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Active Pharmaceutical Ingredient and Impurity Profiling Nimesulide

J. P. Lavande, S. K. Bais, Vaishnavi Kharat
Fabtech College of Pharmacy, Sangola, Solapur, Maharashtra, India
vaishnavikharat077@gmail.com

Abstract: *The first nimesulide was launched in Italy for the first time as Aulin and Mesulid in 1985,it is the most frequently prescribed drug for pain and fever. It is listed as one of the Essential Medicines. Nimesulide is available throughout the world as original product. The first marketing authorization for nimesulide was approved by Italy in 1985.After one quarter of a century we evaluated its peculiar characteristics compared to other NSAIDs. Nimesulide is the only NSAID realted with arylsulfonamide class and is a COX- 2 preferential NSAIDs, because despite having prevalent effect on COX-2,has a balanced action on both cyclooxygenase. The gastrointestinal absorption is rapid and complete and explain the shorts onset of action. Nimesulide is rapidly distributed in the synovial fluid, where it persists longer than in the blood, thus contributing to efectivness of the drug in pain control. From the standpoint of safety, nimesulide arises NSAIDs with lower risk of upper gastrointestinal bleeding thanks to its preferential activity on COX-2.In relation to the risk of severe hepatic reactions, the benefit profile of nimesulide was considered by European regulatory authorities similar to other NSAIDs. Respecting international guidelines, the use of nimesulide in pain management, as that of other NSAIDs, must be considered as that of other NSAIDs alternative therapy when paracetamol is ineffective or where the pain is caused or supported by inflammatory process.*

Objective:
1. To telll, an antipyretic anti inflammatory drug.
2. Describing nimesulide.
3. To use chromatography to evaluate the impurity profile

Keywords: Mimesulide

I. INTRODUCTION

Module 1:

Laboratory safety:

Every time a worker is in a laboratory, basic safety regulations for behaviour should be followed. Below is a collection of many of the most prevalent safety guidelines.

- You are personally responsible for your safety.
- Consistently adhere to the right methods.

Never cut corners.

- If you created a mess, accept responsibility and clean it up.
- Keep your workspace tidy and organised
- Ensure that access to emergency exits and equipment is unobstructed and simple.
- While working, stay awake and alert.
- Be aware of the locations of eyewash stations, fire extinguishers, and lab safety showers.
- Be familiar with emergency exits.
- Prevent all chemical contact with the skin andyucrea
- Limit your exposure to all chemicals.
- Horseplay will not be permitted.

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- Assume that all compounds are very dangerous even if their toxicity is upermitte
- Be sure to protect your eyes.
- Use Fire Safety Procedures
- Do safely handle glassware.
- Retain notes.
- Be Sure to Glow Safely.
- Don closed-toed footwear.
- Don't forget to use electrical Safety

Introduction to hazardous Chemicals and MSD

In Australian workplaces, chemical risks are a significant issue for occupational health and Safety. A variety of specialists must work together to manage chemical dangers. The need of collaborating with OHS experts to guarantee the use of a variety of talents is emphasise they are
frequently connected to Major Hazard Facilities (MHF), chemical dangers are under the purview of all OHS practitioners. The management of bulk chemical or explosive transport, storage, and handling is typically outside the purview of the generalist OHS professional.in Australian workplaces, chemical risks are a significant issue for occupational health and safety. A variety of specialists must work together to manage chemical dangers. The need of collaborating with OHS experts to guarantee the use of a variety of talents is emphasised. Although they are frequently connected to Major Hazard Facilities (MHF), chemical dangers are under the purview of all OHS practitioners. The management of bulk chemical or explosive transport, storage, and handling is typically outside the purview of the generalist OHS professional.

Definition

Any element, chemical compound, or combination of elements and/or compounds is referred to as a chemical. The operational definition of hazardous substances is "substances that, upon worker exposure, may have a negative impact on health" (Safe Work Australia, 2010b). the word Emergency response organisations use the term "hazardous material" to describe substances that require special handling.

