

Stereochemistry in Drug Development: Implications for Physiological Function and Therapeutic Efficacy



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Abstract

Background: Stereochemistry is a key determinant in drug development, as it defines the three-dimensional structure of molecules and their interactions within biological systems. Because most biological targets are inherently chiral, even small differences in molecular orientation can lead to significant changes in drug response.

Objective: This review aims to examine the role of stereochemistry in drug development, with particular emphasis on its influence on pharmacological activity, pharmacokinetics, and overall therapeutic performance.

Methods: An extensive review of published literature was undertaken to outline essential stereochemical concepts, including chirality, enantiomers, diastereomers, and absolute configuration, and to relate these concepts to current approaches in drug design and optimization.

Results: Although stereoisomers share the same chemical composition, they often differ in their biological behavior. One isomer may provide the intended therapeutic effect, while another may be less active or associated with adverse effects. Recent advances in stereoselective synthesis and analytical methods have enabled the production of single-enantiomer drugs, which offer improved selectivity and safety. In addition, the concept of chiral switching has emerged as an effective strategy to enhance the clinical value of existing drugs. Various examples from clinical practice further highlight the importance of stereochemistry in determining drug action.

Conclusion: A clear understanding of stereochemistry is essential for the rational design of safe and effective drugs. Integrating stereochemical considerations into drug development can improve therapeutic outcomes and reduce unwanted effects, thereby supporting the advancement of modern pharmacotherapy.

Keywords: Stereochemistry; Chirality; Enantiomers; Chiral Switch; Drug Development; Pharmacotherapy

Introduction

Background

Stereochemistry is a branch of chemistry that studies how atoms are arranged in relation to one another within molecules. Since the prefix "stereo-" denotes "three-dimensionality," stereochemistry is often referred to as 3D chemistry.[1] Stereoisomers are molecules whose atoms are joined in the same sequence but differ in how they are arranged in space; stereochemistry takes these spatial characteristics of molecules into account.[2] Stereoselectivity is shown in drug deposition, especially in activities that rely on contact with chiral biological macromolecules, such as drug metabolism, binding to plasma proteins, and active transport pathways.[3] Stereoisomers are

molecules with identical chemical formulae that only differ in their spatial arrangement.[4] The study of chiral compounds is the most significant area in stereochemistry. The majority of chiral medicines were given as racemates in the early 1980s. [5] When chiral centers, often referred to as stereogenic or asymmetric centers, occur inside substances, stereoisomerism results. [6] As shown in Table 1, numerous types of chemical structures are included in stereochemistry. Stereochemistry relies heavily on chirality [7] (Figure 1) (Table 1).

Chirality

A geometric characteristic associated with three-dimensional objects' lack of symmetry is called chirality [8] (Table 2). Chirality

is the ability of a molecule to exist in two asymmetric forms that are mirror images of one another but cannot be superimposed, without altering the bond ordering, atom-to-atom interactions, or atomic composition [9]. Drug chirality has emerged as a key subject in the creation, discovery, development, patenting, and promotion of novel pharmaceuticals [10,11]. Chiral compounds

are those that have one or more chiral centers [12]. Chirality also defines a drug's pharmacology by affecting its binding affinity and interactions with its target. (Figure 2) [13] The enantiomers of chiral compounds, such as the right and left hands, are not overlaid on one another [14] (Figure 3).

Table 1: Basic Concepts of Stereochemistry.

Concept	Description	Examples
Chirality & Optical Isomerism:	A molecule is chiral if it contains a carbon bonded to four different groups and is thus non-superimposable on its mirror image. Optical isomers rotate plane-polarized light in a different manner.	L-Dopa (used to treat Parkinson's disease), and D-glucose (the physiologically active form)
Enantiomers & Properties:	Enantiomers are isomers of the mirror image which show varying biological activities because of interaction with chiral biological molecules.	Thalidomide (one of the enantiomers is therapeutic, the other teratogenic), S-Ibuprofen (active) and R-Ibuprofen (inactive).
Racemic Mixtures vs. Single Enantiomer Drugs:	Racemic mixtures have two enantiomers in equal proportion, whereas single enantiomer drugs provide enhanced efficacy and less side effects.	Racemic Omeprazole versus Esomeprazole (S-enantiomer), Racemic Citalopram versus Escitalopram (S-enantiomer)
Diastereomers & Geometric Isomerism	Diastereomers are stereoisomers which are not mirror images, whereas geometric isomers (cis-trans) are found in compounds with restricted rotation (e.g., rings, double bonds).	Ephedrine and Pseudoephedrine (diastereomers), Cisplatin (active anticancer drug) and Transplatin (inactive)

