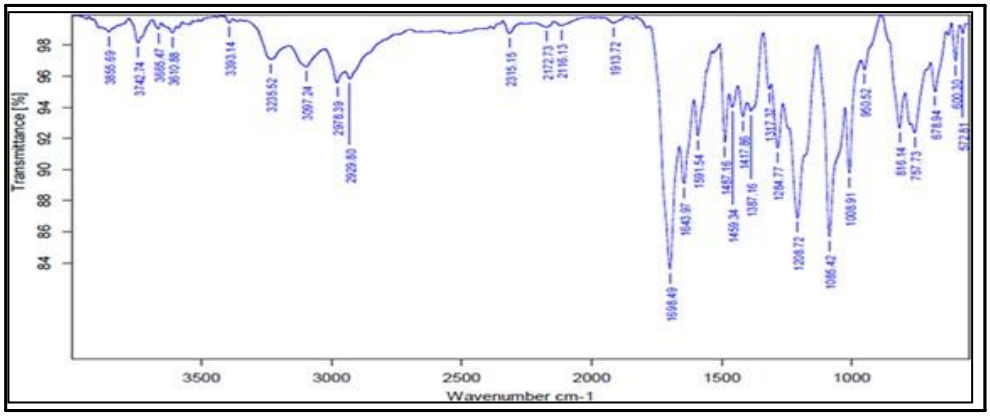

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Fig. 11 FTIR Spectra of Naproxen Sodium Pure Drug

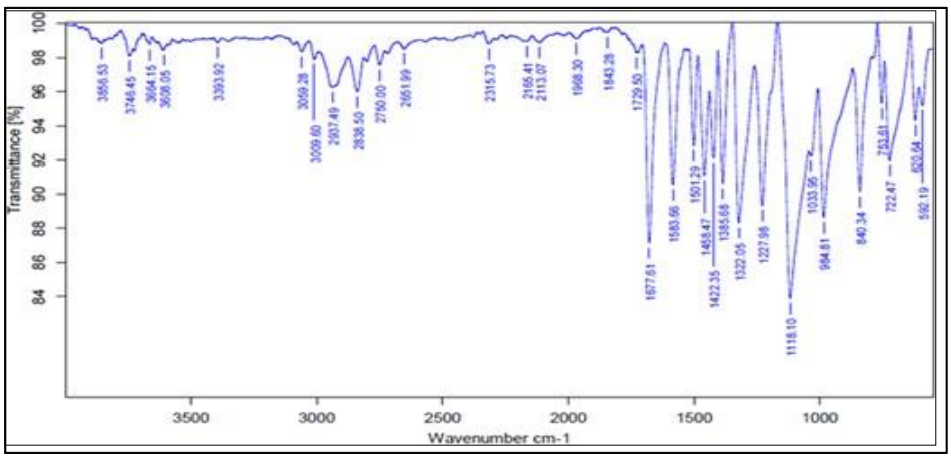

Fig. 12 FTIR Spectra of Naproxen Sodium with Excipients

5.1.4 Preparation of standard Calibration curve of Naproxen sodium in Methanol (λmax 233nm)

Calibration curve of Naproxen sodium was prepared in methanol at 233 nm. The absorbance values (mean of three determinations) with their standard deviation at different concentration in the range of 10-60 µg/ml for methanol are tabulated. The drug obeys Beer's Lambert law in the concentration range. Linear regression analysis for all calibration curves of Naproxen sodium is given in Table. So, this equation was used for the calculation of the solubility of the drug in different solvent, drug content and drug release.