MSDS

A material safety data sheet is a technical document that offers thorough information about a controlled product, including information on the product's potential health consequences. Review of the risks associated with the handling, storage, or usage of the product. Protective measures for exposed workers. Emergency action
Introduction to Handling of chemical and safety requirements:
Chemicals kept in lab vials ought to be labelled with the day, month, and year they were initially received and opened. Only the substances that will be actively used should be stored, at the most. For work with particular chemical dangers, adhere to the following chemical storage recommendations. The programme seeks to give laboratory personnel the instruction, knowledge, and assistance
they need to perform their jobs safely at home and in the lab. Large bottles of acids should be kept on low shelves, on trays, or in cabinets designated "corrosives" or "acids." Separate organic acids, flammable, and combustible compounds from oxidising acids. To move acid bottles, use a trolley or
bottle carriers. Keep a list of all the substances you have on hand at work. Identify safe chemical usage, such as handling guidelines, protective gear requirements, mixing guidelines, and washing guidelines in the event of spills or skin contact. Eat, drink, and smoke should not be done near Chemicals. There are many different physical and health concerns associated with toxic chemicals and substances. Keep a list of all the substances that are kept on hand at work. Request safety data sheets from your chemical supplier and keep them on hand for reference. Eat, drink, and smoke should not be done near chemicals

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Safety Requirements

- Helmets
- Goggles
- Glovees
- Masks
- Safety goggles
- Guards.
- Shields
- A lab coat
- First-aid supply Extinguishers for fire
- A chemical hood

II. LABORATORY TECHNIQUES

Glass, the material used to construct laboratory equipment, is resistant to the majority of chemicals. Typically, two types of glass are utilised to create laboratory equipment. These are both very combustible types of glass: soda-lime glass and borosilicate glass. Soda-lime glass should be heated and cooled gently because abrupt heating and chilling might cause it to shatter. Heating soda, limestone, and silica at a temperature of 300–400 °C produces soda- lime. Breakage is avoided by annealing followed by consistent cooling and a gentle reheat. Borosilicate glass requires an oxygen natural gas flame to work because it does not soften below 700–800°C. The natural gas flame is produced by burning natural gas combined with oxygen. This glass has a low coefficient of expansion, making equipment manufactured with it resistant to abrupt temperature fluctuations

General Techniques:

The book performs a fair job of covering an A to Z of laboratory procedures despite its 1964 copyright. The majority of the more modern methods mentioned are probably irrelevant to the work of the typical high school teacher (e.g., HPLC, TLC, mass spectrometry, etc.). The chapters on the application and maintenance of analytical balances and volume. Glassware are excellently written. It also contains details on calibration procedures and National Bureau of Standards tolerances. Although not all of the topics will be covered by the normal High school
instructor, they are all well written and easy to understand. This publication is "intended for analytical chemists, laboratory technicians, beginners, and students," according to the author. The book's age subtracts from any potential advantages. A glaring omission in the distillation portion is the absence of glassware with conventional taper-r grindings.

Chromatography

In both synthetic and biological chemistry, molecules are created by a series of reactions involving intermediates. Although the molecules (benzene, phenol, and aniline) are similar to one another, they have different physical and chemical characteristics that can be utilised to distinguish them from one another.

Physical Properties:-

1. Molecular weight
2. Boiling point (in case both are liquid, as in this case)
3. Freezing point
4. Crystallization
5. Solubility
6. Density

Chemical Properties

1. Functional Group, for example, phenol has –OH where as aniline has NH2
2. Reactivity towards other reagent to form complex.