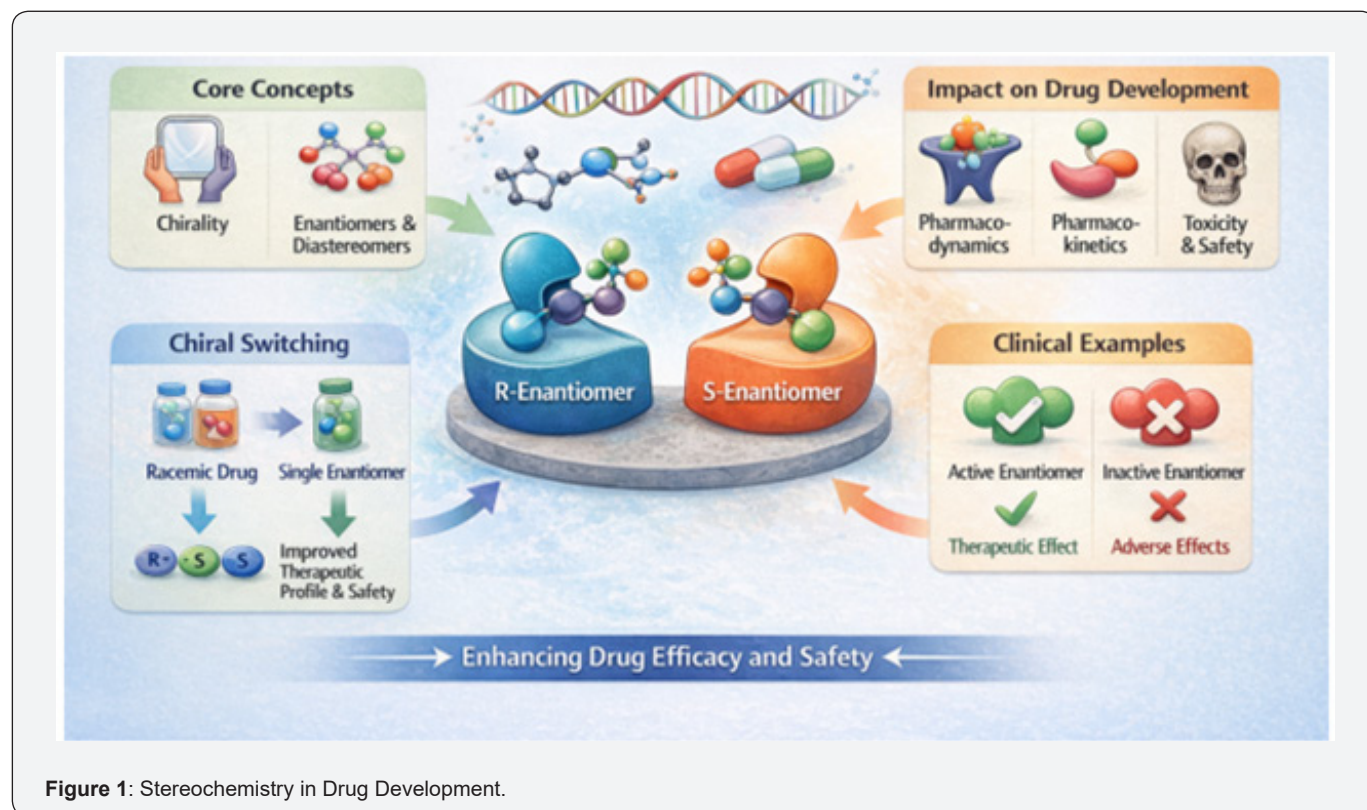


Figure 1: Stereochemistry in Drug Development.

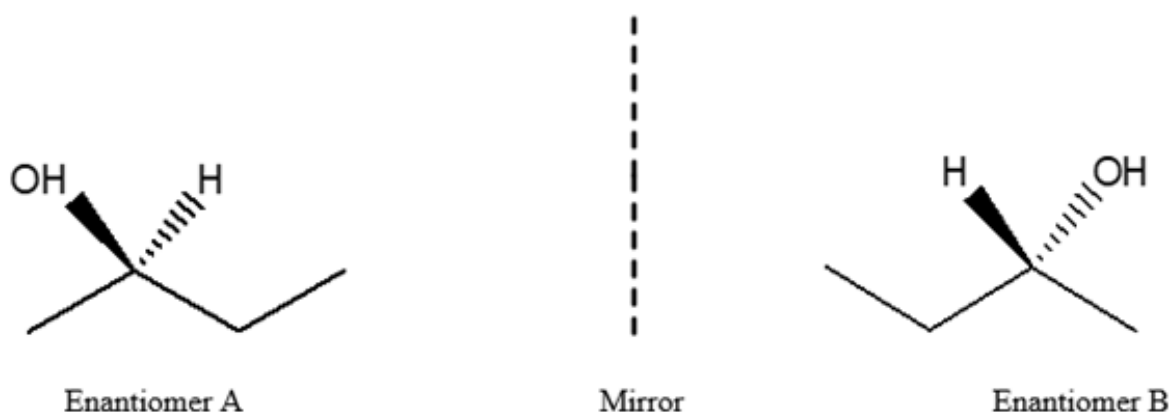


Figure 2: Chiral Structural representation of Enantiomer Forms.

