



# Formulation And Development Of Diclofenac Tablet

1HARIOM DINKAR MALI, 2BHAVIKA SURENDRA JAIN, 3JAYESH VILAS MANDE,  
4KAMLESH ARUN BORSE, 5SHUBHAM RAJESH JAIN.

1Student , 2Student , 3Student , 4Student , 5Student

1Shri. Prakashchand jain College of pharmacy and research Jamner Palaskheda ,

2Shri. Prakashchand Jain College of pharmacy and research jamner ,

3Shri. Prakashchand Jain College of Pharmacy and Research Jamner ,

4 Shri. Prakashchand Jain College of Pharmacy and Research , Jamner,

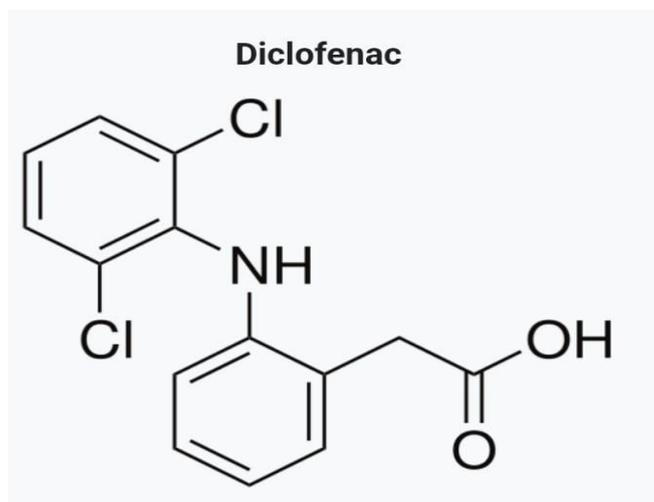
5Shri. Prakashchand Jain College of Pharmacy and Research Jamner

**Abstract:** Diclofenac tablet is non-steroidal anti inflammatory drug [NSAID] used to treat mild-to-moderate pain and helps to relive symptom of arthritis .The creation of alternatives to treat severe dependent on dose gastrointestinal [GI], cardiovascular [CV], in NSAID pharmaceuticals. It can inhibit prostaglandin synthesis by blocking cyclooxygenase[ COX]. It shows some crucial side effect. Biological activities and drug-likeness indicate that all the analogues of DCF have lower action of gastrointestinal hemorrhage. By 2027, the diclofenac, arket is expected to grow to a value.

**KEYWORD-** Diclofenac Sodium, NSAID, COX1 & COX2, coated tablet, hydropropyl cellulose

## INTRODUCTION:-

Diclofenac is a non-steroidal antiinflammatory drug (NSAID) used to treat mild-to-moderate pain and helps to relive symptom of arthritis (eg, osteoarthritis or rheumatoid arthritis), such as inflammation, swelling, stiffness, and joint pain.[1]



[FIG :-1Structure of Diclofenac ]

New chemical synthesis techniques as well as enhanced analytical and screening technologies have fueled the development of new nonsteroidal anti-inflammatory medication (NSAID) products in recent decades. The pharmacological characteristics of these substances have also been enhanced by developments in pharmaceuticals and the science of creating physical pharmaceutical dosage forms like tablets and capsules. These developments include the creation of innovative oral drug preparations including flexible, dispersible, or multiparticulate dosage forms as well as controlled drug delivery systems. Furthermore, the solubility, bioavailability, and effectiveness of oral medicinal products have been improved by novel manufacturing processes that alter the active therapeutic substance's particle size distribution. Clinical advantages like fewer dosages and a better adverse event profile have resulted from these advancements.

The creation of alternatives to treat severe dependent on dose gastrointestinal (GI), cardiovascular (CV), & renal adverse effects (AEs) linked to NSAID use has been the recent focus of advancements in NSAID pharmaceuticals. In order to improve tolerability and, in certain situations, support expanded indications, strategies to address these concerns have focused on pharmacological property modifications, innovative delivery methods, and co-administration via gastro protective agents like proton pump inhibitors.

Is the NSAID that is most frequently administered globally. In 2012, almost 10 million prescriptions for diclofenac medication products were filled in the United States. Numerous novel medications containing diclofenac have been authorized to be utilized and marketed in the United States since its launch in 1973. The launch of new diclofenac medication items has contributed to the rise in NSAID prescribing in the United States. These novel medications are recommended for the management of a variety of acute and/or chronic pain problems and have different pharmacokinetic (PK) characteristics and dosage schedules. The creation of diclofenac medication products provides an example of how medical technology can spur innovation and provide medications with enhanced therapeutic value, safety, and efficacy.

