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Studies on the formulation and evaluation of the Aceclone Matrix Drug Delivery System using Natural Gum from the Satpuda Region

Miss. Monika Shirsath 1st, Miss. Gayatri Mahale 2nd, Mr. Utkarsh Mandage 3rd,
Mr. Nikhil Chaudhari 4th , Miss. Jagruti Patil 5th
Mr. Dr. Pankaj Chaudhari 5th

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I. INTRODUCTION :

KHANDESH REGION:

Khandesh is a geographical area in Central India that makes up a section of the state of Maharashtra to the northwest. The districts of Dhule, Jalgaon, and Nandurbar are located in North Maharashtra. It is located in the northeastern region of Maharashtra, bordered on the north by the Baroda district of Gujarat, on the east by the Nimar district of Madhya Pradesh, on the south by the Jalgaon district, and on the west by the Nashik district of Maharashtra. Maharashtra's east contains Satpuda, a lush area of vegetation with humid and semi-evergreen species. While the western portion of north Maharashtra only has dry scrub in Madhya Pradesh, it breaks into low woodland or scrub elsewhere, while the centre region has a large number of deciduous species. dry forest of trees On the northern side of the Tapi River, these are the Satpuda Hills' forest. It contributes ranges from Chopda, Yawal, and Raver. This area receives rainfall between 70 and 101 cm. Tectona grandis, Acacia cathechar, Anogissus latifolia, Terminalia tomentosa, Boswellia serrata, Terminalia Arjuna, and Butea monosperma are the main species. The forest on the southern bank of the Tapi River is known as a scrub forest and is primarily of this type. The vegetation is poor since the average rainfall ranges from 38 to 63 cm and the summertime high temperature is 48 0C. Acacia cathew, Anogissus latifolia, Boswellia serrata, Hardwikia binata, Zyzipus zuzuba, and other prominent plant species are present. Khandesh is located in Central India on the Deccan Plateau's northwest tip, in the valley of the Tapi River. The Satpura Range, the Berar (Vidarbha) region, the Hills of Ajanta (part of the Marathwada region of Maharashtra), and the northernmost ranges of the Western Ghats form its northern and eastern boundaries, respectively. The Tapi River is the main natural feature. The Tapi flows westward from its sources in southern Madhya Pradesh to empty into the Arabian Sea, in contrast to the remainder of the Deccan, whose rivers start in the Western Ghats and flow eastward to the Bay of Bengal. Thirteen major tributaries join the Tapi as it passes through Khandesh. None of these rivers can be used for navigation, and the Tapi has a deep bed that has historically prevented it from being used for irrigation. The Tapi's tributaries, the Girna, Bori, and Panjhra, drain the majority of Khandesh, which is located south of the river. Some of Khandesh's richest tracts are located on the alluvial plain north of the Tapi, and the land there increases With the exception of a few low ranges of desolate hills, the terrain is level in the centre and east. The plain rises into rough, heavily forested hills to the north and west, where the tribal Bhil people live.

- **Geographic elements Cities:**

Jalgaon consists of the following cities: Jalgaon, Amalner, Bhadgaon, Bhusawal, Bodwad, Chalisgaon, Chopda, Erandol, Dharangaon, Faizpur, Jamner, Pachora, Parola, Raver, Savda, Yawal, General: Burhanpur (in Madhya Pradesh; the capital of the old Khandesh province); Asirgarh (in Madhya Pradesh; a portion of the old Khandesh province); Dhulia: Dhule, Sakri, Sindkheda, Shirpur; Nashik: Deola, Kalwan, Malegaon, Nampur, Tarahbad; Nandurbar: Prakasha, Shahada, Talode; Nav Formerly known as Khandesh District (also Kandesh, Khandeish), it was a section of Nashik District in Maharashtra and encompassed the modern districts of Jalgaon, Dhule, and Nandurbar. Nandurbar is situated in Maharashtra State's northwestern region. Nandurbar is the district's administrative centre. Dhule District borders the district to the south and south-east. Gujarat State borders the district to the west and north. Madhya Pradesh State borders the district to the north and north-east. The enormous Narmada River forms the district's northern border. The Nandurbar district is located between latitudes 2100' and 220 030' north and longitudes 730' and 740' east. On July 1st, 1998, Dhule District was divided into two separate districts, creating Nandurbar District. The district is divided into 6 talukas: Nandurbar, Akkalkuwa,

