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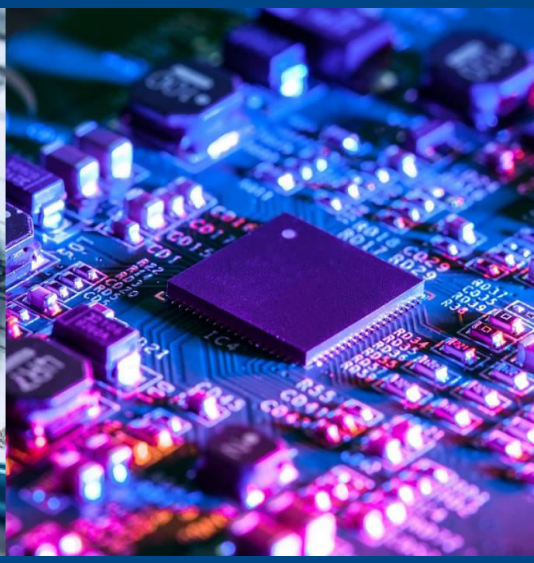

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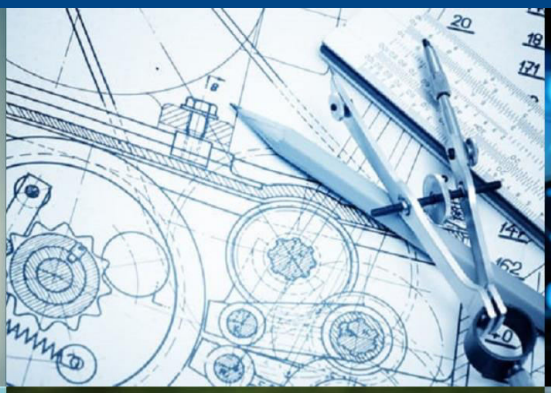

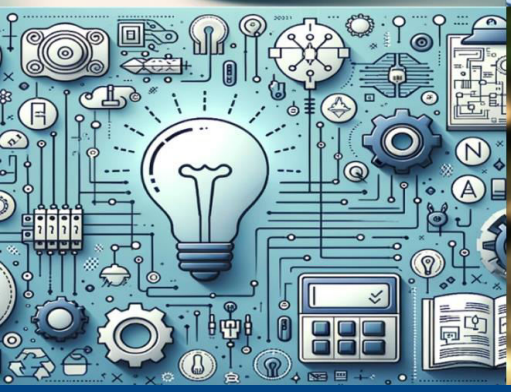

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Formulation & Evaluation of Diclofenac Sodium Capsule for the Treatment of Gout

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ABSTRACT: Diclofenac sodium capsules were formulated and evaluated for the treatment of gout. The formulation involved the preparation of diclofenac sodium granules, which was then filled into hard gelatin capsules. The capsules were evaluated for their physical characteristics, such as weight variation, hardness, and friability. The in vitro dissolution study was also conducted to determine the release profile of diclofenac sodium from the capsules. The formulated diclofenac sodium capsules were found to be suitable for the treatment of gout. The capsules exhibited good physical characteristics, such as uniform weight, adequate hardness, and low friability. The in vitro dissolution study showed that the capsules released diclofenac sodium rapidly, with more than 80% of the drug released within 30 minutes. This rapid release profile is desirable for the treatment of gout, as it allows for quick Gout is well known in medical circles as “the king of diseases and the disease of the kings” because of its occurrence among the rich and powerful and its link with wine and meat. The intense pain experienced during an acute attack of gout is just unbearable.

KEYWORDS: Gout, Diclofenac Sodium, Capsule.

I. INTRODUCTION

Diclofenac sodium is a synthetic, non steroidal anti-inflammatory, and analgesic compound Figure1 New chemical synthesis techniques and enhanced analytical and screening technologies have sparked the development of new non steroidal anti-inflammatory medication (NSAID) drugs in recent decades. Recent developments in NSAID pharmaceutics have concentrated on the creation of solutions to deal with severe dose-dependent GI, CV, and renal adverse effects (AEs) related to the use of NSAIDs. One of the mosto ftenused non steroidal anti- inflammatory medicines (NSAIDs), Diclofenac (DCF), also known as 2-(2-((2,6-dichlorophenyl) amino) phenyl) acetic acid, has both antipyretic and analgesic characteristics. Since1974, research has shown that DCF is quite effective for treating rheumatic symptoms, acute joint inflammation, and mild to moderate pain. Diclofenac is a non steroidal anti-inflammatory drug (NSAID). This medicine works by reducing substances in the body that cause pain and inflammation. Diclofenac is used to treat mild to moderate pain, or signs and symptoms of osteoarthritis or rheumatoid arthritis. Voltaren is also indicated for the treatment of ankylosing spondylitis. The Cataflam brand of this medicine is also used to treat menstrual cramps.