## **HISTORY:-**

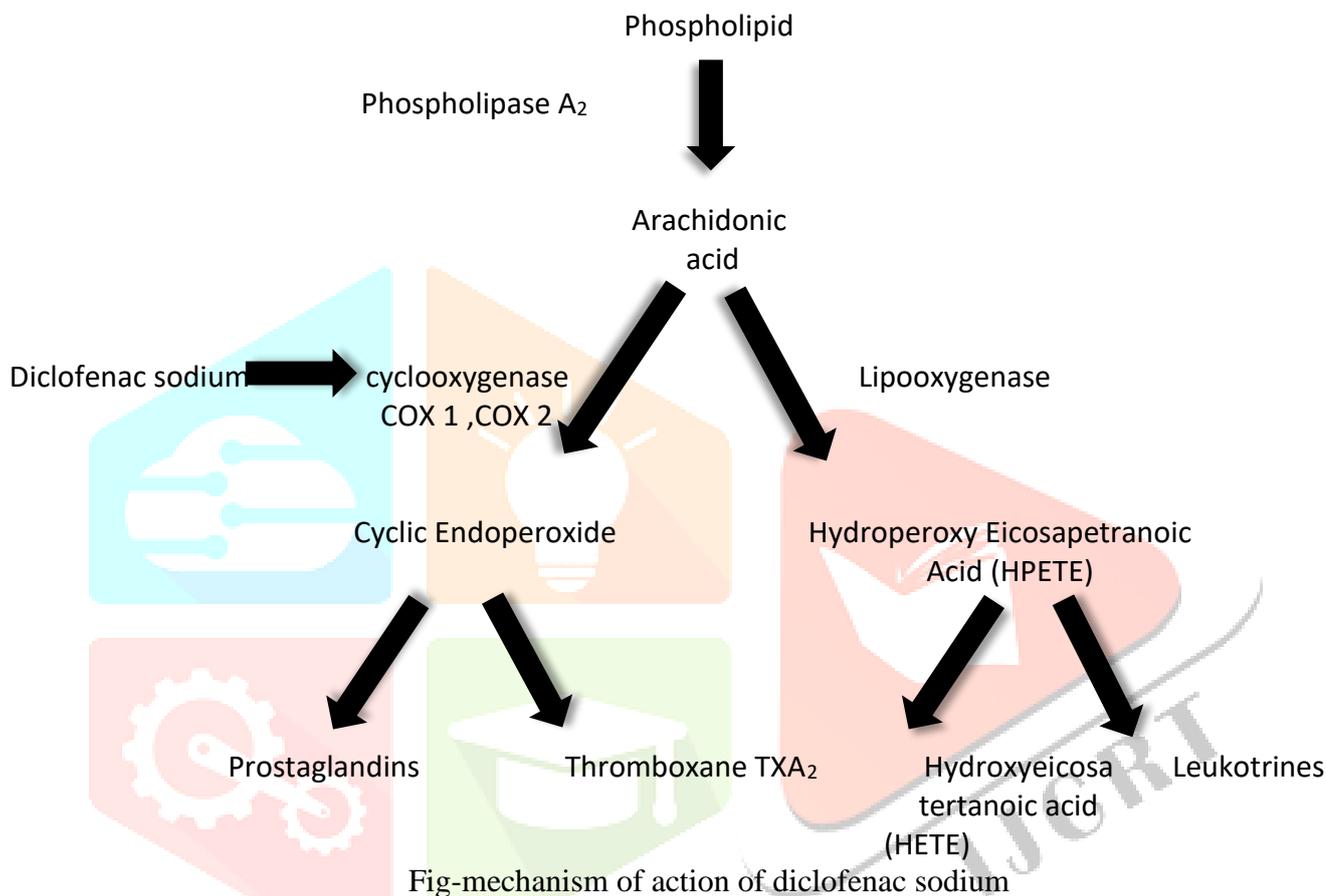
The goal of creating diclofenac sodium was to create a nonsteroidal anti-inflammatory medication with exceptional tolerance and high activity. Drug movement across biological membranes, the molecule's atomic and spatial structure, and its electronic structure were all taken into account. It was hypothesized that an effective antirheumatic agent should possess the following properties based on analysis of various other nonsteroidal anti-inflammatory drugs: two aromatic rings turned in relation to each other, an acidity constant between 4 and 5, and a partition coefficient of roughly 10. Diclofenac sodium, with an acidity characteristic of 4.0 and a partition coefficient of 13.4, was the end product. A secondary amino group, a phenylacetic acid group, and a phenyl ring with chlorine atoms are among the structural components that maximize the twisting [1]

## MECHANISM OF ACTION:-

The way diclofenac functions is by preventing the cyclooxygenase enzymes (COX-1 & COX-2) from creating prostaglandins. Chemical mediators called prostaglandins are important in fever, pain, and inflammation. Diclofenac helps to reduce inflammation and pain by lowering prostaglandin synthesis.

**COX-1:-** Normal kidney function, platelet aggregation (blood clotting), and intestinal function are all influenced by COX-1.

**COX-2:-** The processes of inflammation and pain are the main functions of COX-2. Diclofenac still has some effect on COX-1, however it is more specific for COX-2 than other NSAIDs. [2]



The enzymes cyclooxygenase-1 and -2, which produce prostaglandin (PG) G<sub>2</sub>, the building block of other PGs, are inhibited by diclofenac. The basic mechanism underlying all of diclofenac's effects is the reduction of these molecules' synthesis, which exhibits broad efficacy in pain and inflammation.

The main PG implicated in nociception modulation is PGE<sub>2</sub>. PGE<sub>2</sub> increases the activity of the inositol triphosphate/phospholipase C pathway by activating the G<sub>q</sub>-coupled EP<sub>1</sub> receptor. When this pathway is activated, intracellular calcium reserves are released, lowering the action potential threshold directly and activating protein kinase C (PKC), which supports a number of indirect processes.