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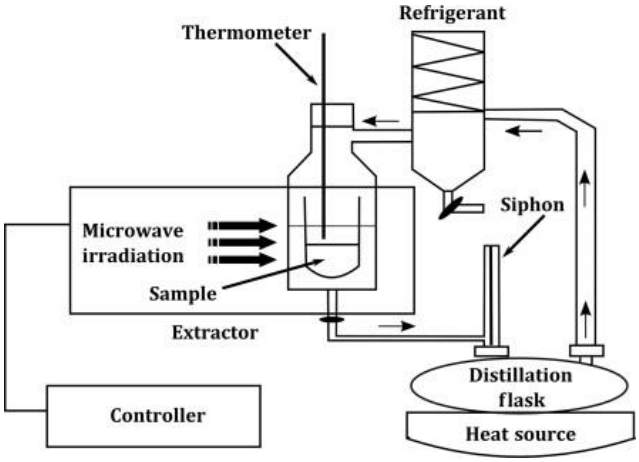
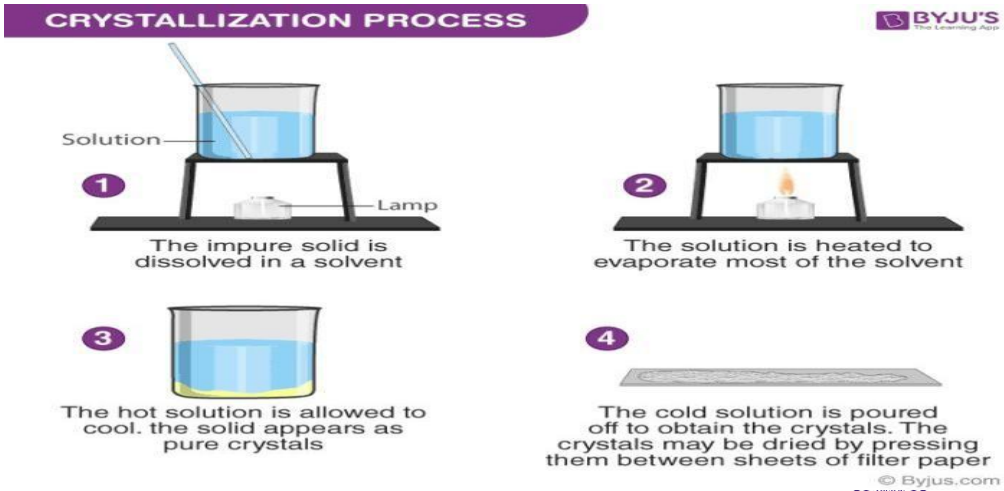
Extraction Technique:

- Extraction, as the term is used pharmaceutically, involves the separation of medicinally. Active portions of plant or animal tissue from the inactive or inert components. Products so obtained
- from plants are relatively. Impure liquids, semisolids or powders intended only for oral or external use.
- One or more components in the mixture are not thermally stable.
- The components in the mixture have a very high or low boiling point requiring vacuum or Cryogenic distillation, which is very energy intensive.
- The boiling points of the components are very close or they form azeotropes
- Two Components with very different boiling points have to be separated at the same time.
- The components to be separated (pollutants or valuable products) are only a small fraction Of the mixture.



Crystallization:

A common separation technique used in the chemical and pharmaceutical industries is crystallisation. Many crystallization-related phenomena are still not fully understood. Research on crystallisation is becoming increasingly popular as consumers demand products with consistent quality (purity, crystal size, etc.). The process of creating a crystalline substance from a liquid, gas, or amorphous substance is known as crystallisation. The crystal lattice serves as the foundation for the very regular interior structure of crystals. In the process industry, crystallisation is crucial since it produces a solid product while also purifying it. The most promising crystals are translucent, have sharp edges, and are ideally between 0.1 and 0.4mm i Size. Techniques used to grow crystals include solvent evaporation. Vapour diffusion, sublimation, solvent/non-solvent diffusion, and gradual cooling of the solution. As long as the sample is almost insoluble in the ether, the solvent combination CH2Cl2/EtOH is an excellent choice. At the boundary where the solvents slowly diffuse into one another, crystals developsize



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Distillation:

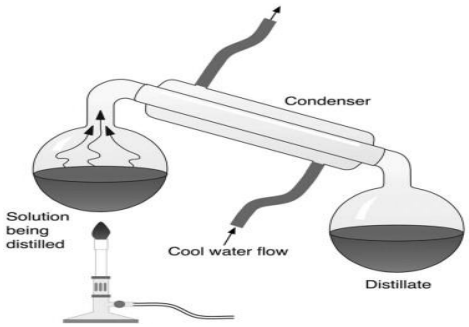
Distillation is the process of selective evaporation and condensation used to separate a component or components from a liquid mixtur.The most fundamental technique for separating liquid mixtures and purifying liquids is distillation. Distillation entails heating a liquid to boiling, gathering the vapours, and condensing them back into the liquid state .Through this,

The separation of the mixture's liquids, which have boiling points that differ by a few degrees Liquid separation from non-volatile components,

Cleaning up the liquid Acted upon A method of separating components from a liquid mixture is distillation. Processes are dependent on the liquid mixes' vapour pressure properties. Packed coluumn have led to increased use in distillation, especially for low-volatility products such as paint and varnish.