Taloda, Shahada, and Akrani Mahal (also known as Dhadgaon). Geographically, Nandurbar District covers 5034.23 square kilometres. 13, 11,709 people live in Nandurbar district, with scheduled tribes making up 65.5% of the population. With a tribal population of 94.95%, Dhadgaon Tahsil ranks first, followed by Navapur, Akkalkuwa, Taloda, Shahada, and Nandurbar (2001 Census). The district's tribal population is primarily concentrated in the Satpuras valleys and extends from the northern side of Tapi. According to the Working Plan, Dhule circle, for the years 1997–1998 to 2006–2007, this hilly tract is divided into 6 ranges: Taloda, Akkalkuwa (E & W), Kathi, Molgi, and Manibeli. These tracts are all the tribal settlements. Padav is the name of the villages. The Bhil Pawara, Tadvi Gavit, Mavchi, and Vasave tribes make up the majority of the district's population. Native to the Satpura ranges are the Tadvi. Although they see themselves as superior to Bhils, they are really groups of Bhils. 'Nayare' is the collective noun for the Bhils, Vasave, and Padvi. They converse in adivasi pawri and Bhil dialects. Shahada, Toranmal, and Akrani are surrounded by the Bhil pawaras. The district's dominant tribe is this one. They converse in Bhilori and Pawara. The Gavit, often referred to as "Mavchi," are mainly found in the Nawapur tehsil. They are a group of Bhils who are frequently referred to as Kokni Maratha due to their Goan ancestry. The practise of polygamy, which emphasises the supremacy of men in society, is the tribe's defining characteristic. There are a lot of superstitious ideas among these folks. Witchcraft, or "Dakin," is a practise that is widely used. Each family typically consists of two to three spouses and 10 to 12 kids. Children are now assigned to "Ashram schools" as a result of government policy. Wagdeo gaga, the sacred grove, is another significant component that the indigenous people view as one of the means of conserving the forest. A variety of treatments for various illnesses have been discovered in recent times thanks to these cultures' innate urge and the collected indigenous knowledge of their surrounding vegetation that was passed down through verbal communication for generations. This fact led to the current investigation being conducted. The current investigation's goal is to catalogue these ethnic groups' indigenous knowledge. The article details the various plants that they employ for their indigenous purposes.

NATURAL GUM FOUND IN KHANDESH REGION:

GUM :

Gums are formed by woody plants either naturally through exudations from bark fractures or from animal or insect damage to the bark. Incisions in the bark can also artificially generate gum flow. The brittle, viscous lump that develops is easily removed by hand. All gums are complex carbohydrate compounds of a polysaccharide origin, and certain gums, like gum arable, are soluble in water. Gums are frequently used by people that live in the jungle, especially tribes in India, for both household consumption and for sale to make some money. India produces about 5,000 tonnes of plant-based gums each year. Some of the most significant gums made in India for commerce include Gum Arabic, Gum Ghati, and Gum Karaya. These are employed in the production of confections, dairy goods, drinks, emulsifiers for food products, petroleum, and in the industry for the purpose of acidifying oil wells. To fulfil the changing demands of domestic and international consumers, processing, value addition, and product creation require ongoing research support. Gums that come from plants are known as "natural gums," which are hydrophilic carbohydrate polymers with large molecular weights that are often made up of monosaccharide units connected together by glucosidic linkages. They often aren't soluble in oils or organic solvents like alcohols, ether, or hydrocarbons. In order to produce a viscous solution or jelly, gums can either be water-soluble or they can absorb water and swell up or scatter in cold water. They produce arabinose, galactose, mannose, and glucuronic acid upon hydrolysis. Typically, broadleaved trees and shrubs produce gums. They are polysaccharide-based complex carbohydrate derivatives that can either dissolve in water, as in the case of gum tragacanth, or absorb a lot of water to generate mucilage. Because of their capacity to impart desired properties to meals by affecting their viscosity, body, and texture, their primary usage is in foodstuffs, most frequently in confectionary food, flavouring, and soft drinks. They are also used in medicine as emulsifying agents, demulcents, and adhesives in the production of pills. Adhesives, lithography, paints, and inks are used in industry. Gums are frequently used by people that live in the jungle, especially tribes in India, for both household consumption and for sale to make some money. Gums provide as a reliable source of income for millions of people who live in forests and subforests in the central and western Indian states. The majority of NTFPs are only available for a brief period (about three months per year), but gums, which may be collected for six to eight months per year, offer dependent gum collectors a reliable source of income. There are about 5,000 tonnes of plant-based gums produced annually in India (guar gum is a seed-based gum, and output is about 2, 10,000 tonnes annually). Andhra Pradesh, Madhya Pradesh, Chhattisgarh, Orissa, Maharashtra, Gujarat, Rajasthan, etc. are some of the key states in India that produce gum. 1,730.24 tonnes of plant-based gums worth Rs. 2,218.27 lakh were exported from India in 2006–07.