**FORMULATION AND DEVELOPMENT :-**

Stage	Goal	Components	Process/Considerations
<b>Pre-formulation Studies</b>	Determine the diclofenac's physicochemical characteristics.	The active ingredient in pharmaceuticals (API)	Stability Testing, pH, and solubility
	Understand interactions with excipients	A variety of excipients, such as lubricants, binders, and fillers	Compatibility investigations between APIs and excipients
<b>Formulation Design</b>	Develop a stable, effective formulation	API and selected excipients	- Select form: immediate or extended-release, dose determination
<b>Granulation</b>	Improve flow and compressibility of powder	Diclofenac powder, binders, and disintegrants	- Wet or dry granulation processes
<b>Mixing and Blending</b>	Make the mixture homogeneous.	Fillers (such as lactose and microcrystalline cellulose) and API	Attain uniformity without segregation
<b>Tablet Compression</b>	Make tablets by compressing the powder mixture.	Blend of powder	Determine the compressive force for tablet disintegration and hardness.
<b>Coating (Optional)</b>	Boost control release and stability	- Coating agents (e.g., hydroxypropyl methylcellulose)	- Film coating for stability, enteric coating for GI protection
<b>Quality Control</b>	Ensure tablets meet specifications	- Finished tablets	Testing: weight uniformity, hardness, friability, dissolution
<b>Quality Control</b>	Ensure tablets meet specifications	- Finished tablets	- Testing: weight uniformity, hardness, friability, dissolution
<b>Packaging</b>	Protect product and ensure patient compliance	- Blister packs, bottles, desiccants	- Packaging materials must maintain stability

Table No 1– formulation and development of diclofenac

There are number of formulation are available in market i.e [3]

**PROPERTIES:-****➤ PHYSICAL PROPERTIES:-****1. Apperance:**

It is an odorless, white to off- white crystalline, slightly hygroscopic powder.

**2. Melting Point:**

302-310°C (dec.)

**3. PKa:**

Diclofenac is a weak acid, poorly soluble in water in its un-ionized form, and mainly formulated as a salt.

**4. Packaging and Storage:**

Store at a controlled room temperature between 20°C and 25°C. Keep away from excess light and moisture.

Keep out of the reach of children.

**5. Solubility:**

- a) Water - Very Poorly Soluble.
- b) Methanol – Soluble
- c) Ethanol - Soluble.
- d) Acetone - Soluble.
- e) DMSO Dimethylsulfoxide - Soluble.
- f) Vegetable oils - Slightly Soluble

**➤ CHEMICAL TESTS FOR DICLOFENAC:-****1. Nitric acid test:**

Add 1 mL of nitric acid to a solution of 1 in 250 diclofenac sodium in methanol to produce a dark red color.

**2. Flame coloration test:**

Perform the test with 5 mg of diclofenac sodium to produce a light green color.

**3. Infrared spectrophotometry:**

Compare the infrared absorption spectrum of dried diclofenac sodium with the reference spectrum.

**4. Visible spectrophotometry:**

Use an aqueous solution of copper (II) to form a green color complex with diclofenac.

**5. DSC curve:**

Determine the endothermic peak in the DSC curve obtained in a nitrogen atmosphere.

**6. Gravimetric method:**

Precipitate diclofenac from an aqueous solution with copper(II) acetate in a pH 5.3 buffer

**Other methods for determining diclofenac include:**

1. Potentiometry
2. Capillary zone electrophoresis
3. High-performance liquid chromatography (HPLC)
4. High-performance liquid chromatography–mass spectrometry (HPLC–MS)
5. Spectrofluorometry
6. Thin layer chromatography
7. Gas chromatography
8. Polarographic analysis[4]

**PHARMACEUTICAL ASSAY :-**

The assay was run on tablets from each formulation to determine the percentage of active medication in each tablet.

The percentage drug concentrations of diclofenac potassium and sodium that are within the permitted limits .

**In-vitro Dissolution Profile:-**

Dissolution data displays the entire drug release profile over time, revealing that all formulations hindered drug release from matrices for the first two hours. However, as the medium was switched to phosphate buffer, drug release began and increased over time, as noted by Kramar, Turk, and Vrečer (2003).

Significant variations in the drug release behavior from hydrophilic matrices were demonstrated by a little change in HPMC concentration between formulations T-01 and T-04. The release of diclofenac sodium was shown to be reliant on the concentration of the polymer utilized, as the concentration of HPMC was primarily in charge of regulating drug release from the swollen matrices. A relationship between the percentage of medication release and time is described by the cumulative dissolution profiles of all formulations.