Overview of distillation:-

A physical separation process called distillation uses the vaporisation of various constituents. It is employed in the refinery sector to convert crude oil into petroleum distillates. Since at least a few thousand years ago, alcohol has been concentrated through distillation, albeit in its most basic form Vapors are created as the liquid heats up and rise to the distilling head, where a thermometer is frequently positioned. The liquid drips to the receiving flask, where the distillate is collected by the action of graviity



Simple Distillation:

- A technique for separating mixes in a boiling liquid combination based on differences in their volatilities.
- Under normal pressure, it is possible to distil compounds with simple structures that are easily flammable and resistant to their own boiling heat. This method can be used to purify substances including hydrocarbons, alcohols, esters, small-molecule fatty acids, and amines.
- Liquids with various boiling points can be successfully separated using straightforward distillation. The component of the combination that boils at the lowest temperature will be the component with the richest vapours as the liquid being distilled is heated. Until every component of the initial mixture has been separated, the procedure can be repeated. The After applying heat to a sample mixture, the components are instantly cooled by the action of cold water in a condenser.
- Instead of distilling the liquid combination as shown in the above picture, simple distillation entails heating it to the boiling point and then condensing it.
- Fractional distillation:-
- By heating chemical mixtures to a temperature where one or more fractions of the mixture evaporate, chemical compounds are separated. Distillation is used to fractionate.
- Typically, the boiling temperatures of the constituent parts differ by no more than 25 °C (45 °F) from one another.
- Fractional distillation can be used to clean up combinations of liquids whose boiling points are relatively near to one another. The difference between the mixture's boiling points is often less than 80 °C, for example, acetone (b.p. 56 °C) and methyl alcohol (b.p. 65 °C).

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Raoult's Rule

The vapour pressure of a solvent above a solution is equal to the vapour pressure of the pure solvent at the same temperature scaled by the mole fraction of the solvent present, according to Raoult's law:

Psolution=χsolvent PoSolvent

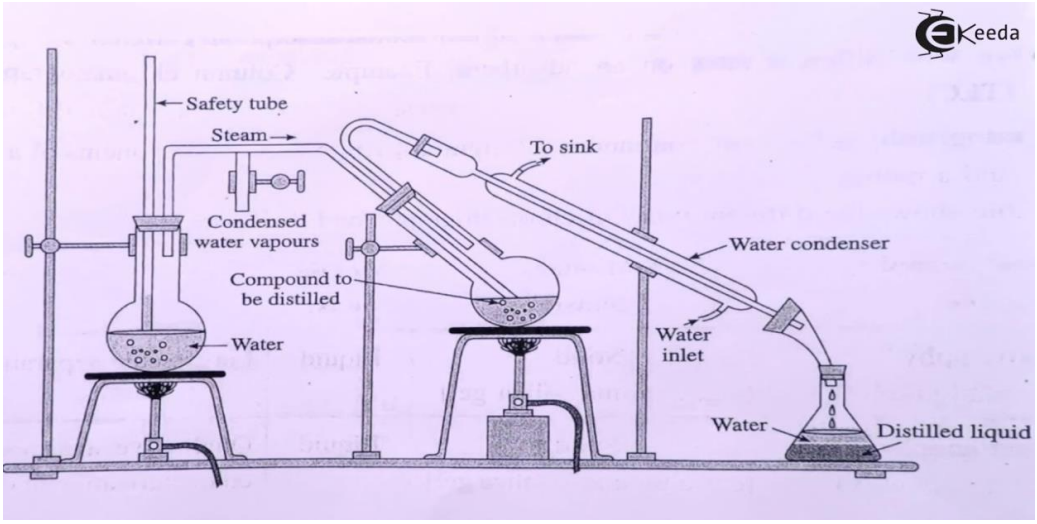
P = atmospheric Pressure X= number of moles