GUM IN KHANDESH REGION:

- In Nandurbar and Dhule District, gum was discovered:
- Known locally as kadai, kadhay, kadoni, kewdi, kandul, kevda, and kuda, Sterculia urens

- Local names for Terminalia crenulata include Sadaba, Haijada, and Sandadi. Names for Garuga pinnata include kakad, kakada, kakod, and kakado.
- Local names for Boswelia Serrate include Dhupali, Salai, Goradu, Sal, and Sayphal.
- Azadirachta Local names include neem, kadu neem, and neemada.
- Acacia Chandra: Khair, Esa, Esan, Kati are the regional names.
- Local names for the Acacia Nilotica species include Babhul, Telya-Babhul, and Sadha Babhul.
- Charoli, Buchanania lanzan Spreng (Anacardiaceae).

ADVANTAGES OF NATURAL GUM:

- Biodegradable
- Biocompatible and non-toxic
- Low cost
- Environmental-friendly processing
- Local availability (especially in developing countries)

DISADVANTAGES OF NATURAL GUMS:

- Microbial contamination
- Batch to batch variation
- Uncontrolled rate of hydration
- Reduced viscosity on storage.

CLASSIFICATION OF GUMS:

The different available gums can be classified as follows:

1) According to the charge

A. Non-ionic seed gums: Guar, Locust Bean, Tamarind, Xanthan, Amylose, Arabinans, Cellulose, and Galactomannans.

B. Anionic gums: Arabic, Karaya, Tragacant, Gellan, Agar, Algin, Carrageenans, and Pectic Acid.

2) According to the source

A. Marine origin/algal (seaweed) gums: Agar, Carrageenans, Alginic acid, Laminarin.

B. Plant origin: Shrubs/tree exudates—Gum arabica, Gum ghatti, Gum karaya, Gum Tragacanth, khaya and Albizia gums. Seed gums—Guar gum, Locust bean gum, Starch, Amylose, cellulose. Extracts—pectin, larch gum Tuber and roots—potato starch.

C. Animal origin: Chitin and Chitosan, Chondroitin sulfate, Hyaluronic acid.

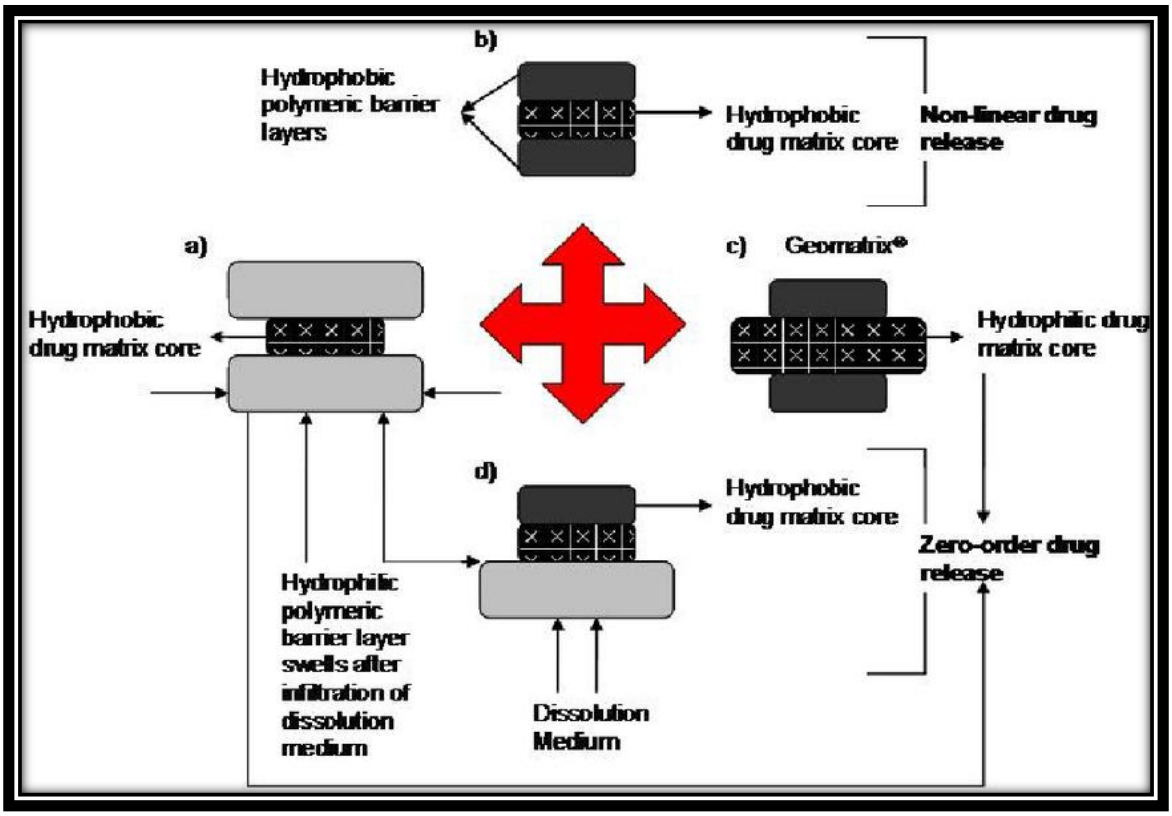
D. Microbial origin (bacterial and fungal): Xanthan, Dextran, Curdian, Pullulan, Zanflo, Emulsan, Baker's yeast glycan, Schizophyllan, Lentinan, Krestin, Scleroglucan.