Enantiomer

Enantiomers are stereoisomers that exist as non-super imposable mirror images [15]. Enantiomers can also be characterized by their absolute configuration, which is determined by the sequence in which the constituents are arranged around the chiral center [16]. While one enantiomer may be active, the other could be inactive and may cause side effects and/or show

toxicity [17,18]. An established instance of enantiomer-related toxicity involves the (R)- and (S) enantiomers of thalidomide [17,19]. R-(-)-thalidomide is a non-harmful substance with calming effects, whereas S-(+) thalidomide is teratogenic and causes deformities in embryos when given to expectant mothers [20] (Figure 4). Enantiomers share the same physical and chemical characteristics, including molecular weight, solubility, and melting point [21] (Table 2) (Figure 5).

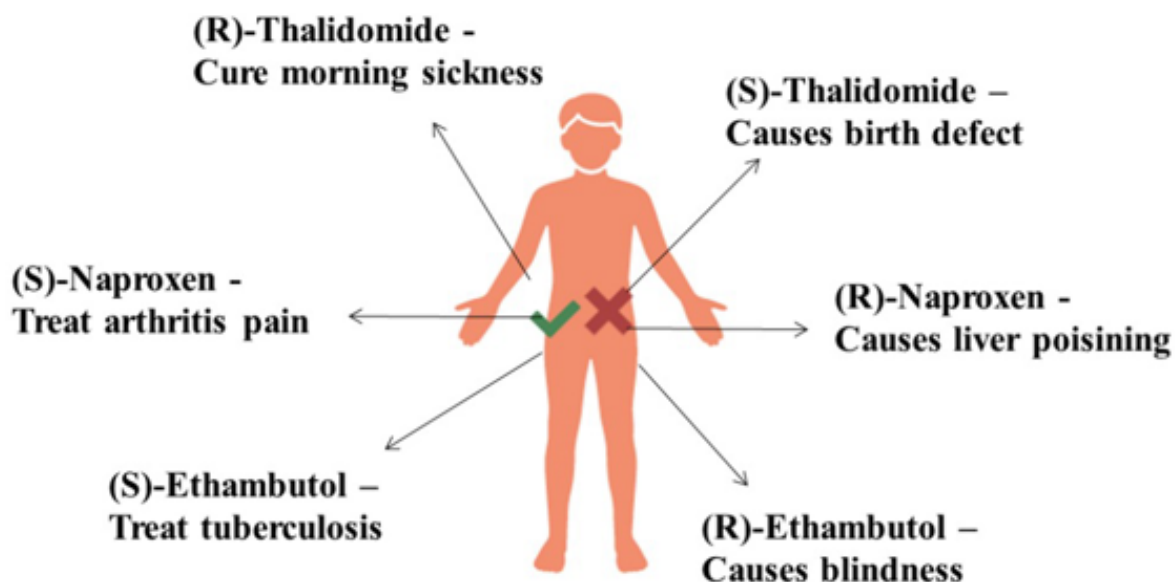


Figure 3: Existence of chirality in the human body.

Table 2: Properties of Chiral compounds.

Properties	Information
Physical Characteristics	Enantiomers share identical physical properties such as molecular mass, elemental composition, melting point, and boiling point.
Optical Activity	The only distinguishing physical property is their ability to rotate plane-polarized light in opposite directions.
Fit in Chiral Systems	Similar to how left and right gloves are non-super-imposable, chiral molecules exhibit unique three-dimensional orientations.
Behavior in Biological Systems	In chiral environments- such as within biological systems- the two enantiomers can show significantly different activity or interactions.

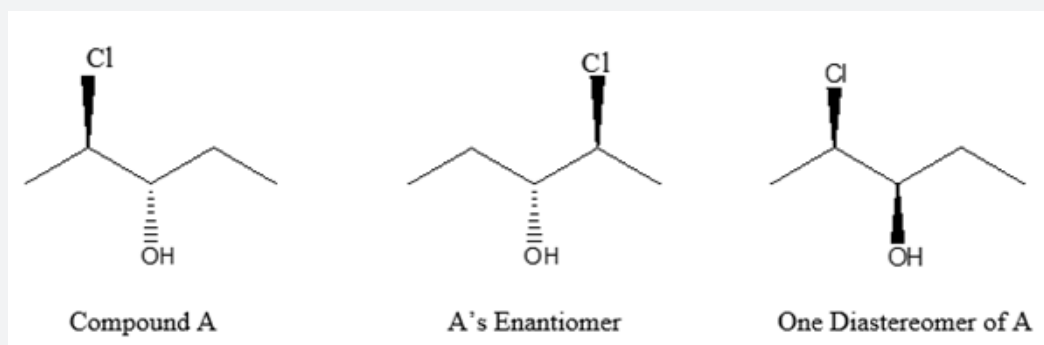


Figure 4: Comparative Structural Illustration of Enantiomeric Pairs.

