IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 6, June 2025
Impact Factor: 7.67

Formulation and Evaluation of Naproxen Sustained Release Tablets

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Abstract: *The main purpose of review of Sustained release dosage form is to achieve the slow release of drug over and extended or long period of time and give the complete knowledge of sustained release dosage forms. Sustained release dosage forms is to provide pharmaceutical ,pharmacokinetic and pharmacodynamics properties of drug that increase the therapeutic efficacy of dosage forms. Sustained release dosage forms is used to improve the patient's compliance. It minimizes the side effects by minimizing the dose frequency .It also increases the safety margin of potent drug and reduction in fluctuation takes place. Basically this dosage form is used to optimize the delivery of medication. By optimizing the delivery of medications we control on the therapeutic effect of dosage forms.*

Keywords: *Sustained release, Dose frequency , Drug properties , Biological half life.*

I. INTRODUCTION

Complications of therapeutic regimen or plan, cost of treatment, local and systemic side effects of the dosage forms.By the administration of sustained release tablets which shows the improvement in problem of lack of patient Compliance.

Reduced fluctuation:-
A sustained release tablets can minimizes the frequency of drug dosing & maintain a concentration in blood circulation & target cells.

Reduced total Dose :-
In this there is no need to increase the frequency of dose because when we administered the sustain release dosage form which shows the effect over an extended period of time.So it minimizes the dose frequency as well as side effects, which is great for economy.

Improved efficiency in treatment :-
Optimal therapy of disease requires effective delivery of medication to the tissue, organ and targeted site. Some doses are requires in large amount for specific therapeutic effect at particular site. When we give the doses in large amount there is
chances to show some toxicological, undesirable and immunological diseases at non
targeted site. For these improvement administered the sustained release dosage form which provides the better management in acute and chronic disease conditions.

Economy:-
The initial cost of sustained release products is greater than the conventional dosage form because of the special nature of these compounds but overall average cost of treatment or therapy over a extended period of time may be less.

DISADVANTAGES OF SUSTAINED RELEASE TABLETS:
Dosage form design:-
The physician has less flexibility in adjusting dosage regimens. This is fixed by the dosage form design.

DOI: 10.48175/IJARSCT-27909

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Patient variation:-
Sustained release dosage forms are designed for the normal peoples that is on the basis of average drug biologic half-life. Some disease conditions which alter drug disposition, patient variation and so this are not accommodated.

Economic factors :-
In the manufacturing of sustained release tablet some products, processes and
equipments are costly so some economic factors are assessed.

Poor In-Vivo and In-Vitro correlat:i-o ns
In sustained release dosage form, the drug release rate is reduced to achieve drug release over a gastro intestinal tract. Here so called "Absorption Window" becomes important may give rise to undesirable drug absorption in-vivo excellent in-vitro release characteristics.

Dose dumping:-
In sustained release formulation dose dumping of a drug introducing potential toxic quantities of the drug into the systemic circulation. Some drugs have a narrow therapeutic index which can lead to those dumping in case of potent drug.
e.g. Phenobarbital.

FACTORS AFFECTING SUSTAINED RELEASED DOSAGE FORMS
1] PHARMACOKINETIC AND PHARMACODYNAMICS FACTORS
> Biological half-life.
> Absorption.
>Distribution.
> Metabolism.
> Margin of safety/Therapeutic index.

2] DRUG PROPERTIES RELEVANT TO SUSTAINED RELEASE FORMULATION
> Dose size.
> Ionisation, pka and aqueos solubility.
> Partition coefficient.
> Drug stability.
> Protein binding.

1] PHARMACOKINETIC AND PHARMACODYNAMICS FACTO>R S
BIOLOGICAL HALF LIFE:-
Those drugs which are having biological half-life of 2-8 hours which are suitable for sustain release dosage forms, since they minimizes the dosing frequency. This drugs having very short biological half-life which is requires a excessive large amount of drug in each dosage form to maintain the sustained effects.

> ABSORPTION :-
Absorption rate of sustained release formulation depends on rate of releasing of the drug from dosage form and the drugs which is absorbed by the active transport and absorption is limited to intestine.

> DISTRIBUTION:-
The distribution of drug in body is most important factors in overall elimination process. This is not only lower's the concentration of drug in blood but it also can we read limiting in it's equilibrium with blood. The apparent volume of

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distribution is depending on the time of drug disposition. So for sustained release product one more thing is added that is information of disposition of drug.

> METABOLISM :-

Drugs which are metabolized before absorption either in the lumen or tissue of the intestine, which can show lower bioavailability from slower releasing dosage form. Drugs which are having variation in bioavailability due to the first pass metabolism or intestinal metabolism which are not suitable for sustain release dosage forms.