The matrix system characters

For a drug-controlled release from a pharmaceutical dosage form, the matrix system is most frequently utilised. The matrix system, which is a release system for delaying and controlling the release of the drug that is dissolved or dispersed in a resistant support to disintegration, is the approach most frequently employed in controlled release medication from pharmaceutical dosage form. Knowing the characteristics that set matrix apart from other controlled release dosage forms is crucial to describe it. The following are the characters:

- The physical state of drug.
- The chemical nature of support.
- The route of administration
- The matrix shape and alteration in volume as a function of time.
- The release kinetic model. Advantages of Matrix system
- Easy to manufacture.

Classification of Matrix Tablet



A) Lipid matrix system

These matrices were created using lipid waxes and associated substances. In this technique, the medicine is released from an intact hydrophobic matrix that contains the active ingredient. Release is dependent on the channelling agent, which leaches out of the compact and dissolves in an aqueous media, creating a porous matrix of tortuous capillaries. Through the water-filled capillaries, the active substance diffuses out of the matrix after dissolving in the aqueous media.

B) Insoluble polymer matrix systems

The medicine in this approach is enclosed in an inert polymer that is not soluble in digestive juices. Drug molecules in aqueous solution diffuse through a network of capillaries generated between compressed polymer particles to determine the release rate. Changes in the porosity and tortuosity of the matrix can alter the pace at which a medication releases from it. The hydrophilic salts or solutes that form pores will significantly affect how quickly drugs are released.

C) Hydrophilic Matrices

The term "swellable-soluble matrices" is another name for these delivery techniques. The systems have the ability to expand, then form gel, erode, and dissolve in aqueous conditions. When in contact with water, the hydrophilic colloid components expand to produce a hydrated matrix layer. This regulates the water's subsequent diffusion into the matrix. The rate of release of the medicine is regulated by diffusion through the hydrated matrix layer. As it becomes more diluted, the outer hydrated matrix Layer will erode. The type of colloid affects how quickly erosion occurs.

D) Biodegradable Matrices

These systems have unstable linkage in the backbone and are made up of monomers connected to one another by functional groups. By enzymes produced by nearby live cells or by non-enzymatic processes, they are biologically eroded or decomposed into oligomers and monomers that can be metabolised or expelled.

E) Mineral Matrices

These are made up of polymers that come from different kinds of seaweed. An illustration would be alginic acid, a hydrophilic carbohydrate extracted using diluted alkali from several brown seaweed species (Phaeophyceae).

Polymers used in matrix tablets

Depending on the physicochemical characteristics of the drug component to be included into the matrix system and the needed drug release profile, several polymers may be utilised to make matrix tablets. The following types of polymers can be used to make matrix tablets:

1) Hydrogels:

(a) Poly-hydroxyethyl methacrylate (PHEMA).
(b) Cross-linked polyvinyl alcohol (PVA).
(c) Cross-linked polyvinylpyrrolidone (PVP).
(d) Polyethylene oxide (PEO).
(e) Polyacrylamide (PA).

2) Soluble polymers:

(a) Polyethylene glycol (PEG).
(b) Polyvinyl alcohol (PVA).
(c) Polyvinylpyrrolidone (PVP).
(d) Hydroxypropyl methylcellulose (HPMC).

3) Biodegradable polymers:

(a) Polylactic acid (PLA).
(b) Polyglycolic acid (PGA).
(c) Polycaprolactone (PCL).
(d) Polyanhydrides.
(e) Polyorthoesters.

4) Non-biodegradable polymers:

(a) Polyethylene vinyl acetate (PVA).
(b) Polydimethylsiloxane (PDS).
(c) Polyether urethane (PEU).

II. LITERATURE AND REVIEW :

- **Syed Nisar Hussain Shah et al. (2009)**

have created oral sustained release matrix tablets of the water-insoluble medication flurbiprofen utilising natural gums as the matrix polymers, and have used response surface methods to assess drug release characteristics. Method: The direct compression technique was used to create matrix tablets. The independent variables used were xanthan and acacia gums. Studies using the Fourier transform infrared spectrometer were also carried out to investigate interactions between polymers and drugs as well as the stability of the medication under direct compression. Both polymers were discovered to significantly affect the release of the medication.

- **D.K.Gupta et al. (2012)**

by employing several natural matrix forming gums, such as Xanthan gum and locust bean gum (as a release modifier), separately, have created control release matrix tablets of Aceclofenac. Different concentrations of Xanthan gum, Olibanum gum, and locust bean gum were used to make six batches. Wet direct compression was used to make the tablets. Dependent on the amount of gums in the pills, the drug was released. Drug release was lowered as the percentage of gum rose. Aceclofenac, a non-steroidal anti-inflammatory drug with a biological half-life of four hours, is used to treat the symptoms of rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis.Studies on the stability, in vitro drug release, and physicochemical properties of the tablets were conducted.