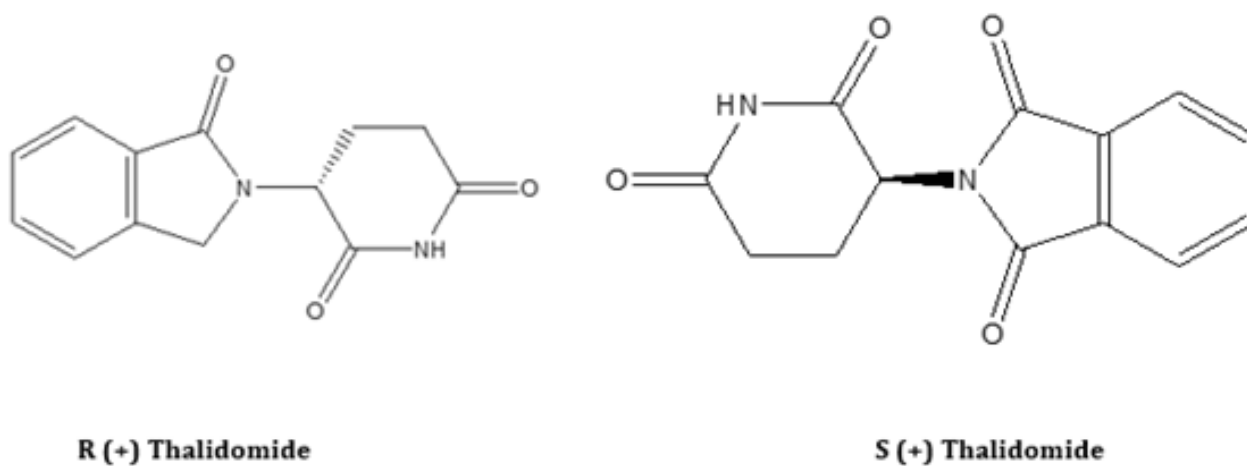


Figure 5: Stereochemistry of Thalidomide.

Diastereomer

Stereoisomers which cannot be superimposed and are not mirror images of each other [22]. Diastereomer are distinguished by variations in their physical properties, as well as some differences in their chemical behavior towards both achiral and chiral reagents [23]. Two molecules (or substances) are classified as Diastereomer if they are stereoisomerically related but not enantiomerically related [7].

Chiral Switch

Chiral switching is a phrase used to characterize the creation of single enantiomers from outdated racemate medications [24] (Figure 6). By increasing selectivity and potency towards receptors, lowering side effects, lowering inter-individual variability of the therapeutic response, lowering administered doses, improving the pharmacokinetic profile, and lowering drug-drug interactions, the chiral switch strategy may have therapeutic benefits linked to an improved therapeutic index [25] (Table 2).

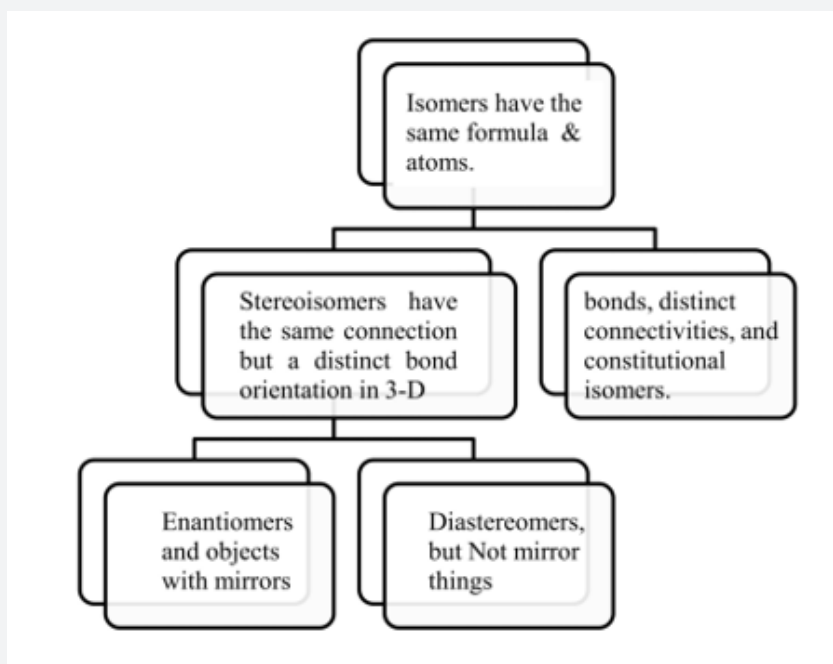


Figure 6: Hierarchical Representation of Isomers and Stereoisomers.

Isomers

A molecule having a distinct chemical structure but the same chemical formula is called an isomer [26] (Figure 6).