> MARGIN OF SAFETY / THERAPEUTIC INDEX :-

Safety margin of a drug can be considered as therapeutic index. It can be show as; Therapeutic index = (TD)50 / (ED)50. If the therapeutic index is more than 10 then a drug is considered to be safe i.e larger the ratio then drug is more safe. Safety margin is directly proportional to the ratio of therapeutic index. Some drugs having narrow therapeutic index which is more accurate maintain the plasma concentration within the narrow therapeutic range.

DRUG PROPERTIES RELEVANT TO SUSTAINED RELEASE FORMULATION

> DOSE SIZE :-

The maximum dose size for a conventional dosage form is range between 500- 1000mg. This dose size is also apply for sustained release dosage forms. Dose size is important parameter for the safety involved in large amounts administration with narrow therapeutic range.

> IONISATION, PKA AND AQUEOUS SOLUBILITY :-

Most of the drugs having weak acids or weak bases for a drug to be it get absorbed. It must be dissolves surrounding the site of action in aqueous phase and then partition into the absorbing membrane takes place.

PLAN OF WORK:-

Literature review
Selection of the drug and ingredients
Collection of the drug and ingredients
Preparation of sustained release tablets
Evaluation of prepared sustained release tablets
Result and discussion
Conclusions

2) Naproxen is acts as a anti- inflammatory agent which is used To.
3) minimizes the excessive inflammation of rheumatoid
rthritis osteoarthritis and kidney stones.
4) Naapprrooxxeenn i ss haonwalsg tehseic ms worhei cthh egriavpese uthtiecr eafpfeeuctt ioc fe affnetci-tisn.f lammatory drugs
5) as compare to other drugs like Aspirin, Ibuprofen.
6) Naproxen is also used to reduce the pain and symptoms of dysmenorrhea.
7) Naproxen is acts as a painkiller in menstrual cramps.
8) It is also used to reduce the dental pain.

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3.LITERATURE REVIEW:-

1] Sandhya Mishra "et al. "Traditional drug delivery system has been characterized by immediate release and repeated dosing of the drug which might lead to the risk of dose fluctuation, this arises the need of a formulation with control release that maintain a near-constant or uniform blood level. Sustain release system are considered a wiser approach for the drug with short half-lives and which require repeated dosing, they are easy to formulate and are irrespective of absorption process from gastrointestinal tract after oral administration. The basic objective of these dosage forms is to optimize the delivery of medications so as to achieve a measure of controls on therapeutic effect in the face of uncertain fluctuation in the in vivo environment in which drug release takes place. Sustained release systems include any drug-delivery system that achieves slow release of drug over an extended period of time. Sustained Release is also providing promising way to decrease the side effect of the drug by preventing the fluctuation of the therapeutic concentration of the drug in the body. The basic rationale of sustained drug delivery system optimizes of the biopharmaceutical, pharmacokinetic and pharmacodynamics properties of the drug in such a way that utility is maximized, side-effects are reduced and cure of the disease is achieved. The principal goal of sustained release forms is the improvements of drug therapy assessed by the relationship between advantages and disadvantages of the use of sustained release system.

2] Patil Harshal Santoshrao "et al. "Now a days as very few drugs are coming out of research and development and already existing drugs are suffering the problem of resistance due to their irrational use specifically in case of drugs like antibiotics. Hence, change in the operation is a suitable and optimized way to make the some drug more effective by slight alteration in the drug delivery. Sustained Release is also providing promising way to decrease the side effect of drug by preventing the fluctuation of the therapeutic concentration of the drug in the body. This article contains the basic information regarding sustained-release formulation and also the different types of the same.

3] H.D.Zalte "et al."Sustained release matrix tablet is formulated mainly by wet granulation or direct compression method or by dispersion of solid particle within solid particle within a porous matrix formed by using different polymers like Polymethyl methacrylate (PMMA), Polyglycolic acid, HPMC etc. The matrix controls the release rate of drug. Release retardants like HPMC can aid in sustained release and thus they form core excipient of the formulation. The method involves the direct compression of blend of drug, retardant material and additives to formulate a tablet in which the drug is embedded in a matrix core of the retardant, alternatively granulation can be carried out prior to compression. The matrices used may be of hydrophilic, hydrophobic, mineral, or biodegradable types. The drug release rate can be studied by in-vitro dissolution studies. Some drugs that have been formulated as sustained release matrix tablets are Ambroxol HCl, Nateglinide etc. Thus, sustained release matrix tablets can assure better