Table 13: Data of standard calibration curve of naproxen sodium in methanol

S.No.	Concentration (µg/ml)	Absorbance (nm)
1.	0	0
2.	10	0.125
3.	20	0.22
4.	30	0.317
5.	40	0.419
6.	50	0.533
7.	60	0.635

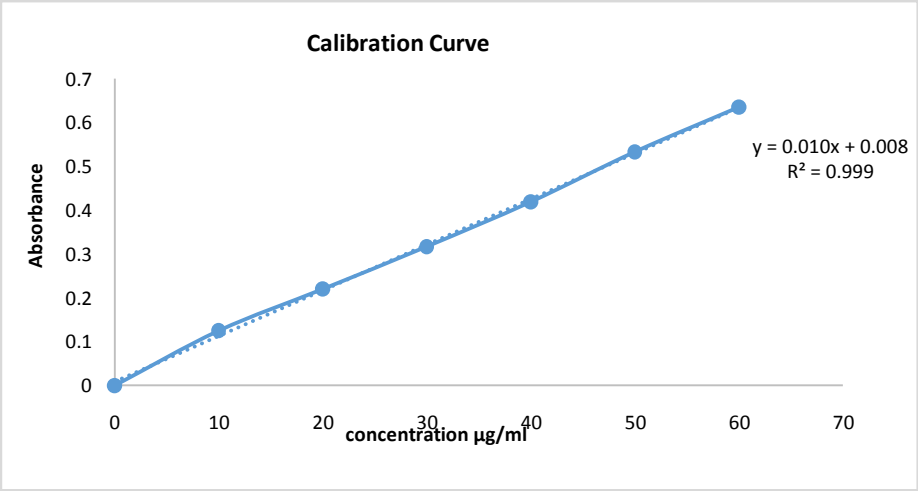

Fig 14 : Calibration curve of Naproxen Sodium in Methanol.

5.1.5 Determination of solubility of naproxen sodium in different solvents: solubility analysis for drug naproxen sodium was determined in different solvents. Results are disclosed in the table 15.

Table no. 15 : Solubility data of Naproxen Sodium in different mediums:

S.NO.	Solvent	Solubility(mg/ ml)	Inference
1	Water	0.015	Practically in soluble
2	Phosphate buffer 6.8	0.120	Slightly soluble
3	Methanol	0.127	Slightly soluble
4.	Hcl	0.097	Sparingly soluble
5	Chloroform	0.098	Sparingly soluble

5.2 EVALUATION PARAMETERS:

5.2.1 Determination of solubility of inclusion complex: solubility of inclusion complex in phosphate buffer was studied. Results are disclosed in the table 16.

Table no.16: Solubility data of inclusion complex:

S.No.	Phosphate buffer pH 6.8	Solubility (mg/ml)	Inference
1	Pure drug	0.015	Practically Insoluble
2	Drug:β-CD (275:10)	0.101	Slightly Soluble
3	Drug:β-CD (275:20)	0.109	Slightly Soluble
4	Drug:β-CD (275:30)	0.112	Slightly Soluble

5.2.2 EVALUATION OF PRE-COMPRESSION PARAMETERS OF POWDER:

The bulk density, Tapped density, Hausner's ratio, Carr's index and angle of repose of all the formulations were performed. Results are shown in the table no. 17.

Table no. 17: Evaluation of Pre compression Parameters of powder

Formulation	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index (%)	Angle of repose (^{o})	Hausner'sratio
F1	0.314	0.358	14.645	25.446	1.170
F2	0.289	0.368	14.624	29.343	1.166
F3	0.286	0.385	16.323	27.616	1.176
F4	0.335	0.365	13.937	26.946	1.16
F5	0.317	0.383	15.240	25.59	1.176
F6	0.283	0.345	17.360	27.4	1.206

5.2.3 EVALUATION OF POST-COMPRESSION PARAMETERS OF FAST DISSOLVING TABLETS:

The fast dissolving tablets of naproxen sodium like weight variation, hardness, thickness, friability, disintegration time, drug content, wetting time and water absorption ratio. The results of the studies were shown in below table:

Table no. 18 : Weight variation, Hardness, Thickness, and Friability ofFormulation (F1-F6)

Formulation	Weight variation(mg)	Hardness(Kg/cm^2)	Thickness (mm)	Friability(%)
F1	210.16	2.6	3.1	0.460
F2	211.75	2.4	3.1	0.750
F3	214	3.0	3.2	0.460
F4	223	2.9	3.3	0.672
F5	232	3.0	4.06	0.346
F6	233	3.0	3.4	0.343

Table no. 19 : Disintegration Time, Drug Content, Wetting time & waterabsorptionRatio

FormulationF1-F6.

