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Review Article

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A review of pharmaceutical preformulation studies in the formulation and development of new drug molecules

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ABSTRACT

Preformulation studies are a critical early phase in drug development that focus on understanding the physicochemical properties of a novel drug candidate. These studies provide essential data on solubility, dissolution rate, molecular dissociation, pKa, diffusion, and partition coefficient. Permeability, which influences the drug's pharmacokinetics, bioavailability, and overall performance. They also assess solid-state properties such as polymorphism, crystallinity, and hygroscopicity using analytical techniques like Differential Scanning Calorimetry (DSC) and powder X-ray diffraction. Stress testing under various environmental conditions (pH, temperature, humidity, light, oxidising agents) evaluates the stability of both active pharmaceutical ingredients (API) and excipients, helping to predict shelf life and ensure stability during manufacturing, transportation, and storage and packaging requirements, minimising risks along with costs associated with later

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development stages and regulatory approval.

Ultimately, preformulation aims to create a drug product that is not only effective and stable but also manufacturable at a commercial scale, ensuring smooth transition from development to market.

KEYWORDS

Preformulation studies, Drug development, Physicochemical characterization,Solubility and dissolution,Stability testing,partical size.

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INTRODUCTION

Preformulation studies originated in the 1950s and represent the initial step in the systematic development of drug dosage forms. The primary goal of preformulation testing is to produce data that assist the formulator in developing dosage forms that are stable, safe, and bioavailable. Preformulation studies generate crucial information on physicochemical, physicomechanical, and biopharmaceutical properties not only of drug substances but also excipients and packaging materials[1].

Besides aiding formulation development, preformulation also plays a significant role in the drug discovery process by evaluating the "drugability" of new chemical entities. Preformulation provides critical insights into the physicochemical and biological behavior of molecules, thereby supporting lead selection and helping foresee drug delivery challenges. Consequently, preformulation serves as a key decision-making tool during both drug discovery and development phases by offering a thorough understanding of a molecule’s properties and their impact on biological performance. This comprehensive knowledge facilitates the design of effective and manufacturable pharmaceutical formulations[2,3].

During the early stages of new drug development, synthetic chemists, alone or collaborating with formulation experts, collect data that are categorized as preformulation, including drug properties, potency, stability, dosage form, literature on bioavailability, proposed administration routes, and formulation strategies.

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Preformulation studies are not only essential for formulation development but also help assess the "drugability" of new chemical entities during drug discovery. Potency and selectivity alone do not guarantee therapeutic viability; thus, preformulation evaluates biopharmaceutical properties and helps anticipate drug delivery challenges. Once a candidate passes biological screening and proceeds to clinical trials, formal preformulation studies are initiated, guided by regulatory frameworks such as the IND, NDA, and ANDA guidelines from the US FDA and ICH. These studies provide a stable, effective, and manufacturable pharmaceutical products[4,5].

MATERIALS AND METHODS

This review article looks at various studies done before making new medicines to understand the basic properties of the drug molecules. It gathers information from different research papers about important features like how well the drug dissolves, stays stable, and mixes with other ingredients. It also explains the tools and tests used to study these features, such as chromatography and heat tests. The main aim is to show how learning about these drug properties early helps scientists create safe, effective, and long-lasting medicines.

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RESULTS

Various Area Of Preformulation Research:

BULK CHARACTERS[9,10,11]

- Crystallinity and Polymorphism
- Hygroscopicity
- Fine particle characterization
- Powder flow properties

SOLUBILITYANALYSIS

- Ionization constant-PKA
- PH solubility profile
- Common ion effect-Ksp
- Thermal effects
- Solubilization

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BULK

CHARACTERS:

Category of Crystalline Solid	Type of Bonding/Force Holding Particles	Key Features	Typical Examples
Ionic Solids	Electrostatic attraction between ions	High melting points, hard, brittle, poor conductors as solids, good conductors when melted or dissolved	Sodium chloride (NaCl), Magnesium oxide (MgO)
Molecular Solids	Hydrogen bonds, dipole interactions, London dispersion forces	Low melting points, generally soft, poor electrical conductivity	Hydrogen (H_2), Carbon dioxide (CO_2)
Metallic Solids	Metallic bonding (delocalized electrons)	Varying hardness and electricity as solids and liquids	Iron (Fe), Magnesium (Mg)
Covalent Network Solids	Covalent bonds forming an extended network	Very high melting points, very hard, usually poor electrical conductors	Diamond (C), Quartz (SiO_2)