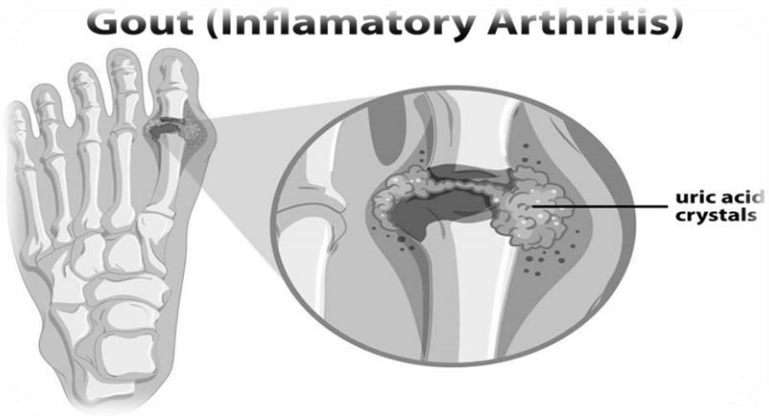

Fig. no. 1: gout (inflammatory arthritis)

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Phases of gout:

1. Asymptomatic Hyperuricemia

Asymptomatic hyperuricemia is the term for an abnormally high serum urate level, without gouty arthritis or nephrolithiasis. Hyperuricemia is defined as a serum urate concentration greater than 7 mg per dL (416 µmol per L), the approximate level at which urate is supersaturated in plasma. Although gouty arthritis characteristically occurs in patients with hyperuricemia, it is incorrect to equate hyperuricemia with clinical gout. Researchers from the Normative Aging Study followed 2,046 initially healthy men for 15 years by taking serial measurements of serum urate levels.

2. Acute gout

Acute gout is characterized by the sudden onset of pain, erythema, and limited range of motion and swelling of the involved joint. Often quoted, the English physician Thomas Sydenham's classic description of his own gouty sufferings is as true today as it was in the 17th century:"The victim goes to bed and sleeps in good health. About two o'clock in the morning he is awakened by a severe pain in the great toe; more rarely in the heel, ankle or instep. This pain is like that of dislocation then follows chills and shivers and a little fever. The pain, which was at first moderate, becomes more intense So exquisite and lively meanwhile is the feeling of the part affected, that it cannot bear the weight of bedclothes nor the jar of a person walking in the room.

3. Intercritical gout

Recovery from acute gouty arthritis, the patient reenters an asymptomatic phase of the disease. This phase is referred to as "intercritical gout" It is during this intercritical phase that the physician should focus on secondary causes of hyperuricemia. Medications should be assessed to identify those that may aggravate the patient's condition (e.g., diuretics) and dietary education regarding purine-rich foods (which contribute to higher serum uric acid levels) should be provided to the patient at this time. The patient should also be counseled about limiting alcohol consumption and gradually losing weight, if obese.

4. Chronic tophaceous

Tophi are chalky deposits of sodium urate that are large enough to be seen on radiographs and may occur at virtually any site. The most common sites include the joints of the hands or feet. The helix of the ear, the olecranon bursa and the Achilles tendon are classic, albeit less common, locations for tophi. Articular tophaceous gout can result in a destructive arthropathy and chronic secondary osteoarthritis.