**PHARMACOKINETICS AND PHARMACOLOGY OF DICLOFENAC:-**

Diclofenac is a commonly recommended drug for pain, inflammation, and fever relief. The drug is used in conditions such as rheumatoid arthritis and pain related to surgery.[5][6] As the name implies, diclofenac is a derivative of phenyl acetic acid that comes in sodium, potassium, or sodium/misoprostol salt form. Its molecular weight is 318.14 and its formula is  $C_{14}H_{10}Cl_2NaO_2$  [7]. It was first synthesized by Alfred Sallmann and Rudolf Pfister in 1973. In contrast to other classical NSAIDs, diclofenac is known to inhibit the COX-2 enzyme with greater efficiency than the COX-1 enzyme.[8] Diclofenac is a weak acid and has limited solubility in both aqueous and hydrophobic media [8][9]. Diclofenac is known to be absorbed completely and is directly proportional to the dose applied [10][11]. The peak plasma concentration is observed within a range of 10 min to 2 h, depending on the dosage form, viz., enteric coated tablets, solution, etc., and individual-

based parameters such as gastrointestinal pH [12][13][14]. Diclofenac sodium salt is a gradually releasing formulation that has high dissolution in the high pH environment present in the duodenum in comparison with the low pH environment in the stomach [15]. The potassium salt of diclofenac was developed to increase the rate of diclofenac absorption, which could be used in conditions where rapid pain relief is needed. Nearly sixty percent of intact diclofenac reaches the circulation [16].

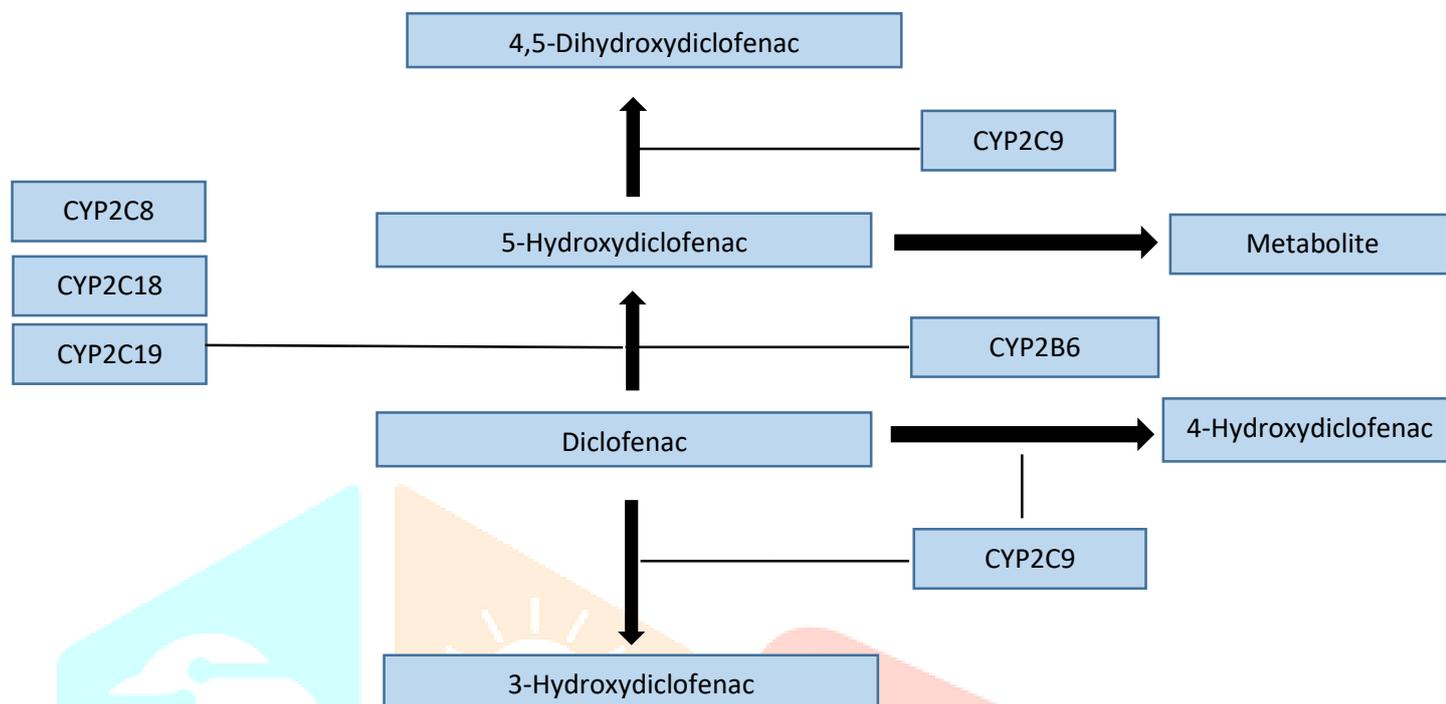


Fig: Diclofenac Metabolic Pathway

#### PHARMACODYNAMIC OF DICLOFENAC TABLET :-

Diclofenac reduces inflammation and by extension reduces nociceptive pain and combats fever. It also increases the risk of developing a gastrointestinal ulcer by inhibiting the production of protective mucus in the stomach.[17]