Formulation	Disintegration Time (sec)	Drug Content(%)	Wetting time(sec)	Water absorption Ratio(%)
F1	47	91.833	32.7	98.24
F2	43	93.36	31.37	111.91
F3	49	95.84	30.05	103.42
F4	60	92.19	32.38	101.92
F5	55	99.25	29.71	99.51
F6	50	96.85	31.06	100.24

5.2.4 In vitro drug release studies:

The in vitro drug release profile of all the formulations from F1 to F6 in dissolution medium are shown in figure (7.13, 7.14, and 7.15). Fast dissolving tablets of Naproxen Sodium showed a significant increase in the drug release. In the formulations F1, F2 showing 95.18%, 91.48% drug release. F3, F4 showing 91.42%, 95.09% drug release and F5, F6 showing 96.70%, 95.72% drug release respectively. Formulation F5 shows the highest drug release 96.70% within 10 minute

Table no 20 : Percentage cumulative drug release data of F1 to F6formulationoffast dissolving tablets:

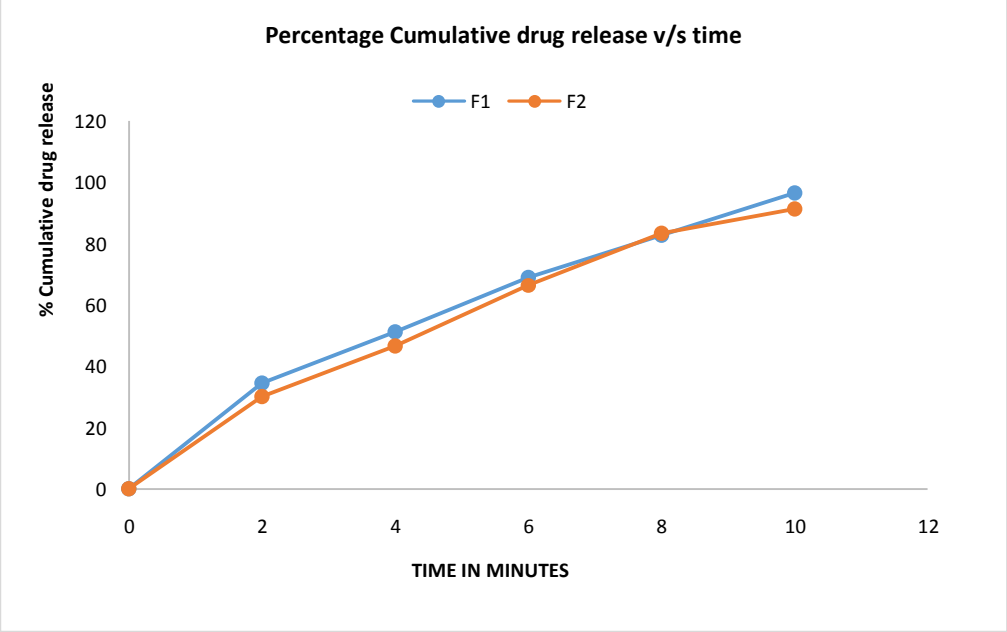

Fig. 21 : Cumulative drug release of formulation F1-F2

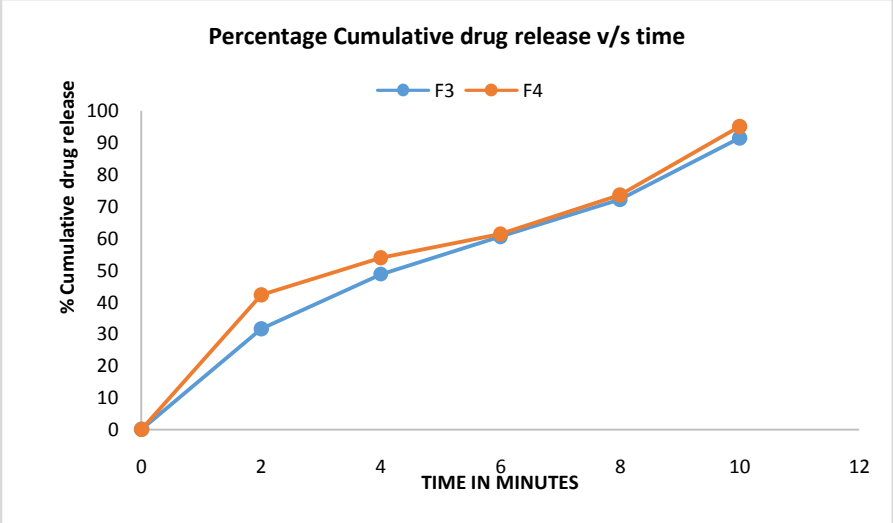

Fig. 22: Cumulative drug release of formulation F3-F4

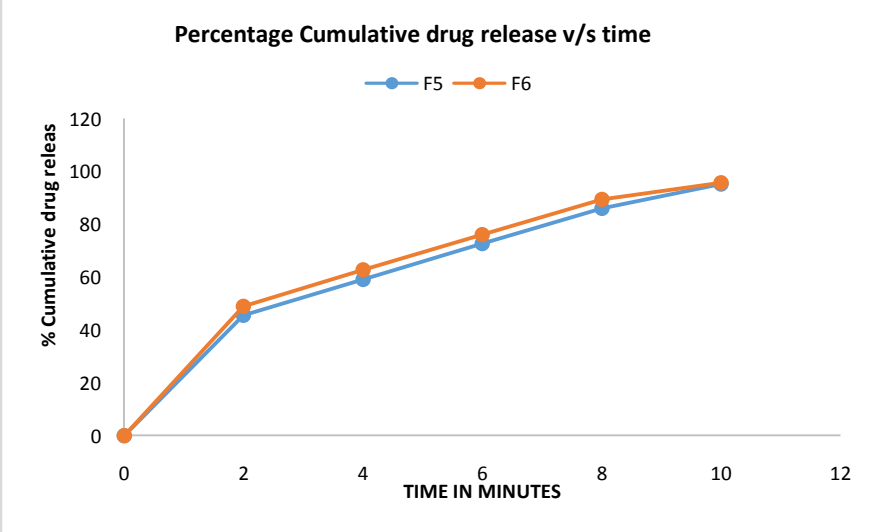

Fig. 23: Cumulative drug release of formulation F5-F6

7.3.4 Stability study:

Stability studies for one month were performed at different storage condition for optimized fast dissolving tablet (F5). The optimized fast dissolving tablets were found to be stable with no change in physical appearance were found similar at different storage condition at different time interval. It was concluded that the formulation is stable at different storage conditions.

Table no. 24: Stability data of optimized formulation (F5):