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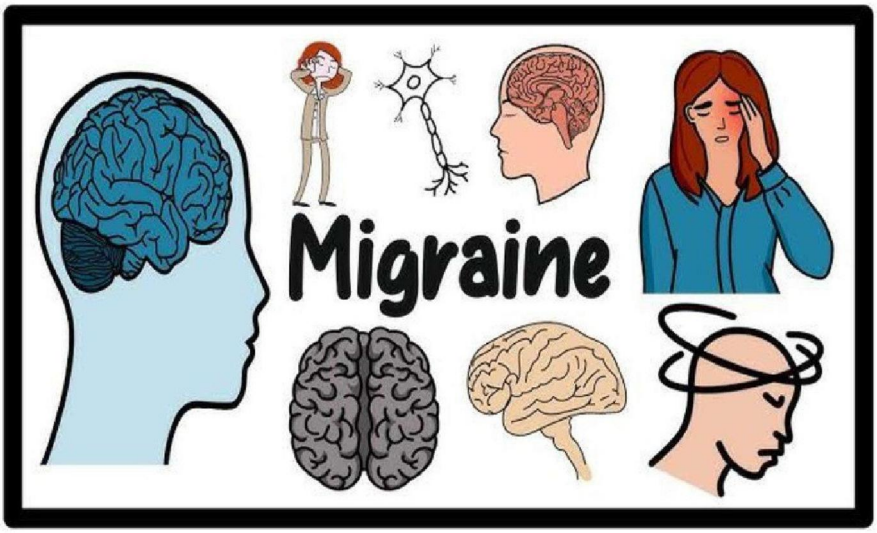
5. MIGRAINE :-



The term migraine is originated from Greek word "hemicranias" meaning one side of the head. Migraine is a severe condition which is having a wide variety of symptoms. Painful headache is a main feature of the migraine in many patients. It involves pulsating headache, usually occurs to one side (unilateral) which comes in attacks lasting 4-48 hours. Other symptoms like feeling sick, vomiting, irritability, dizziness, nasal congestion and sensitivity to light sound and smell. Migraine is one of the common causes of throbbing headaches. According to IHS, migraine mainly contains 16% of primary headaches. Migraine affects the 10-20% of the general population. In India 15 - 20% of people suffer from migraine. Migraine majorly affects 18% of women and 6% of men in the United States so, migraine affects women more than men. For both men and women, the prevalence of migraine is increases in adult life and decreases after midlife. In girls and women's, the rate of migraine is greater between age 10 and 30 years. Migraine is and undertreated.

5.1 DEFINITION OF MIGRAINE :- "Migraine is a familial disorder characterized by recurrent attacks of headache widely variable in intensity, frequency and duration. Attacks are commonly unilateral and are usually associated with anorexia, nausea and vomiting."

5.2 DIAGNOSIS OF MIGRAINE:-

> Headache attacks are occurs for 4-72 hours (which is untreated).

> Headache has atleast two of the following;

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- Unilateral location.
- Pu Isating quality.
- severe pain intensity.
- It is caused by avoidance of daily routine physical activity like walking or climbing stairs.

> During a headache at least one of the following;

- Nausea and vomiting.
- Photophobia and phonophobia.

5.3DRUG USED IN MIGRAINE :-

1] ABSORPTIVE MEDICATIONS :-

1) ANALGESICS WITH CAFFEINE :-

Ex :- Acetaminophen, Aspirin and Caffeine.

2) TRIPTANS :-

Ex :- Suma, Riza, Nara, Algo, Zolmi 5-HT antagonists.

3) NON-STEROIDAL ANTI INFLAMMATORY DRUGS (NSAIDS) :-

Ex :- Ibuprofen, Naproxen sodium.

4) ANTIEMETICS :-

Ex :- Domeperidone.

5) ANALGESICS WITH CAFFEINE AND BARBITURATES.

2] PREVENTIVE MEDICATIONS :-

1) NSAIDS :-

Ex :- Ketoprofen, Naproxen sodium.

2) BETA BLOCKERS :-

Ex :- Propanol , Timolol maleate and Metoprolol.

3) CALCIUM CHANNEL BLOCKERS :-

Ex :- Diltiazem and Nifedipene.

4) ANTIDEPRESSANTS :-

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MATERIAL AND METHOD:-
Following ingredients are used in formulation of naproxen sustained release tablet;
1] Active pharmaceutical ingredients; Naproxen 2] Excipients :-
Hydroxy propyl methyl cellulose. Ethyl cellulose.
Microcrystalline cellulose.
Sodium bicarbonate. Starch.