Absolute Configuration

Using the stereochemical descriptors R and S, the absolute configuration (AC) of an entity, such as an organic molecule, specifies the spatial arrangement of its atoms [27]. R, which comes from the Latin rectus, indicates clockwise or to the right, while S, which comes from the Latin sinister, means counterclockwise or to the left. A certain chiral center's R or S configuration can be ascertained using exact rules based on mass and atomic number [28]. The R, S system, commonly known as the Cahn-Ingold-Prelog rules of chiral chemical naming, was introduced by three chemists: R. S. Cahn, C. K. Ingold, and V. Prelog [2].

Importance

In order to accurately describe chemical reactions, stereochemistry takes into account both static (configuration)

and dynamic (conformation) temperature-dependent conditions [29]. Drug stereochemistry has gained attention recently due to developments in the techniques for stereoselective synthesis and stereospecific analysis of chiral drug molecules, as well as growing awareness of the possible importance of the distinct biological characteristics of stereoisomers [30]. Stereochemistry plays a crucial role in therapeutic pharmacology as pure enantiomers of chiral substances have the same physical properties, but their properties in biochemical processes can be radically different. The following scenarios are possible:

- One or both enantiomers may have the desired effect, but only one may cause undesired side effects.
- The inactive enantiomer might function as an antagonist that competes.
- The actions of the enantiomers may differ or be opposing.
- Only one enantiomer may result in undesirable side effects, while one or both enantiomers may produce the intended effect.

e) The adverse effects of the active enantiomer may be counteracted by the inactive enantiomer [20].

Chiral compounds make up more than half of the medications now on the market, and many of them are sold as racemates, which are equimolar mixtures of two enantiomers. Unlike many chiral man-made substances, chiral natural molecules only occur in one enantiomeric form (natural sugars are (+)-isomers, while amino acids are (-)-isomers) [31]. Enantiomer separation can be accomplished using chiral chromatographic techniques as well as kinetic and thermodynamic resolution [9].

Differences in a single stereocenter can have a significant impact on biological activity in both natural products and FDA-approved medications. For instance, 1,4-dihydropyridins are L-type calcium channel ligands that show stereoselectivity for the activity type. More specifically, the R-enantiomer inhibits the channel whereas the S-enantiomer activates it. Chirality frequently affects how a chemical smells, with enantiomers frequently smelling entirely different. For instance, carvone is what gives spearmint and caraway their respective scents (Figures 2 & 7) [32] (Table 3).

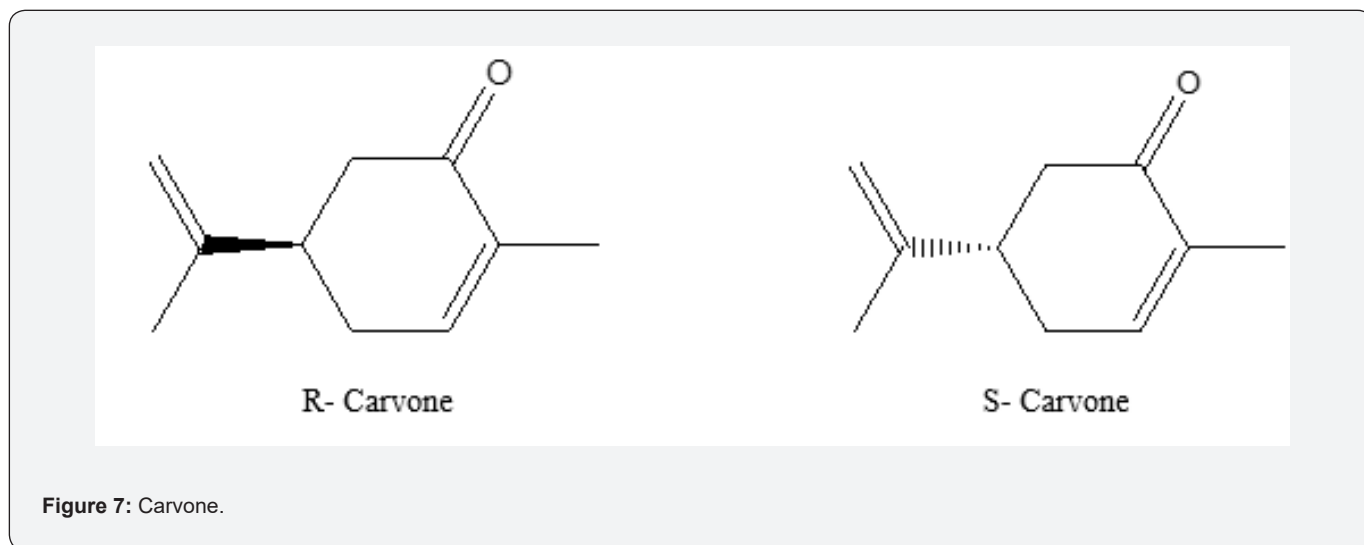


Table 3: Some examples of Drugs with Stereochemistry, Configuration, and Active Enantiomer.