#### DICLOFENAC TABLET ARE AVAILABLE IN DIFFERENT FORM :-

SR NO	FORMULATION	BRAND NAME	USES
1.	Tablet	Voltarol, Dicloflex, Diclomax	<ul style="list-style-type: none"> <li>▪ Anti-inflammatory</li> <li>▪ Relief pain</li> <li>▪ Tenderness</li> </ul>
2.	Gel	Voltaren Gel	<ul style="list-style-type: none"> <li>▪ Muscle Pain relief</li> <li>▪ Pain removal</li> </ul>
3.	Aerosol	Moov, DFO Spray	<ul style="list-style-type: none"> <li>▪ Swelling from injuries</li> <li>▪ Relief pain and swelling due to trauma in small and medium joints</li> </ul>
4.	Capsule	Voltaren XR	<ul style="list-style-type: none"> <li>▪ Stiffness</li> <li>▪ Joint pain</li> <li>▪ Inflammation and swelling</li> </ul>

Table no. 2 Diclofenac various forms available in market

**STANDARD METHOD TO PREPARATION OF DICLOFENAC TABLET :-**

1. Several formulations (Tables I and II) were examined according to the type and degree of polymer coating. In a polybag, the drug and intragranular components were combined for ten minutes after passing through a #30 mesh filter. A 5% (w/v) solution of hydroxypropyl cellulose in water was used to granulate the mixture, and the wet granules were dried for one to two hours at 60°C in an oven. After passing through a #30 sieve, the dried granules were combined with croscarmellose sodium and left in a polybag for five minutes. The aforementioned powder mixture was combined with magnesium stearate (0.95% w/w, previously sieved through #60 mesh) and stirred for five minutes in a polybag. The lubricated blend was compressed using a rotary tablet punching machine (Kambert machines, Ahmedabad, India) with an average weight of 160 mg.[18]
2. Method according to claim 1, is characterized in that described organic solvent is: methylene dichloride, trichloromethane, tetracol phenixin, oil of mirbane, acetonitrile, tetrahydrofuran (THF), Isosorbide-5-Nitrate-dioxane; Chlorination reagent is: NaOCl, t-BuOCl, NaOCl/HAc, NaOCl/HAc/t-BuOH, Ca (OCl) 2/ HAc, Ca (OCl) 2/ Al 2O 3(wet), TCCA,
3. Method according to claim 1, is characterized in that described organic solvent is that Lewis acid is: aluminum trichloride (anhydrous), iron trichloride, titanium tetrachloride, zinc chloride.
4. Method according to claim 1 is characterized in that the mol ratio of described Lewis acid catalyst and N-chlorine N-used (substituted aryl) substituted-phenyl ethanamide (II): 0.3-1:1.
5. Method according to claim 1, is characterized in that described temperature is: 0 °C-reflux temperature.
6. Isolation of corn silk powder: The collected Fresh corn silk cleaned with tap water, soaked in a distilled water, dried in oven at 45oC upto constant weight. The obtained dried silk was converted into a state of fine powder and it was extracted with 40% v/v ethanol - distilled water. The dried sample macerated with three times of 40% v/v ethanol (1.5 L) for 24 h at room temperature, digested with distilled water (1.5 L) for 1 h at 45oC. The collected extract solution was separately filtered using filter paper and the used solvents evaporated at 40oC. The final sample was dried and used in the form of solid powder and stored at 20oC.[19]\*

**SIDE EFFECT AND RISK:-**

Side effects from diclofenac (also known as diclofenac sodium) can range from minor to severe. A number of the most frequent diclofenac side effects that can happen during treatment are listed below. Not every potential adverse impact is listed in these lists.

Check your physician or pharmacist for additional details regarding the potential adverse effects of diclofenac. They can offer you advice on how to deal with any negative effects that could be distressing or worrisome.

**MILD SIDE EFFECTS OF DICLOFENAC CAN INCLUDE:-**

1. abdominal pain
2. diarrhea
3. dizziness
4. fluid retention (buildup)
5. feeling sleepy
6. hair loss
7. headache

**SERIOUS SIDE EFFECTS CAN INCLUDE:-**

1. changes in blood cell levels, including thrombocytopenia (low platelet level)
2. breathing problems, such as shortness of breath or asthma
3. heart problems, including high blood pressure or heart failure
4. kidney problems, such as kidney failure
5. liver problems, including liver failure
6. increased risk of cardiovascular problems

## ADMINISTRATION:-

Preparations of diclofenac combine the medication with a salt, such as potassium, sodium, or epolamine salt. Oral dissolution of diclofenac sodium, intramuscular solution, intravenous solution, transdermal gel, or rectal routes like a suppository are all possible. Tablets or suspensions of diclofenac potassium are available for use by mouth. A transdermal patch with diclofenac epolamine is available.

When orally administered, diclofenac is absorbed rapidly and binds to albumin in the plasma. The drug concentrates in synovial fluids, where it renders its targeted action as an NSAID for relief musculoskeletal inflammation and ailments.[11] It has both extended-release and immediate-release forms that vary in doses. Oral administration of diclofenac, like other NSAIDs, carries the risk of gastrointestinal upset and is recommended to consume the medication with food or milk in all age groups. In addition, there are formulations of diclofenac combined with misoprostol to mitigate gastrointestinal adverse effects. It is common practice for clinicians to prescribe gastric acid-reducing therapies such as proton pump inhibitors (PPI) for concomitant use with NSAIDs to reduce the risk of more serious gastrointestinal (GI) adverse reactions. Recommendations may include taking over-the-counter antacids as a form of gastro protection.