1] ACTIVE PHARMACEUTICAL INGREDIENTS:-
Active Pharmaceutical Ingredients are the active ingredients contained in
a medicine. It is that part of the medicine that produces the intended therapeutic effects. For example, in a painkiller, the active ingredient relieves pain.
> NAPROXEN :- This is the active pharmaceutical ingredients responsible for the therapeutic effect.

2] EXCIPIENTS:-
These are the inactive ingredients that helps in the formulation and release of the medication.
Some common excipients are used in naproxen sustained release tablet include :
Hydroxy propyl methylcellulose (HPMC) :- it is a polymer that forms gel like matrix, controlling the release of drug.
Ethyl cellulose: - It is another type of polymer that provides sustained release properties.
Microcrystalline cellulo: s- eIt act as a filler and binder in tablet formulation
Magnesium stearate :- Alubricant that aids in tablet compression.
Providone :- It helps in improving the dissolution of the drug.

METHOD OF PREPARATION:-

Following methods are used in the preparation of naproxen sodium.

- Determine the desired release profile and select the appropriate excipients and release mechanisms.
- Take the Naproxen as a API and excipients like Starch, Sodium bicarbonate , Ethyl cellulose , Microcrystalline cellulose , Hydroxy propyl methyl cellulose .
- Weigh the required amount of naproxen(0.36 gm) and excipients according to the formulation starch (0.04 gm), Sodium bicarbonate (0.01gm), Hydroxy propyl methyl cellulose (0.03gm), Microcrystalline cellulose (0.03gm), Ethyl cellulose (0.01gm).
- Mix all the ingredients one by one to ensure uniform distribution except starch.
- Prepare a slurry of starch and make dough.
- Make granules from a dough by passing through sieve no.10.This can be done using wet granulation method.
- These granules are placed in air to dry.
- Then dried granules are passed through sieve no.22 again passed through sieve no.44 to make fine granules.
- Compress the granules into tablet form using a tablet press. The tablets should be designed to provide sustained release of the medication.
- Apply a coating to the tablets. The coating can be designed to dissolve slowly.

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RESULT AND DISCUSSION

From the above discussion we will found that the Naproxen sustained release tablet are highly efficient than the other tablets like aspirin, ibuprofen and shows the sustained release. These are determined by performing various quality control tests like Hardness test, Thickness test, Friability test, Weight variation test.

a) Hardness Test:-

Hardness test was conducted for tablets to calculate hardness of tablet by using monsanto hardness tester .So, the hardness of tablet was found to be 2kg/cm². The resistance of tablets to shipping or breakage under conditions of storage, transportation and handling before usage depends on its hardness. The hardness of tablet of each formulation was measured by Monsanto Hardness Tester. The hardness was measured in items of kg/cm².Hardness or tablet crushing strength is the force required to break a tablet in a diametric compression. The force is measured in kg and the hardness of about 3-5 kg/cm² is considered to.be satisfactory for uncoated tablets.

b) Thickness Test:-

Thickness and diameter of tablets were important for uniformity of tablet size. Thickness and diameter were measured using Vernier Calipers. The thickness test of tablet was calculated by vernier caliper. So, the thickness of naproxen tablet was found to be 4 mm.

c) Friability Test: -

Friability of the tablet determined using Roche friabilator. This device subjects the tablet to the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and dropping a tablet at a height of 6 inches in each revolution. Pre weighted sample of tablets was placed in the friabilator and were subjected to the 100 revolutions. Tablets were dusted using a soft muslin cloth and reweighed.

USP limit is 0.5 to 1%. The friability (F) is given by the formula. The 20 tablets were tested for friability testing using roche friabilator which resolves at 25 rpm at 4 minutes. So, the friability was found to be 1.07 % .

d) Weight Variation Test :-

Weight variation was determined to know whether different batches of tablets have uniformity. Weighed 20 tablets individually, calculated the average. weight and compared the individual tablet weights to the average. The tablets meet the test if not more than two tablets are outside the % limit and none of the tablet differ by more than two times the limit.Twenty tablets were weighed individually and then calculated the total weight and the average weight found to be 504.65. So, the Weight variation test allow is 5%.according to this the upper limit is 529.88 mg and lower limit is 479. 12 mg. So the weight of all 20 tablets are comes under this range so, the test is passed.

CONCLUSION

From the about discussion it is concluded that Sustained Release Tablet is one of the most effective dosage forms. It is helpful in increasing patients compliance and also improves efficiency in the treatment of migraine. It minimizes the side effects by minimizing the dose frequency. So, the developed tablet can show the maximum therapeutic effect as compared to other like Ibuprofen, Aspirin on the treatment of migraine.