Generic Name	Brand Name	Available as	More Active Form
Citalopram	Celexa, Cipra Mil, Zetalo, Lexapro	Racemate and (S)-citalopram	(S)-citalopram
Amisulpride	Barhemsys	Racemate	(S)-enantiomer
Bupivacaine	Marcaine, bupivacaine liposomal	S and R enantiomer	S-bupivacaine
Fenfluramine	Fintepla	Racemate	(+)- fenfluramine
Ibuprofen	Ibugesic Plus, Brufen	R & S Ibuprofen	S-Ibuprofen
Lansoprazole	Lansoprax, Lanzol	R & S Lansoprazole	R (+)- Lansoprazole
Modafinil	Modalert, Modafil	R & S Modafinil	R (-)- Modafinil

Pharmacology

Stereoisomers have different pharmacokinetic and pharmacodynamic characteristics [19]. As a remarkable chiral selector, the body's many homochiral molecules will interact with each racemic medication in a unique way and metabolize each enantiomer via a distinct pathway to produce distinct pharmacological activity. Consequently, one isomer may exhibit

the intended therapeutic effects, whilst the other may be inert or, in the worst situations, exhibit toxic or undesirable side effects [4,33]. Stereoisomerism can lead to pharmacokinetic differences such as L-methotrexate being better absorbed than D-methotrexate, Esomeprazole being more bioavailable than racemic omeprazole, and S-warfarin having a lower volume of distribution because it is more extensively bound to albumin than R-warfarin [19].

Enantiomers with equal qualitative and quantitative properties, enantiomers with different quantitative properties, and enantiomers with other qualitative attributes are the three main categories of chiral medications based on the pharmacological features of the enantiomers [34].

Enantiomers with equal qualitative and quantitative properties

Propafenone (antiarrhythmic), flecainide (antiarrhythmic), cyclophosphamide (antineoplastic), and fluoxetine (antidepressant) are among the few racemic medications that fall into this category [4].

Enantiomers with different quantitative properties

The pharmacological activity of this kind of chiral medication

is attributed to one enantiomer, whereas the other enantiomer exhibits minimal or no pharmacological activity [4].

Enantiomers with other qualitative attributes

These enantiomers exhibit distinct pharmacological actions, which encompass several circumstances:

1. enantiomers that share a biological target yet exhibit opposing actions;
2. enantiomers containing different biological objectives
3. Among the enantiomers that may have adverse effects
4. an inactive enantiomer capable of counteracting the adverse effects of the active enantiomer [4], (Figure 8).

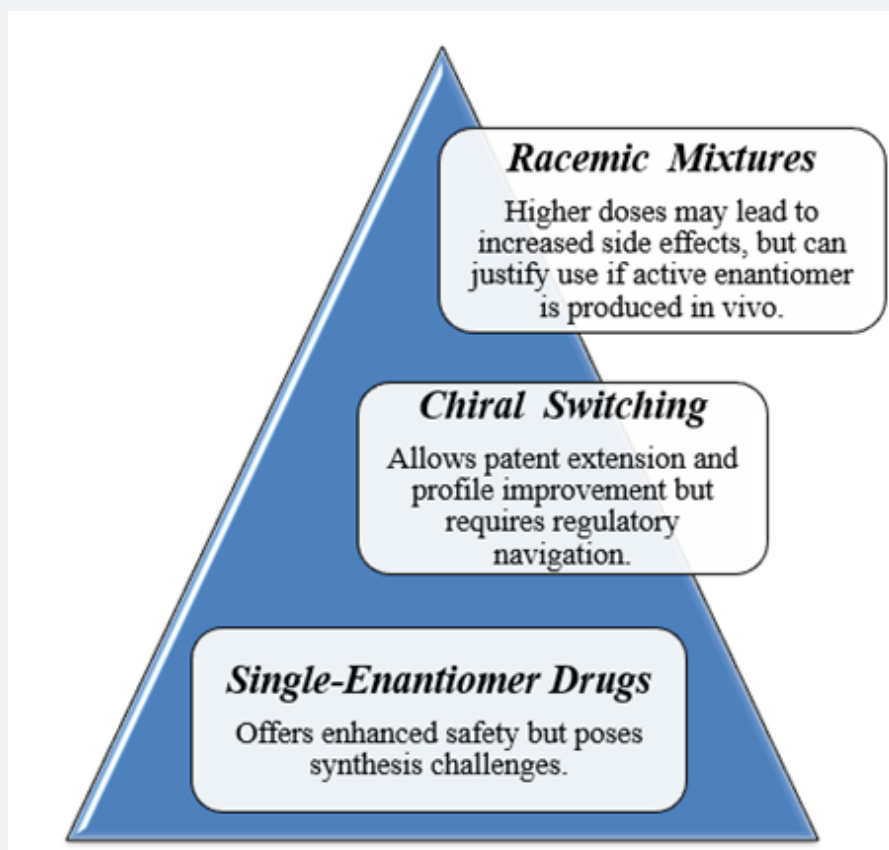


Figure 8: Drug Development Approaches.