Vacuum Distillation

Vacuum distillation is the process of distilling under low pressure, which enables the purification of chemicals that are difficult to distil at ambient pressures or is done merely to save time and energy. Using this method, substances are separated based on the differences in their boiling points.Low pressure distillation or vacuum distillation. Organic substances that decompose at or below their boiling points are employed for it. Consider glycerol. The temperature at which the total vapour pressure equals the atmospheric pressure is known as a liquid's boiling point. This implies that the boiling point of the liquid can be decreased by lowering the pressure.We can get an organic substance to boil at a lower temperature if it breaks down at its boiling point. The substance boils at a considerably lower temperature and distils over undecomposed under reduced pressure. This is the purification procedure used to remove contaminants from non-volatile solid materials such as resin, stain, and others. Consider glycerol.

Stem Distillation

A separation technique called steam distillation involves distilling water along with other volatile and non-volatile ingredients. The separation technique of steam distillation is used to extract or purify components that are sensitive to temperature, such as natural aromatic compounds. A separation technique called steam distillation is employed to extract or purify components that are sensitive to temperature, such as natural aromatic compounds. The distillation apparatus is given steam or water to lower the compounds' boiling points. These substances ought to be water insoluble. The purification of organic molecules can benefit from steam distillation. The vapour from the distillation of organics is then condensed into a liquid. Due to the immiscibility of water and organics, the resultant liquid often consists of two phases: water and the organic substance. Organic distillate



Rotary Evaporation

A rotary evaporator, commonly known as a "rotovap" or "rotovap," is a tool used in labs to gently and effectively evaporate solvents from samples. An illustration of a conventional rotary evaporator may be seen on the right. Rotating an evaporator under steady heating and particular pressures can create a thin film (vacuum or atmospheric). Effective evaporation results in the vapours being separated, collected, and condensed. Application: Concentration vapour extraction Crystallization in particular materials that are temperature-sensitiveThe most efficient and significant tool in the biological, biochemical, pharmaceutical, chemical, food, and fragrance industries for research and development,

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educational purposes, and pilot testing is the rotary evaporator.

- Other Techniques:
- Boiling point:

The temperature at which a liquid's saturated vapour pressure equals the air pressure outside is known as the boiling point. When liquids are heated at constant pressure, like at atmospheric pressure, their vapour pressure, r, rises according to the amount of heat applied. The temperature at which a liquid's vapour pressure equals the pressure of the surrounding atmosphere is known as the boiling point of the liquid.

Melting point:-

The temperature at which a substance transforms from a solid to a liquid is known as its melting point. The solid and liquid phases are in equilibrium at the melting point. Pressure affects a substance's melting point, which is typically reported at a standard pressure such 1 atmosphere or 100 kPa.

Wikipedia. The temperature at which a solid transforms from a solid to a liquid under atmospheric pressure is known as the melting point. Both the solid and liquid states coexist at the melting point because these two phases, solid and liquid, are in equilibrium.

Sublimation:-

When heated, a solid transforms immediately into a gas without first becoming liquid. Used to separate non-volatile contaminants such naphthalene, benzoic acid, anthracite, and camphor from volatile organic molecules. If the impurities present do not sublime, this process can be used to purify substances that do. When heated, many organic substances that are solids initially turn into vapour without ever becoming liquids. When the vapour is cooled, a solid is produced immediately. Sublimation is a method for separating a combination of two substances.Solid plus heat equals gas or vapour (Heat=ΔHsub)

Chemical Test

The following characteristics are not generally included in chemical tests: PH, hardness, presence of a selected group of chemical metres, biocides, and highly poisonous symbols.The degree at which a liquid reaches its boiling point and becomes a gas.The pH is a unit of measurement and a gauge of the relative acidity or alkalinity of water. The answer is indicated by a PH 07 value. Alkalinity is indicated by neutron values of 2-1 and higher, while acidity is indicated by neutron values of 6-9. & lower.

Reaction Workup

The reaction work-up, which happens right away after the reaction is finished, is an important stage in this sequence.The work-up refers to a material purification procedure that typically takes place in a separatory funnel.Adding solutions to the funnel. Either to extract or combine with. In order to separate the finished product from excess reagent, catalysts, side products, solvers, or chemicals derived from side reactions.