- **K. P. R. Chowdary et al. (2006)**

The effectiveness of olibanum as a matrix material for regulating the pace of diclofenac's controlled release in tablets was examined. Olibanum and its resin and carbohydrate fractions were used to manufacture diclofenac matrix tablets, which were then tested for several tablet characteristics, such as drug release kinetics and mechanism. Even at very low quantities, 1 and 2% w/w in the formula, olibanum and its resin component displayed excellent delaying effects on drug release from the matrix tablets. Olibanum and its resin component were used in the formulation of the diclofenac matrix tablets, which allowed for the delayed and controlled release of diclofenac for more than 24 hours.

- **Bharat W Tekade et al. (2017)**

intestinal medication delivery method created using natural boswellia serrata gum. Gum's physicochemical characteristics, such as its micrometric characteristics, pH, and viscosity, were investigated. Using Diclofenac sodium as a model medication, the matrix tablets were made using the direct compression technique. Various drug and polymer concentrations were employed to select the right concentration of gum to be combined with the drug for colonic drug administration.

- **Md. Bala Pasha et al. (2017)**

tested natural gums such as gum olibanum, gum tiruman, and gum karaya as indomethacin sustained release carriers. The different types of natural gums were compared. These three all-natural gums have not previously been studied. The Eastern Ghats woodlands are abounding with the three gums.

- **Srivastava Pranati et al. (2010)**

developed prolonged release matrix tablets employing pectin and tamarind gum as release modifiers in an effort to improve patient compliance, decrease dosage frequency, and maximise therapeutic effectiveness.

NEED AND OBJECTIVES :

NEED OF STUDY

In the modern period, pain and inflammation continue to be important issues. An important aspect of autoimmune illness is inflammation. As the immune system responds to injury, infection, environmental factors, cancer, and cellular changes, inflammation develops. Inflammation, which shows as redness, heat, discomfort, swelling, and loss of function, is the outcome of any attack on living tissue, whether it is caused by physical, chemical, or microbiological origin. The maintenance of an effective drug concentration level in the body, for which a constant and uniform supply of drug is sought, is essential to the treatment of inflammation. This goal is accomplished by sustained release dosage forms, which release the medicine slowly over a lengthy period of time. The oral route of drug administration for continuous release systems has, by far, drawn the most attention due to its complexity, practicality, and safety. The easiest method for creating a sustained release system is to use matrix tablets that include both the medicine and a release delaying substance. The oral route of drug administration for continuous release systems has, by far, drawn the most attention due to its complexity, practicality, and safety. The easiest method for creating a sustained release system is to use matrix tablets that include both the medicine and a release delaying substance. A safe and effective anti-inflammatory matrix tablet containing aceclofenac and boswellia serrata was thus developed and evaluated in this work utilising a combination of hydrophobic and hydrophilic polymers. Aceclofenac is a non-steroidal anti-inflammatory (NSAID) medication that is frequently used to treat osteoarthritis, ankylosing spondylitis, and rheumatoid arthritis. Aceclofenac is a more recent derivative of diclofenac and is a prime option for modified release multiple unit production due to its reduced GIT complications, short biological half-life of 4 hours, and frequent dosing. Aceclofenac is suitable for making sustain release dosage, which can lower the frequency of administrations and increase patient compliance. Guggul is the oleo gum resin of the native Indian plant Commiphora mukul, and its extracts contain substances such the Zand E- isomers of guggulsterone and its associated guggulsterols that are renowned for its hypolipidemic effects. Inactive medicinal components such binding agents and rate-retarding polymers have been employed in guggulresin-based products. The treatment of mental disorders, leprosy, muscle spasms, ophthalmic, skin, ulcerative pharyngitis, hypertension, ischaemia, and urinary disorders are among the therapeutic uses of guggul. Aceclofenac is a member of the BCS system's class II of medications, and when taken orally, it can cause significant stomach irritation as well as other adverse effects like nausea and vomiting. Therefore, matrix tablets were created as a solution to this issue. Drug addition to natural polymers can address the solubility issue.

III. OBJECTIVES:

- To research the aceclofenac preformulation factors, such as melting point and drug calibration curve at pH 7.4 in phosphate buffer.
- In order to research the drug excipients compatibility study
- To investigate the pre-compression factors for a powder blend
- HMPC K 200m and Guggul gum, two natural and synthetic polymers, were used to create the sustained release matrix tablets of aceclofenac.
- To analyse various postcompression characteristics in order to assess the manufactured Sustained release matrix tablet.
- The usage of various natural polymers at various concentrations to achieve the sustained release target profile of a drug and its impact on drug release are being studied and investigated.