Pharmacologically Active Enantiomers: Configuration & Clinical examples

Avapritinib

When it comes to mutant KIT and the KIT-D816V mutation of platelet-derived growth factor receptor alpha (PDGFRA),

Avapritinib, a selective orally accessible tyrosine kinase inhibitor, exhibits strong action [35]. In 2020, the FDA authorized it for the treatment of gastrointestinal stromal tumors (GISTs) with PDGFRA exon 18 mutations, and patients have shown that using it has a positive therapeutic impact. Additionally, avapritinib is being tested in clinical settings to treat several conditions, including indolent systemic Masto cytosis.

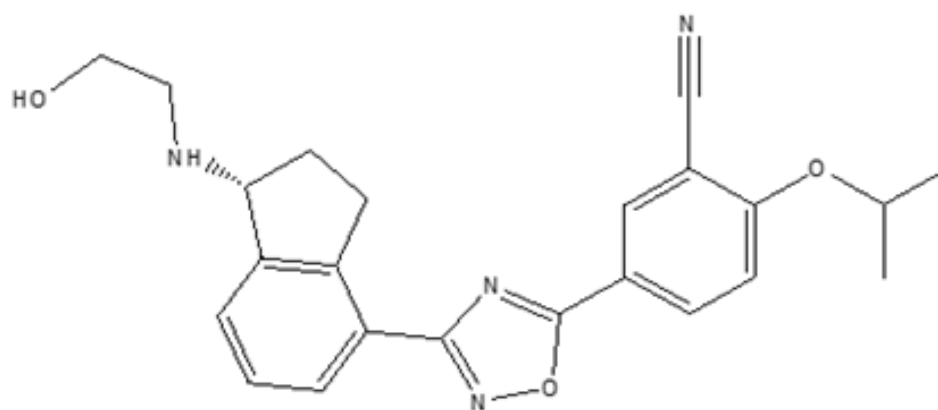
In terms of structure, avapritinib is a flexible, linear molecule with a chiral center on its rotational chain. When compared to its (R)-(+)-counterpart, (S)-(-)-avapritinib demonstrated higher c-KIT D816V inhibitory action [36].

Ozanimod

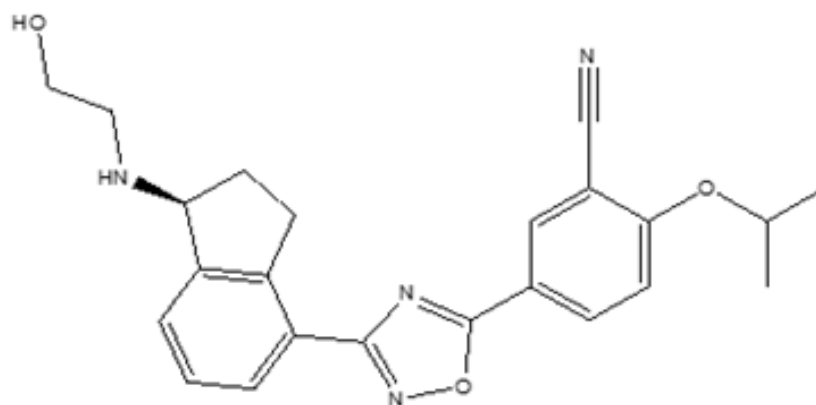
Ozanimod's unique capacity to modify immunological response and its more patient-friendly oral delivery method make it a promising option for treating multiple sclerosis in the clinical setting [37]. On March 25, 2020, Ozanimod received approval in the United States for the treatment of relapse multiple sclerosis in

adults, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive illness [38]. With a selectivity of 27 times for S1P1 over S1P5 receptors and more than 10,000 times for S1P1 over S1P2,3,4 receptors, ozanimod is a powerful agonist of both S1P1 and S1P5 receptors [39].

S-ozanimod, or simply ozanimod, and R-ozanimod are the two enantiomeric forms of ozanimod that are implied by its single chiral carbon atom [40]. The S-enantiomer, which is more effective, is used in medicinal applications. As a result, regulatory bodies require the R antipode in an ozanimod sample to be determined as part of the required evaluations [25] (Figure 9).



a. (S)- Ozanimod (Oza)



b. (R)- Ozanimod (R- Oza)

Figure 9: Ozanimod (eutomer) and (distomer).

Lonafarnib

Under license from Merck & Co., Eiger Biopharmaceuticals developed lonafarnib (Zokinvy™), an oral active FTase inhibitor, to treat progeria and progeroid laminopathies as well as hepatitis D virus (HDV) infections [41]. Lonafarnib was first approved in

the USA on November 20, 2020 to treat progeroid laminopathies (with either homozygous or compound heterozygous ZMPSTE24 mutations or heterozygous LMNA mutation with progerin-like protein accumulation) in patients \geq 12 months of age with a body surface area (BSA) of \geq 0.39 m² [42] (Figure 10).