Like other NSAIDs, diclofenac should be utilized at the lowest dose that works best to meet clinical objectives and reduce potential toxicity and adverse effects.

The daily dosage of oral diclofenac sodium might be 100–150 mg, which can be taken as 25–150 mg delayed-release or immediate-release tablets. These dosages are intended for rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis. Diclofenac sodium can be applied topically in gel formulations with concentrations ranging from 1% to 3%. For osteoarthritis, topical use of gel containing 1–2% diclofenac sodium is recommended for up to 16 g per day for monoarthritic bones and up to 32 g per day for polyarthritic joints. The 3% diclofenac sodium formulation is intended for use as hybrid treatment twice daily to treat actinic keratosis. For acute moderate pain, a 37.5 mg bolus injection of iv diclofenac sodium can be given every 6 hours.

Diclofenac potassium is typically given in doses of 25 mg or 50 mg one to 4 times every day, for a daily total of 50 to 200 mg. This is the recommended course of treatment for rheumatoid arthritis, osteoarthritis, migraines, primary dysmenorrhea, and nonspecific pain.[20]

## ADVANTAGES OF DICLOFENAC :-

1. Diclofenac is well-known for being able to effectively relieve moderate to severe pain, particularly in relation to ailments like arthritis, pain in the back, and pain following surgery.
2. Anti-Inflammatory Properties: It is effective in treating inflammatory diseases because it inhibits specific enzymes (COX-1 and COX-2) to reduce inflammation.
3. Different Forms: Diclofenac available in a variety of forms, such as pills, topical gels, patches, other injections, which gives patients more treatment options depending on their individual needs.
4. Relatively Quick Action: Diclofenac, particularly in immediate-release versions, can begin to reduce symptoms after an hour of intake.
5. Long-Lasting Relief: Diclofenac extended-release formulations offer long-lasting relief, lowering the frequency of dosage requirements.

## DISADVANTAGES OF DICLOFENAC :-

1. Gastrointestinal Problems: Since diclofenac affects the protection of the stomach lining, it might result in stomach issues such as ulcers, bleeding, and indigestion.
2. Heart Risks: Taking diclofenac for an extended period of time, especially at high dosages, may raise your risk of heart attack and stroke.
3. Kidney and Liver Damage: Long-term diclofenac use can harm the liver and kidneys, especially in those who already have liver or kidney disease.
4. Possible adverse Effects: Headache, nausea, skin rash, and dizziness are typical adverse effects. Breathing problems and severe allergic reactions are examples of serious effects, though these are uncommon.

5. Diclofenac is not appropriate for all patients. Individuals with severe kidney or heart disease, stomach ulcers, or NSAID allergies should not take this medication.

### MARKETING VALUE OF DICLOFENAC :-

Topical diclofenac therapies are widely promoted to treat a range of sports-related issues and injuries, as well as those with conditions including osteoarthritis in the knee. The market expanded as a result of all those factors that created a high demand for diclofenac sodium. A comprehensive analysis of the market is given in the Global Diclofenac Sodium Market study. The research provides a thorough examination of the market's major segments, trends, drivers, constraints, competitive environment, and significant factors.

### GLOBAL DICLOFENAC SODIUM MARKET OVERVIEW:-

A low dose of diclofenac sodium can quickly alleviate symptoms and diseases like rheumatoid arthritis, osteoarthritis, sprains and strains in muscles and ligaments, back pain, toothache, migraine, gout, and ankylosing spondylitis. This has led to an increase in demand for diclofenac sodium in the pharmaceutical and healthcare industries. Diclofenac sodium is also used to relieve inflammation and discomfort related to minor surgery and dental procedures.

Topical diclofenac therapies are widely promoted to treat a range of sports-related issues and injuries, as well as those with conditions including osteoarthritis in the knee. The market expanded as a result of all those factors that created a high demand for diclofenac sodium. The growth of the industry may also be hampered by the adverse effects of anti-inflammatory medications and issues with medicinal patent expiration. There are numerous opportunities for market expansion throughout the anticipated period due to the strong demand for novel and improved anti-inflammatory medicines with less side effects and increased efficacy.[21]

### MARKETING VALUE OF DICLOFENAC TABLET :-

By 2027, the diclofenac market is expected to grow to a value of \$6.1 billion. Additionally, it is anticipated to expand at a compound annual growth rate (CAGR) of 3.9% from 2022 to 2027. A class of nonsteroidal-inflammatory medications known as diclofenacs is used to treat patients in a number of ways. The medicine was first developed to treat inflammation-related conditions in individuals with eye issues, but after more research, it is currently being actively administered to patients with ankylosing spondylitis, joint pain, strains, migraines, and toothaches. Diclofenac sodium is the main component of the same. The sustained release (SR) characteristic of the tablets, which can be easily changed, enables the patient to experience pain relief for extended periods of time.