DRUG, POLYMER AND EXCIPIENT PROFILE

ACECLOFENAC:

Aceclofenac is a site-specific NSAID for inflammation, and inflammation significantly boosts its activity. As a result, it is quite effective at reducing inflammation while still being well tolerated by the rest of the body.

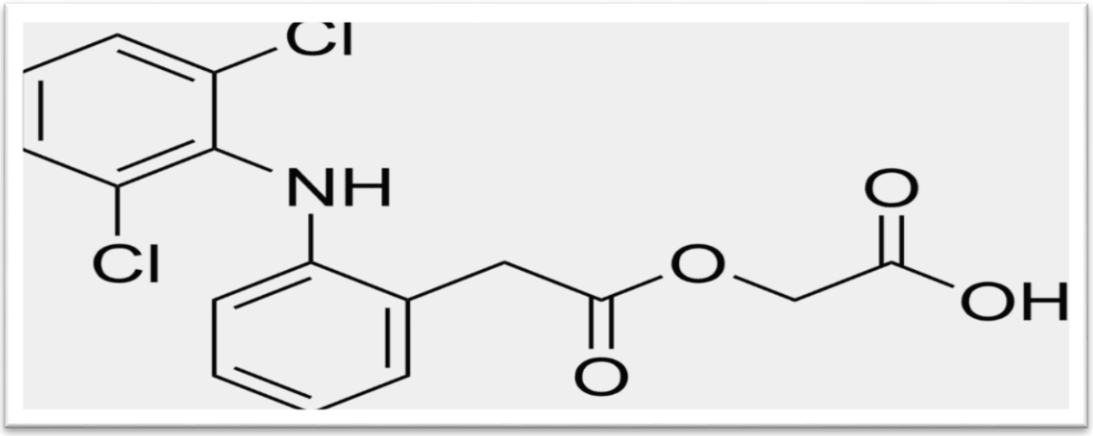
1. Appearance: White or almost white crystalline powder

2. Dose : Maximum recommended dose is 200 mg, taken as two separate 100 mg doses, one tablet in the morning and one in the evening.

3. Solubility : Practically insoluble in water freely soluble in acetone. Soluble in alcohol, methanol.

4. CAS Registry Number: 89796-99-6

5. Molecular Weight: 354.190002441
6. Molecular Formula : C16H13Cl2NO4
7. BCS Class - II
8. Structural formula of Aceclofenac



Structure of Aceclofenac

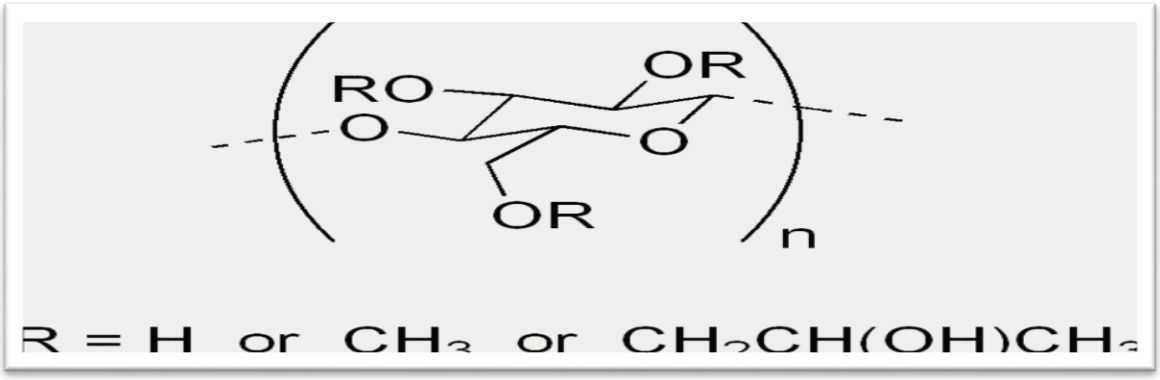
9. IUPAC Name: - 2-[(2, 6-Dichlorophenyl) amino] phenyl] acetyl] oxy] acetic acid.
10. Route - Oral Tablet
11. Half life - 4 - 4.3 hrs
12. Mechanism of Action
An innovative NSAID with many mechanisms of action is aceclofenac. By preventing IL-beta and TNF in the inflammatory cells, aceclofenac directly inhibits PGE2 release at the site of inflammation. The human articular cartilage's extracellular matrix is stimulated by aceclofenac. Aceclofenac prevents Neutrophil adhesion and accumulation at the inflammatory site in the first stages, which stops Neutrophils from acting in a pro-inflammatory manner. As an NSAID, Aceclofenac is also more selective for CoX-2 than Diclofenac sodium.
13. Absorption: After oral treatment, aceclofenac is quickly absorbed and has a bioavailability of about 100%; the peak plasma concentration occurs 1.25 to 3 hours after intake. While the degree of absorption is unaffected by concurrent food consumption, tax is delayed.
14. Distribution: Aceclofenac penetrates into the synovial fluid, where its concentration reaches about 60% of that in plasma, and is strongly protein bound (99.7%). 30 Lit or so is the distribution's volume.
15. Metabolism: The enzyme CYP2C9 transforms aceclofenac into its main metabolite, 4-OH aceclofenac. Other metabolites found include 4-OH diclofenac and diclofenac, as well as diclofenac.
16. Elimination: Plasma half-life elimination takes on average 4–4.3 hours. Urine is used to eliminate drugs in 2/3 of cases. The predicted clearance rate is 5 litres per hour. A single oral dose is excreted unaltered in only 1% of cases.
POLYMER PROFILE:
GUGGUL GUM
Guggul is the gum resin made from Boswellia serata and Commiphora, two distinct plants.
Synonyms : Guggul, Guggulu, Guggal; Guggala, Gulgulu, Guggalu, Maishakshi, Gukkal; Guggal
Family : Burseraceae
Biological source : Guggul gum obtained by stem of plant *commiphra mukul.and commiphra weightali.*
Isolation of Guggul gum
Oleo-gum resin was first extracted with alcohol after being cleaned with water to remove contaminants from the coarsely powdered form. The precipitated gum was filtered through a cotton cloth before being fully dried in an oven at 45 degrees Celsius. A 80# sieve was used to filter the gum powder, and the percentage yield was calculated.