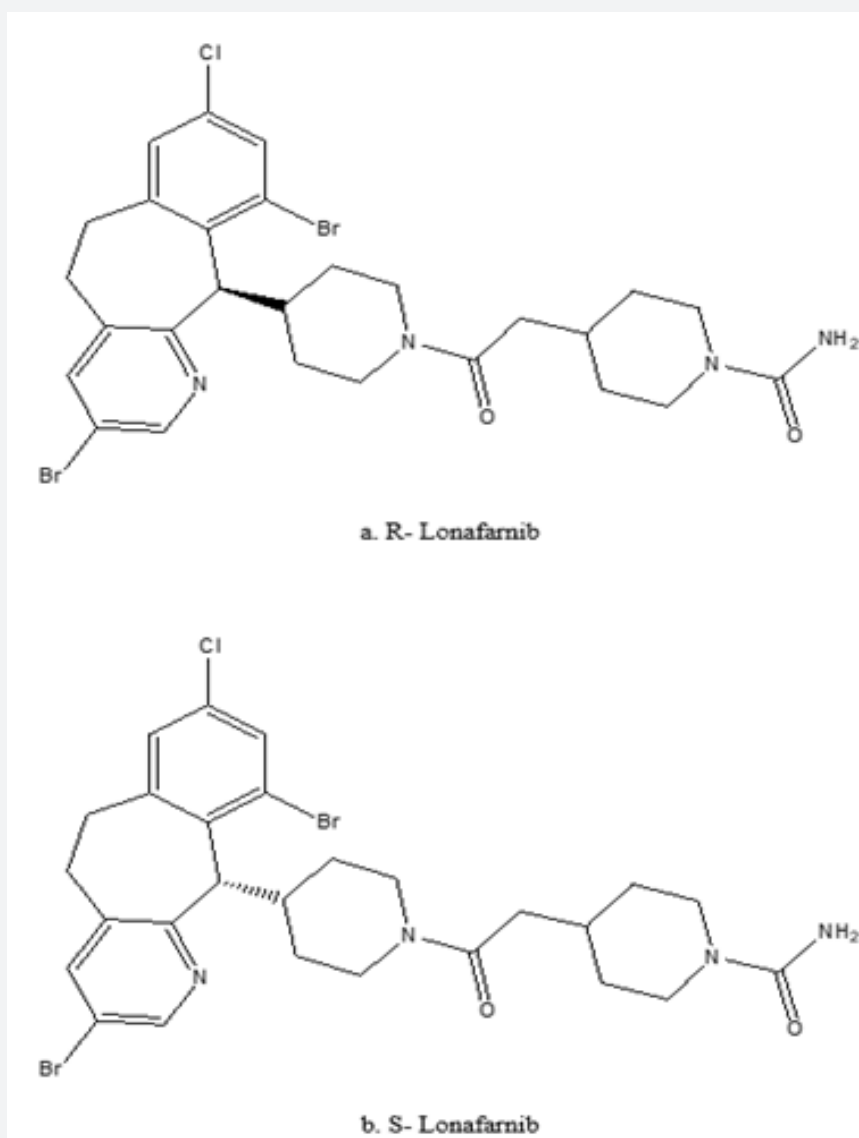


Figure 10: Lonafarnib.

Thalidomide

Initially introduced as a sedative in the late 1950s, thalidomide was used to relieve pregnant women's nausea. About 10,000 babies were born with phocomelia within a few years of thalidomide being widely used in Europe, Australia, and Japan [43]. Nevertheless, thalidomide has an impact on a wide range of other tissues, such as the spine, gastrointestinal tract, reproductive system, eyes, ears, legs, face, and cardiovascular system. Unfortunately, it has been estimated that up to 40% of babies die in their first year of life due to internal organ developmental variations, such as atresia of the colon and heart problems [44]. As a result, thalidomide was outlawed in the majority of nations in 1961 [43]. Pregnancy-related drug usage has been a major source

of concern since the thalidomide disaster in the 1960s because of the possibility of undesirable effects on the fetus, particularly severe congenital malformations (MCM) [45,46] (Figure 4).

Conclusion

Stereochemistry plays a crucial role in determining how drugs interact with biological systems and ultimately affects their safety and effectiveness. Differences in the spatial arrangement of molecules can lead to significant variations in therapeutic outcomes, even when the chemical composition remains the same. As discussed in this review, the use of single-enantiomer drugs and advances in stereoselective techniques have improved drug specificity while reducing unwanted effects. Approaches such as chiral switching have further strengthened the clinical value of

many existing drugs. However, challenges related to synthesis, cost, and regulatory requirements still need to be addressed. A better understanding of stereochemical behavior will continue to support the development of safer and more efficient medicines in the future.

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