S.No	Time	Physical appearance	Result	Storage condition
1	InitialDay	Whit to creamy crystalline	No change inappearance	40°C±2°C/ 75%RH±5%RH
		Whit to creamy crystalline	No change inappearance	Room temperature
2	1 month	Whit to creamy crystalline	No change inappearance	40°C±2°C/ 75%RH±5%RH
		Whit to creamy crystalline	No change inappearance	Room temperature

CONCLUSION

The study was conducted to formulate and evaluate fast dissolving tablet of naproxen sodium to achieve patient compliance for the management of different types of pain. Fast dissolving tablets of Naproxen Sodium showed a significant increase in the drug release. In the formulations F1, F2 showing 95.18%, 91.48% drug release. F3, F4 showing 91.42%, 95.09% drug release and F5, F6 showing 96.70%, 95.72% drug release respectively. Formulation F5 shows the highest drug release 96.70% within 10 minutes.

As the concentration of superdisintegrant that significant effect on disintegration characteristics as well as drug release.

Addition of Drug: β-cyclodextrin inclusion complex leads to improve the dissolution characteristics and solubility of drug at optimum concentration. So, considering the above results it was found that the formulation F5 was found to be optimized formulation from the data obtained. It is observed from the formulation F5 which shown disintegration time 55 sec. and percentage cumulative drug release shown 96.70% within 10 minutes. The best formulations F5 was analyzed for stability testing. The formulations were found to be stable.

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