Properteis :
- The dried gum-resin has a bitter aromatic taste and balsamic odour
- The colour of guggul varies from transparent golden brown to dark brown.
- It is soluble in most organic solvents.
- It burns readily and diffuses an pleasant odour.

Uses : Guggul is currently used to treat a variety of medical conditions, including hemiplegia, leprosy, musclespasms, neuralgia, ophthalmia, pyelitis, pyorrhea, scrofula, skin conditions, spongy gums, ulcerative pharyngitis, hypertension, ischemia, and hypertension. Inula racemosa, an Ayurvedic herb, is used with C. mukul

to lessen angina-related dyspnea and chest pain. Guggul is beneficial against some elements of cardiovascular disease, according to research investigations. Gugulipid has been demonstrated to be an effective and affordable treatment for hyperlipoproteinemia, while Guggul has been shown to decrease the stickiness of platelets.

HYDROXY PROPYL METHYL CELLULOSE:
Non-proprietary names:
BP: Hypromellose
JP: Hydroxypropylmethylcellulose
USP: Hypromellose
Synonym: Benecel MHPC,E464,hydroxypropyl methylcellulose; HPMC; Methocel; methylcellulose propylene glycol ether; methyl hydroxypropylcellulose
Chemical name and CAS registry number: Cellulose hydroxypropyl methyl ether [9004-65-3]
Structural formula:



Hydroxy Propyl Methyl Cellulose

Functional category:

Coating agent, film-former, sustained-release rate-controlling polymer, stabilising agent, suspending agent, tablet binder, and viscosity-increasing agent. Applications in Pharmaceutical Technology or Formulation Pharmaceutical formulations for topical, ocular, and oral usage frequently contain hypromellose. Hypromellose is predominantly utilised in oral goods as a matrix for usage in extended-release tablet formulations, a film coating, and a tablet binder. In either wet- or dry-granulation processes, a binder may be utilised at concentrations of 2% to 5% w/w. In tablets and capsules, high-viscosity grades may be employed to delay the release of medicines from a matrix at values of 10–80% weight/weight (w/w)28–39. For film-forming solutions to film-coat tablets, concentrations of 2-20% w/w are employed, depending on the viscosity grade. Higher-viscosity grades are utilised with organic solvents, while lower-viscosity grades are employed in aqueous film-coating solutions. Commercially available examples of film-coating materials include Spectracel and Pharmacoat are two examples of commercially available film-coating materials. Hypromellose AcryCoat C is also utilised in topical formulations as a thickening and suspending agent. Hypromellose is favoured in formulations for ocular use because it creates aqueous solutions that are clearer and contain fewer undispersed fibres than methylcellulose does. Hypromellose can be used as a thickening agent in eye drop and artificial tear solutions at concentrations of 0.45 to 1.0% w/w. Hypromellose is also employed in topical gels and ointments as an emulsifier, a suspending agent, and a stabilising agent. It can prevent droplets and particles from congregating or agglomerating as a protective colloid, preventing the development of sediments.

Description :
HPMC is a fibrous or granular, white or creamy-white, flavourless powder.
Melting point :
Browns at 190–200°C; chars at 225–230°C. Glass transition temperature is 170 – 180°C.
Solubility :
Practically insoluble in chloroform, ethanol (95%) and ether, but soluble in mixtures of ethanol and dichloromethane, methanol and dichloromethane, and combinations of water and alcohol. Soluble in cold water, forming a thick colloidal solution.