II. MATERIAL & METHODS

List of chemical:

S. No.	Name of chemical	Manufacture Name/ Supplier Name
1.	Diclofenac sodium	Elder bio drugs pvt. ltd
2.	Sodium starch glycolate	Naksh enterprises
3.	Magnesium stearate	Shree Ambe Pharma & chemicals
4.	Mannitol	Gonane Pharma
5.	Lactose	DFE Pharma
6.	Acetone	Arpana industries
7.	Methanol	Oxford lab fine chem.LLP

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List of Glassware:

Table no. 1: List of Chemical

S. No.	Name of Glassware	Manufacture Name / Supplier Name
1.	Beaker	Nandini enterprises
2.	Funnel	Nandini enterprises
3.	Measuring Cylinder	Nandini enterprises
4.	Glass rod	Dawa-bazar
5.	Pipette	Nandini enterprises
6.	Watch Glass	Dawa-bazar
7.	Test tube	Indian scientific
8.	Mortal pastel	Dawa-bazar

Salicylic acid, a historically used therapeutic medicine made from the active ingredient in willow bark salicin, has antipyretic, analgesic, and anti-inflammatory actions. Salicylic acid was utilized globally in the late nineteenth century for a number of diseases.There was a need for new, better chemical derivatives of salicylic acid due to its bitter taste and accompanying gastrointestinal discomfort. In order to create a mildly acidic acetylsalicylic acid with a more pleasing taste, Felix Hoffman and Arthur Eichengrun acetylated the salicylic acid molecule in 1897. Bayer (Berlin, Germany) patented this compound as aspirin in 1899. The Geigy Corporation (Basel, Switzerland) produced a novel molecule with significant anti-inflammatory and uric acid excretion-promoting properties in the early 1950s.This substance created water-soluble salts of amino phenazone.

Excipient

1. Diluents, binders or granulating agents, glidents and Lubricants to ensure efficient capsule;
2. Disintegrates: to promote capsule break up in the digestive tract;
3. Sweeteners or flavors: to enhance the taste;

- Wet granulation
- Dry granulation

III. METHODOLOGY

Preparation of capsule:

Diclofenac sodium was used as a model drug in the formulations, while HPMC 100 cps and Na CMC was used a state-controlling polymer. Magnesium stearate or talc were utilized as lubricants, while lactose monohydrate was used as a compression assist. In all tests, all formulation ingredient so the than magnesium stearate and talc were dry mixed and subsequently granulated by adding water. Then a 20-mesh screen was used for wet screening. Granules were dried for one hour at 50 C. The dried granules were lubricated by combining them with talc and magnesium stearate. Lists the several formulations that were created to get her with information on their compositions and average weights. These are the ingredients which are used in below formulation for formulating capsule of Diclofenac sodium:

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Formulation table:

S. No.	Ingredient	F1	F2	F3
1.	Diclofenac sodium	37.5 mg	37.5 mg	37.5 mg
2.	Sodium starch glycolate	31	30	32
3.	Magnesium stearate	4.35	4	4
4.	Mannitol	51.25	51	52
5.	Lactose	8.25	9.1	8.1

Table no. 3: Formulation table

Preparation of Granules:

The wet granulation process involves several steps, including:

Weighing of Ingredient:

⇩

Mixing of powders with other Excipient

⇩

Preparation of dump mass and sizing the granulation by wet screening

⇩

Wet screening / screening the damped powder into pellets or granules

⇩

Drying of moist granules

⇩

Sizing the granulation by dry screening

The preparation of the granulation mixture involves blending the active pharmaceutical ingredient with Excipient such as binders, fillers, and lubricants. After the powder mixture is wetted with a binder solution, it is mixed to form a wet mass. The wet mass is then passed through a wet screen to breakdown any large aggregates before being dried. Finally, the dried granules are screened to obtain the desired particle size range. Wet granulation, granules are formed by the addition of a granulation liquid onto a powder bed which is under the influence of an impeller (in a high-shear granulator), screws (in a twin screw granulator) or air (in a fluidized bed granulator). The agitation resulting in the system along with the wetting of the components within the formulation results in the aggregation of the primary powder particles to produce wet granules.

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Capsule filling process:

Step 1: Filling

1. Load the capsules: Load the empty capsules into the capsule filling machine.
2. Fill the capsules: The machine fills the capsules with the powder or granules.
3. Adjust the filling volume: Adjust the filling volume to ensure accurate filling.

Step 2: Capping

1. Cap the capsules: The machine caps the filled capsules.
2. Inspect the capsules: Check the capsules for any defects or damage.

Figure no. 2: Capsule filling

IV. EVALUATION OF FORMULATED CAPSULE

Weight variation test

Twenty capsules were weighed separately for the IP weight variation test, and the average weight was computed and compared to the weights of the individual capsule against the average.