III. API TECHNOLOGY

With customers ranging from big pharma to virtual companies, we have a long history of providing reliable service. Our manufacturing and development service. Routinely support for APIs.

Drugs that require advanced. My highly effective chemicals are created using knowledge in synthesis, which calls for specialised infrastructure and handling capabilities.

Industrial process and scale up technique industrial manufacturing method and flow of charts:

The state of the pharmaceutical industry, including information on formulations, natural products, and bulk drugs India's position in relation to developed countries

- Scale-up techniques, including techniques for process control, productivity maximisation, and process optimization
- Case studies focusing on the logic behind the selection of routes, raw materials, process control techniques, pollution control procedures, etc. for selected drugs' chemical technologies

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- Data collection during pilot plant trials, preparation of flow diagrams, material balance sheets, and technical data sheets are all aspects of the chemical technology of some drugs.
- Process technologies for a few natural products of interest to businesses. For instance, 4-hydroxyisoleucine
- Scale-up strategies for industrial pharmacy, typical SOPs for various dosage forms, and in- process control techniques
- manufacturing equipment: Tools used in the production of large-scale drugs.
- Formulation-related equipment used in pharmaceutical manufacturing.

3.1 Method and Materials

As it melts Open capillary tubes were used to determine the points of the organic compounds, and they were not adjusted. TLC, or thin layer chromatography, was used. On the manually made silica Gel G-coated glass slides (Rankem). DRS 8000 Spectrometer was used to record IR spectra in the IR Affinity-1 FTIR Shimadzu. Using Tetramethylsilane as the internal standard, 1H NMR spectra were captured at 400 MHz using a Bruker Avance 400 spectrometer. The variation in thermal enthalpyShimadzu's DSC-60 (Differential Scanning Calorimetry) was used to record the temperature, and the output was recorded as mW.

Chirality in API Industry, Resolution of racemate, asymmetric synthesis,few case studies:

Louis Pasteur, a French scientist and biologist, made the discovery of chiral chemistry in 1848 when he manually separated the two isomers of sodium ammonium tartrate for the first time (1, 2). It took approximately a century, though, for researchers to discover that the phenomenon of chirality is crucial to the health of both plants and animals as well as to the pharmaceutical, agricultural, and other chemical sectors. The majority of alkaloids, hormones, nucleosides, proteins, enzymes, amino acids, carbohydrates, and carbohydrates are all chiral substances. In the pharmaceutical industry, 88% of the most recent medications are sold as racemates, which are composed of an equimolar mixture of two enantiomers, and 56% of the drugs now in use are chiral products (3-5).All natural compounds have a single enantiomeric form, as opposed to chiral artificial products. For instance, all natural amino acids are the l-isomer (levorotatory), and all natural sugars (carbohydrates) are the d-isomer (dextrorotatory). Despite sharing the same chemical structure, the majority of enantiomers of racemic medications show distinct variances in pharmacology, toxicology, pharmacokinetics, metabolism, etc. Now it is clear how chiral medicines interact with the biological environment. In order to remove the undesirable isomer from the preparation, determine the best course of action for the patient, and establish the proper therapeutic monitoring, it is crucial to enhance chiral separation and analysis of racemic pharmaceuticals in both the pharmaceutical industry and the clinic.

Chirality Chirality Defined

A molecule's capacity to exist in two asymmetric forms that are not superposable mirror images of one another without altering its atomic structure, atom-to-atom connections, or bond ordering is known as chirality. Fig. (la) (la). This phenomenon typically results in what might be called left-hand and right-hand copies of the same molecule due to a change in the three- dimensional orientation of four separate substituents connected to a single core atom.