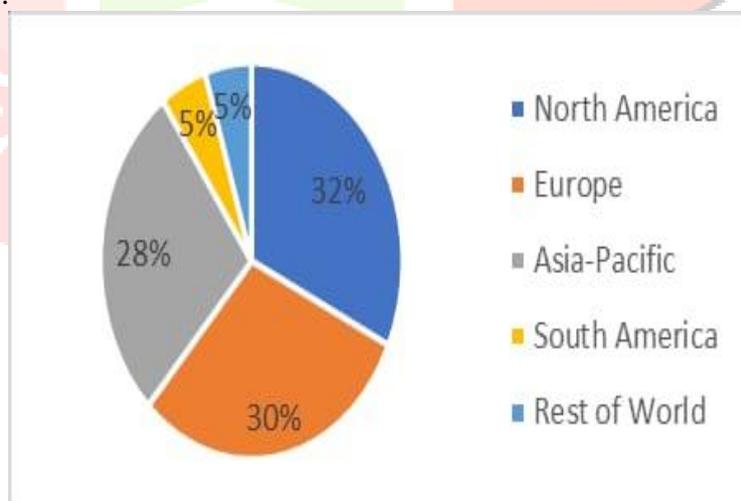


Fig- diclofenac market –geography (%) for 2021

### DICLOFENAC MARKET SEGMENTATION ANALYSIS- BY ADMINISTRATION ROUTE:-

Osteoarthritis, Ankylosing Spondylitis, Dysmenorrhea, Rheumatoid Arthritis, Migraine, Dental Pain, Sports Injury, Chronic Pain, and Others are the other indication-based segments of the diclofenac market. In 2021, the segment that dealt with chronic pain had a large market share. The broad range of topics covered by the following indication is the reason for this. For instance, injuries related to sports are more frequently classified as chronic pain. Furthermore, diclofenac is widely utilized in nations like Canada and Japan due to their sizable senior populations.

Additionally, it is projected that the chronic pain segment would increase at the quickest rate, with a compound annual growth rate (CAGR) of 4.7% from 2022 to 2027. Due to the increasing number of sporting

events, the most common method by which sponsors are attempting to raise awareness is by securing well-known starters and linking injuries to the relevant sport. The market will expand at a significant rate thanks to the following.

## DICLOFENAC SODIUM MARKET OVERVIEW:-

### ➤ Key Drivers

**Rising Prevalence of Chronic Pain:** The increasing incidence of conditions such as arthritis and other inflammatory disorders drives demand for effective pain management solutions like diclofenac sodium.

**Expanding Geriatric Population:** The growth of the elderly demographic, who are more susceptible to chronic ailments, propels the need for NSAIDs, including diclofenac sodium.

**Advancements in Formulation Technologies:** Innovations in drug delivery systems, such as topical formulations and extended-release variants, enhance the efficacy and safety profile of diclofenac sodium.

### ➤ Restraints

**Side Effects and Health Risks:** The potential for gastrointestinal complications and cardiovascular risks associated with long-term use limits the widespread adoption of diclofenac sodium.

**Regulatory Challenges:** Stringent regulations and potential market withdrawal of formulations due to safety concerns may impede market growth.

**Competition from Alternative Therapies:** The availability of other NSAIDs and alternative pain management therapies can constrain the market for diclofenac sodium.

### ➤ Trends

**Shift Towards Personalized Medicine:** Increasing emphasis on tailored therapeutic approaches is leading to the development of personalized formulations of diclofenac sodium.

**Growing Preference for Topical Applications:** The demand for topical formulations is on the rise due to their localized effects and reduced systemic side effects.

**Integration of Digital Health Solutions:** The incorporation of telemedicine and digital health tools for pain management is changing how diclofenac sodium is prescribed and monitored [22]

## DISCUSSION:-

Orally administered dosage forms are made to release the majority of the drug in the GIT segment where the integrated drug is most readily absorbed. However, it has been demonstrated that the dissolution profiles of weakly acidic drug salts are significantly higher than those of their free acidic counterparts. Diclofenac, a derivative of phenylacetic acid, comes in sodium and potassium salts in addition to free acid. Since sodium or potassium salts have a better solubility profile than the free acid form, the majority of diclofenac's commercially accessible products are currently available in these forms. Diclofenac typically comes in two dosage forms: immediate release (IR) for the sodium salt and delayed release (DR) or sustained release (SR) for.

Given that diclofenac sodium is sensitive to the gastric environment, it is manufactured as a prolonged release core to endure the harsh environment of the stomach, whereas diclofenac potassium is formulated as an orodispersible layer to enable quick release in the oral cavity.

The tablet is disrupted either by capillary action that increases its volume by many times or by the enlargement of the super-disintegrant. Orodispersible tablets (ODT), which have an extremely short disintegration period, use sodium starch glycolate, the anionic sodium salt of carboxymethyl ether, as a super-disintegrant. While the degree of crosslinking lowers the water-soluble fraction of the polymer and the viscosity of the dispersion medium, the addition of large hydrophilic carboxymethyl groups aids in breaking the hydrogen bond between the polymer, allowing water to enter the molecule. The pill in the current experiment disintegrated without the need for water in a matter of seconds thanks to the sodium starch glycolate's perfect super-disintegrant qualities. The results of formulation T-02, where the amount of Primogel® is reduced to 20 mg/tab and the disintegration time is increased to 30 sec, clearly show that the concentration of super-disintegrant significantly affects disintegration time, whereas formulation T-03 showed the opposite effect. HPMC's capacity to gel in physiological salt solution. Because of the shorter dosage frequency and immediate and prolonged start of effect, this initiative will assist patients improve their

compliance. It will also provide researchers with new opportunities to apply this technology to other medications that require rapid action and are appropriate for oral administration.