Disintegration Time in Vitro

Six tablets were randomly chosen from each brand, one from each of the tubes in the basket-rack assembly of the disintegration device, and placed in each tube. At 370C, the assembly was placed in the artificial gastric fluid. After 120 minutes, take the basket-rack assembly out of the liquid and give it a gentle water rinse. Any enteric coated tablet that clearly displays signs of disintegration fails the test. Now swap out the simulated stomach fluid with simulated intestinal fluid in the jar.

Table no. 4: Disintegration test

Evaluation Parameter	Formulations(Min.)		
	F1	F2	F3
Disintegration Test	9	10	12

Table no. 4: Disintegration test

Figure no.3: Disintegration test

Figure no.3: Disintegration test

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Dissolution Test:

Drug release was assessed using equipment II to conduct an enteric coated tablet disintegration test in accordance with IP using method B. This approach utilized two distinct pH levels at two separate time periods. The tablets were submerged in 900 ml of 0.1 N hydrochloric acid in the USP dissolving bath for the first stage (pH 1.2), which was carried out at a temperature of 37 0.5o C. The 50 rpm paddle stirring speed was chosen. The device was filled with six tablets, and it was run for two hours.

Evaluation Parameter	Formulations(min.)		
	F1	F2	F3
Dissolution Test	20	25	23

Table no. 5: Dissolution Test.

Figure no.3: Dissolution test

V. RESULT & DISCUSSION

The active ingredient tested in this paper exhibit the considerable properties as mentioned below. As per our formulation has been developed in which the formulation contain Diclofenac sodium as API and various exipients like Sodium starch glycolate, Magnesium stearate, Mannitol and Lactose are mixed with API and formulation was developed.

- **Organoleptic properties**:

As per the method given in the following result obtain the color was seen white, the odor of the API is odorless, the state of the API was solid amorphous in nature. The Organoleptic property of the API before formulation was the color of the API was seen

S. No.	Organoleptic properties	Observation
1.	State	Solid fine powder
2.	Color	White
3.	Odor	Slightly sweet & better

Table no. 7: Organoleptic properties

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- **Solubility :**

In the solubility test of the API was dissolved in 10ml of distilled water, acetone & menthol after dissolution we observe in water the API was soluble, in chloroform the API was slightly soluble & in menthol API was soluble. As per the method given the following result obtain

S. No.	Solvent	Observation
1.	Water	Slightly soluble
2.	Methanol	Soluble
3.	Acetone	Soluble

Table no. 8: solubility

Flow properties:

The flow property of API was performed through which the bulk density of the preparation was 0.58 g/ml, tapped density of preparation after 50times = 0.66 g/ml and angle of repose of API is 0.78 which is fair (aid not needed), Hausner's ratio of the API was 1.13 g/m^3 & Carr's compressibility index of the API was 12%. As per the method given the following result obtain that The bulk density of the preparation was 0.58g/ml. Tapped density of preparation after 50 times = 0.66g/ml

Angle of repose: As per the method given the following result obtains that angle of repose of Diclofenac sodium 0.78

**Hausner`s Ratio:** As per the method given the following result obtains that Hausner`s Ratio of the API was 1.13

**Carr`s index:** As per the method given the following result obtains that Carr`s index of the API was 12.12

VI. CONCLUSION

Diclofenac sodium capsules were formulated and evaluated for the treatment of gout. The formulation involved the preparation of diclofenac sodium granules, which was then filled into hard gelatin capsules. The capsules were evaluated for their physical characteristics, such as weight variation, hardness, and friability. The in vitro dissolution study was also conducted to determine the release profile of diclofenac sodium from the capsules. The formulated diclofenac sodium capsules were found to be suitable for the treatment of gout. The capsules exhibited good physical characteristics, such as uniform weight, adequate hardness, and low friability. The in vitro dissolution study showed that the capsules released diclofenac sodium rapidly, with more than 80% of the drug released within 30 minutes. This rapid release profile is desirable for the treatment of gout. The intense pain experienced during an acute attack of gout is just unbearable. The inflammation of the tissue around the joint causes the skin to become swollen, tender and sensitive to even a slight touch. Even a thin cloth/saree draped over the affected area causes extreme pain. Intense pain, redness, and swelling around the joints area are the main symptoms of gout.

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