Enantiomers are the names given to these two different forms of the molecule. There will always be at least one substituent attached to the chiral atom that cannot be superimposed when various versions are attempted to be combined.The Cahn-Ingold-Prelog system, or simply the R/S notation, is used to distinguish between the two enantiomers, as advised by the International Union of Pure and Applied Chemistry (IUPAC) [4] Fig (lb). The D / L nomenclature, which stands for dextrorotatory (clockwise) and levorotatory (counter-clockwise) optical rotation of polarised light, is only used for amino acids and sugars, two different sorts of molecules. As a result of the R/S notation for chirality and the +/- symbol for optical rotation [5], this practise is no longer widely used. In achiral contexts, enantiomers are typically said to have identical physical characteristics.With the rotation of plane polarised light being the one exception.In reality, chiral circularly polarised light has left- and right-handed components that make up plane polarised light. The phenomenon of optical rotation is caused by slight variations In how chiral molecules interact with these components. Achiral molecules are those that can be superimposed on their mirror images.

Fig. (1)

a)basic chirality.

These two molecules cannot completely superimpose despite sharing the identical atoms and atom-atom interactions. As

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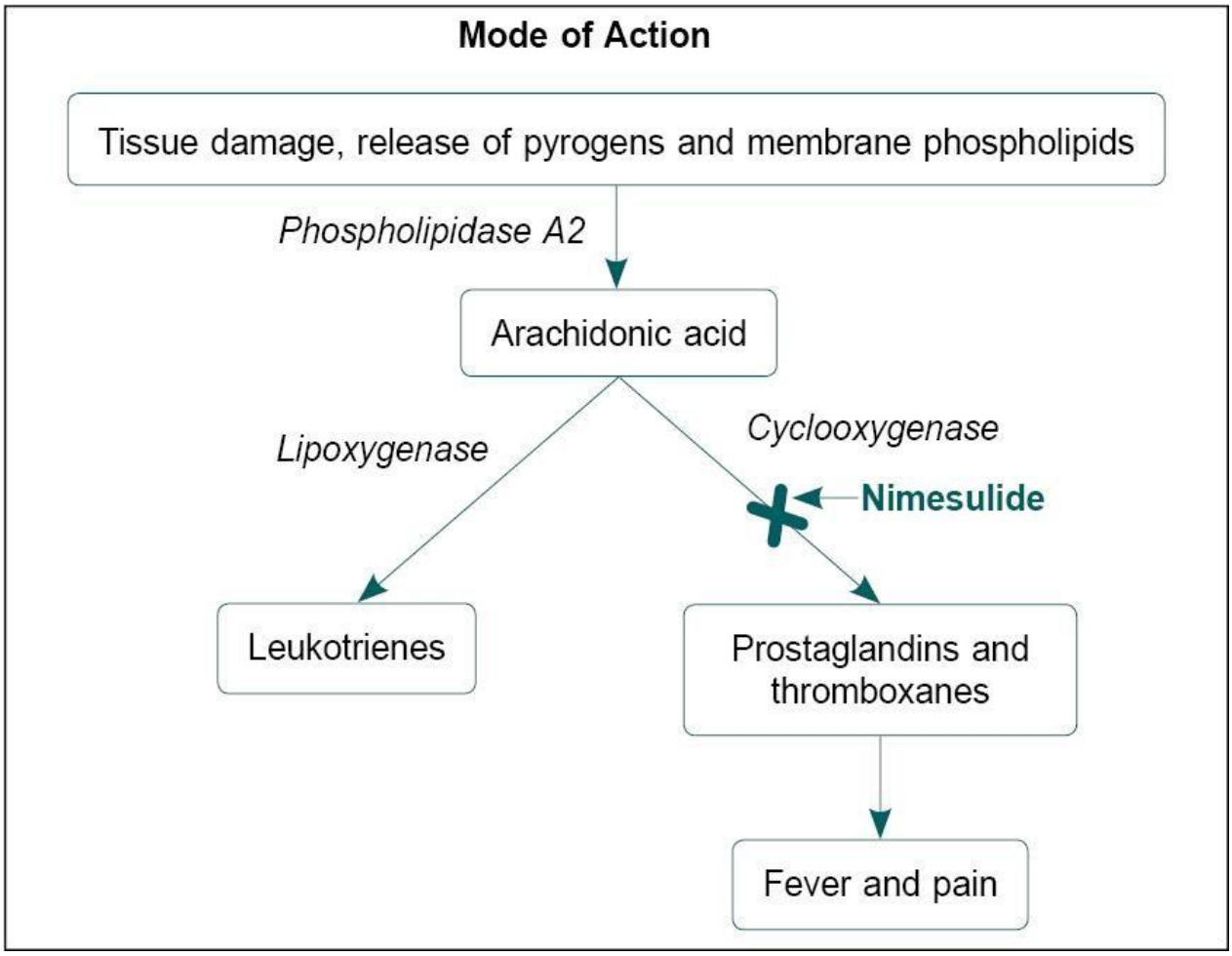
a result, they are known as enantiomers and can be seen in three dimensions as mirror images. The main…