## CONCLUSION :-

The main goal of the study was accomplished when the outer orodispersible layer of diclofenac potassium and the sustained release inner core of diclofenac sodium were successfully combined into a single tablet. Increasing the concentration of HPMC was substantially linked to the retarding effect on drug release. Therefore, it is advised that future research focus on the tablets' stability studies and in-vivo evaluation.

## REFERENCE :-

1. Alfred R. Sallmann Ph.D., The history of Diclofenac, The American Journal, Volume 80,issue 4 ,Supplement 2 28 April 1986, Pages 29-33
2. Roy Altman et.al Advance in NSAID Development : Evolution of diclofenac product use in pharmaceutical technology, springer nature link (pubmed) review article ,volume 75, (2015), pages 895 to 877
3. V Ravichandiran Modern J Pharm Res20114825902
4. Godman and Gilman the pharmacological basis of therapeutics. I FDA approves Zederid OTC for over the counter treatment of frequent Heartburn Merck Essential of pharmacology basic principle and general concept 3rd edition, cbs publisher.[4]
5. Derry P et.al, Single dose oral diclofenac for acute postoperative pain in adults. Cochrane Database Syst. Rev. 2009:CD004768. doi: 10.1002/14651858.CD004768.pub2. [DOI] [PMC free article] [5]
6. Atzeni F., Masala et.al, A Review of Chronic Musculoskeletal Pain: Central and Peripheral Effects of Diclofenac. Pain Ther. 2018; volume 7 , pg no. 163–177[6]
7. Rodrigues E.B et al, CHAPTER 29—Nonsteroidal anti-inflammatory drugs (NSAIDs) in the treatment of retinal diseases 2010. pp. 196–200. [Google Scholar][7]
8. Altman R., Bosch B. et.al, Advances in NSAID Development: Evolution of Diclofenac Products Using Pharmaceutical Technology. Drugs year 2015 pg 859–877
9. Fini A., Bassini G et.al, Diclofenac Salts, VIII. Effect of the Counterions on the Permeation through Porcine Membrane from Aqueous Saturated Solutions. Pharmaceutics. 2012, volume 4 p no.413–429.pharmaceutics4030413. [DOI] [PMC free article][9]
10. Skoutakis V. A et.al Review of diclofenac and evaluation of its place in therapy as a nonsteroidal anti-inflammatory agent Clin. Pharm 850-859[10]
11. Davies N.M,et al Clinical pharmacokinetics of diclofenac. Therapeutic insights and pitfalls. Clin. Pharmacokinet. 1997;33:184–213[PubMed][11]
12. Reiner V., Reiner A,et al, Increased absorption rate of diclofenac from fast acting formulations containing its potassium salt. Arzneim. Forsch. 2001;51 pg no. 885–890.[12]
13. Macia M.A.et.al, Comparative bioavailability of a dispersible formulation of diclofenac and finding of double plasma peaks. Int. J. Clin. Pharmacol. Ther. 1995 volume 33, pg no.333–339. [PubMed] [Google Scholar][13]
14. Garbacz G.,et al Investigation of dissolution behavior of diclofenac sodium extended release formulations under standard and biorelevant test conditions. Drug Dev. Ind. Pharm. 2010 volume 36, pg no.518–530.
15. Birmingham B., Buvanendran A. 40—Nonsteroidal Anti-inflammatory Drugs, Acetaminophen, and COX-2 Inhibitors. In: Benzon H.T., Rathmell J.P., Wu C.L., Turk D.C., Argoff C.E., Hurley R.W., editors. Practical Management of Pain. 5th ed. Mosby; Philadelphia, PA, USA: 2014. pg.no.553–568.[15]
16. John V.A. The pharmacokinetics and metabolism of diclofenac sodium (Voltarol) in animals and man. Rheumatol. Rehabil. 1979 ,volume 2, pg no.22–37
17. Brunton LL, Hilal-Dandan R, Knollmann BC. eds (2018). Goodman & Gilman's: The Pharmacological Basis of Therapeutics (13th ed.). McGraw-Hill Education. [ISBN:978-1-25-958473-2]

18. Obeidat WM, Abuznait AH, Sallam AS. Sustained release tablets containing soluble polymethacrylates: comparison with tableted polymethacrylate IPEC polymers. AAPS PharmSciTech. 2010;11:54–63.
19. C Limmatvapirat Phytochemical analysis of baby corn silk extracts J Ayur Integrat Med 2019;11:334-45
20. Julie S. Eggleton et al, Highly Active Antiretroviral Therapy (HAART), National Library of Medicine, StatPearls Publishing LLC 2024
21. Global Diclofenac Sodium Market  
Report ID: 11850 | Published Date: Aug 2024 | No. of Pages: 202
22. Global Diclofenac Sodium Market Size By Type (Tablet, Injection), By Application (Elderly, Adults), By Geographic Scope And Forecast  
Report ID: 11850 | Published Date: Aug 2024 | Base Year for Estimate: 2024