EVALUATION OF PREPARED BATCHES OF ACECLOFENAC MATRIX TABLET:

A. Thickness : Twenty tablets were chosen at random from the representative sample, and each tablet's thickness was measured using a digital vernier calliper. Values for the average thickness and standard deviation were computed.

B. Hardness : Monsanto's hardness tester was used to gauge the hardness of tablets. Six pills from each batch were tested for hardness, and the average of the six results was recorded along with standard deviations.

C. Friability : Test Ten pills were carefully weighted from each batch and placed in the Roche friabilator to test for friability. Tablets were watched as they rotated while the apparatus was run at 25 rpm for 4 minutes. After 100 rotations, the tablets were removed, dusted, and reweighed. The percentage weight loss was used to calculate the friability.

% friability was calculated as follows.

% Friability = (W1 – W2) x 100/W1

Where, W1 = Initial weight of the 20 tablets.

W2 = Final weight of the 20 tablets after testing. Friability values below 0.8% are generally acceptable.

D. Drug Content (Assay)

When the amount of the active ingredient in each of the 10 tested tablets falls between 90% and 110% of the standard level, the drug content of the matrix tablets is considered to be within acceptable limits. This was evaluated using internal standards. Ten pills were measured, placed in a mortar, and ground into an extremely fine powder.

SUMMERY AND CONCLUSION :

The project's objectives are formulation optimisation and evaluation of the Aceclofenac Matrix tablet. In accordance with their ratios, the drug, guggul gum, and HPMC K 200 might be used to create aceclofenac matrix tablets. It can be noticed that the drug release rate from the tablets was found to be increased by increasing the concentration of Guggul gum and decreasing the content of HPMC K 200M in the formulation. The medication and polymer ratio in formulation F3 provides the best release. GuggulGum, HPMC, K200, PVPK30, Talc, magnesium stearate, lactose (1:0.3:0.15:0.2:0.5:0.7:1.23) are some examples of the drug. Results from F3 were satisfactory. However, it was shown that the drug release rate was decreased as HPMC K200 concentration increased and guggul gum concentration decreased. The formulation F3 was chosen as the optimised formulation out of the formulations F1, F2, F3, F4, F5, F6, F7, F8, and F9 because it demonstrated the greatest release, or 100.89% drug release in 8 hours. It has also been determined that there is no incompatibility between polymers and the pure drug due to the compatibility of Aceclofenac with polymers HPMC K100M and Guggul gum. IR investigations have shown that all of the aforementioned characteristic peaks of Aceclofenac were seen close to their respective values. The initial assessment of Aceclofenac-like melting points was made using the capillary tube method, and their calibration curve was taken using a UV spectrophotometer at 275 nm in phosphate buffer with a pH of 7.4. Pre-formulation or physical studies of tablets have been conducted, including measurements of their hardness, friability, thickness, weight fluctuation, surface pH, uniformity of the drug content, and invitro residence time. Using a Monsanto hardness tester, the hardness of all factorial and trail-designed batches was determined, and it was found to be between 5.0 and 6.0 kg/cm2 and 7.0 to 8.0 kg/cm2, respectively. The hardness result demonstrates that tablets become harder as polymer content rises. Because synthetic polymers have better binding properties than natural polymers, their hardness is greater than that of natural polymer batches. The hardness of tablets has an impact on how easily they can break, and research demonstrates that harder pills break less easily and have fewer chances of being used illegally. The percentage of friability was good, falling between 0.4 and 0.7%, while the typical range is less than 1%. The results showed that the pills were compact and had good mechanical strength. Natural polymers' batches have a thickness that ranges from 4.42 to 4.72 mm, which is better than synthetic polymers' batches because natural polymers have high compressible properties that allow for the desired thickness of the tablets and lower thicknesses that are more comfortable for the oral cavity. All trial and factorial planned formulation batches' weight variations ranged from 3001.46 to 3002.67, respectively. The acquired results show that all of the pills, regardless of their various formulations, complied with IP requirements. The amount of medicine in the tablet must be tracked from tablet to tablet and batch to batch in order to assess the tablet's potential for efficacy. The average drug concentration was discovered to be between 97.11 and 101.65%. All trial and factorial developed formulations' in-vitro medication dissolution was investigated in phosphate buffer pH 7.4. Drug release percentages were observed to range between 91.89 and 95.62% and 99.42 and 100.89%, respectively. The stability research was carried out in accordance with ICH recommendations. The tablet exhibits extremely minor or insignificant alterations in its outward appearance, such as Hardness. After a month, it was discovered that the percentage drug release of tablets stored under two distinct stability settings was 99.21% and 98.43%, respectively. The outcomes are all within the pharmacopoeial range. It succeeds in every test.

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