A racemate, also known as a racemic mixture, is a sample that contains both enantiomers of a substance in equal amounts. Enantiomer separation can be achieved via chiral chromatographic techniques as well as kinetic and thermodynamic resolution. One enantiomer may be preferred over the other by stereoselective chemical processes such as asymmetric synthesis (also known as chiral synthesis) or stereoselective enzymes.

Chirality can still exist as increasingly complicated compounds are taken into account, with more complex substituents connected to a single or several chiral centres. These molecules are referred to as diastereoisomers when they are not enantiomers of one another. Similar to how varied physical characteristics like melting and boiling temperatures are possible for these molecules

To determine precedence and hence nomenclature when a possible chiral centre has two
identical atoms linked to it, the following "level" of atoms must be taken into account. The carbon-oxygen substituent has higher precedence than the carbon-hydrogen substituent in identifying the R or S, for instance, if two carbons are connected to the chiral centre and one of them just has hydrogens attached while the other has an oxygen atom attached.



Average: 308.31
Monoisotopic: 308.04669219

Formula:
$C_{13}H_{12}N_2O_5S$

Molar mass:
308.31 g·mol^{-1}

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Protein binding	>97.5%
Metabolism	Hepatic
Elimination half-life	1.8–4.7h
Excretion	Renal (50%), fecal (29%)

Uses of Nimesulide:-

- Lower fever
- lessen minor to moderate discomfort
- Headaches
- Minor headache
- Low back discomfort
- Gastritis or peptic ulcers
- Propensity to bleed
- Aspirin allergy
- Viral contamination
- Pregnancy
- Osteoarthritis

Pharmacology[edit]

Pharmacodynamics[edit]

Nimesulide is a nonsteroidal anti-inflammatory drug (NSAID), acting specifically as a relatively selective cyclooxygenase-2 inhibitor.[3][7] However, the pharmacological profile of nimesulide is peculiar, and additional, unknown/yet-to-be-identified mechanisms appear to also be involved.[3][7] One pathway that has been implicated in its actions is the ecto-5'-nucleotidase (e-5′NT/CD73)/adenosine A2A receptor pathway.[3]

Pharmacokinetics[edit]

Nimesulide is absorbed rapidly following oral administration.[8]

Nimesulide undergoes extensive biotransformation, mainly to 4-hydroxynimesulide (which also appears to be biologically active).[8]

Food, gender, and advanced age have negligible effects on nimesulide pharmacokinetics.[8]

Moderate chronic kidney disease does not necessitate dosage adjustment, while in patients with severe chronic kidney disease or liver disease, nimesulide is contraindicated.[9]

Nimesulide has a relatively rapid onset of action, with meaningful reductions in pain and inflammation observed within 15 minutes from drug intake.[10][11]

The therapeutic effects of nimesulide are the result of its complex mode of action, which targets a number of key mediators of the inflammatory process such as: COX-2 mediated prostaglandins, free radicals, proteolytic enzymes, and histamine.[10] Clinical evidence is available to support a particularly good profile in terms of gastrointestinal tolerability.[12]

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IV. CONCLUSION

One of the most beneficial biological activities of nimesulidel can be found. Numerous medical conditions, including gastric ulcers, pregnancy, and muscle tension, are treated with nimesulide. This review's presentation of effective and affordable processes for producing chemists to obtain first-hand knowledge of the process for producing nimesulidel and Develop procedures for the mass manufacture of nimesulide, which will be highly helpful to chemists and professionals in this field. And this can expand over time to create novel, environmentally friendly, economically sound protocols for the large-scale manufacturing of significant pharmacophores based on synthetic nimesulide

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