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Hygroscopicity Class	Relative Humidity Range	Moisture Uptake Behavior	Moisture Gain After One Week Storage
Class I: Non-Hygroscopic	Below 90% RH	Negligible moisture absorption	Less than 20% increase after storage above 90% RH
Class II: Mildly Hygroscopic	Below 80% RH	Minimal moisture uptake	Less than 40% increase after storage above 80% RH
Class III: Moderately Hygroscopic	Below 60% RH	Moisture increase under 5%	Less than 50% increase after storage above 80% RH

Hygroscopicity Class	Relative Humidity Range	Moisture Uptake Behavior	Moisture Gain After One Week Storage
Class IV: Very Hygroscopic	As low as 40– 50% RH	Noticeable moisture absorption even at low humidity	Significant moisture rise after storage

Angle of repose:-

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Angle of Repose (degrees)	Flowability Description
Less than 20	Free flowing
20 to 30	Excellent flow

Angle of Repose (degrees)	Flowability Description
30 to 34	Good flow
Greater than 40	Poor flow

The Compressibility:-

1. The Carr's compressibility index [20].

Compressibility (%)	Flow Quality
5 to 15	Excellent flow
12 to 16	Good flow
18 to 21	Fair to passable flow

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23 to 35	Poor flow
33 to 38	Very poor flow
Above 40	Extremely poor flow

2. Hausner's ratio[21]

Hausner's Ratio Range	Flow Description
1.00 – 1.11	Excellent flow

Hausner's Ratio Range	Flow Description
1.12 – 1.18	Good flow
1.19 – 1.25	Fair flow
1.26 – 1.34	Passable flow
1.35 – 1.45	Poor flow

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1.46 – 1.59	Very poor flow

SOLUBILITYANALYSIS:

Drug Type	Ionization Behavior	pKa Range
Very weak acid	Remains un-ionized at pH values above 8	> 8
Moderately weak acid	Un-ionized at stomach pH (~1.2)	2.5 – 7.3
Strong acid	Ionizes at pH values below 2.5	< 2.5
Very weak base	Un-ionized at pH values below 5	< 5
Moderately weak base	Un-ionized at intestinal pH range (5 – 11)	5 – 11
Strong base	Ionizes at pH values above 11	> 11

For acidic compounds:

For basic compounds:

Determination of solubility[23].

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Solubility Category	Approximate Amount of Solvent (g) Needed to Dissolve 1 g of Solute	Solubility Range (% w/v)
Very soluble	Less than 1	10–50
Freely soluble	Between 1 and 10	3.3–10
Soluble	Between 10 and 30	1–3.3
Sparingly soluble	Between 30 and 100	0.1–1
Slightly soluble	Between 100 and 1,000	0.01–0.1
Very slightly soluble	Between 1,000 and 10,000	0.001–0.01
Practically insoluble or poorly soluble	More than 10,000	Less than 0.001

BCS Class	Permeability	Solubility	Description

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Class I	High	High	Drugs that dissolve easily and are readily absorbed.
Class II	High	Low	Drugs with good permeability but limited solubility, dissolution limits absorption.
Class III	Low	High	Drugs with good solubility but poor permeability, absorption is permeability-limited.
Class IV	Low	Low	Drugs with both poor solubility and permeability.

Po/w = (Conc. of the drug in organic phase / Conc. of the drug in water) equilibrium.

ANALYSIS OF STABILITY:-

Preformulation goals:

STABILITY ANALYSIS

- Solution stability

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• pH rate profile

• Solid-state stability

• Bulk stability

• Compatibility

1. Crystallinity and polymorphism:-

It refer to the ability of drugs and excipients to exist in different crystalline or amorphous forms based on their chemical composition and crystallization method. Crystals have ordered, repeating molecular arrangements in three dimensions. Preformulation studies focus on analyzing crystal structure and polymorphic forms because these can affect bioavailability, stability, and manufacturing processes. Understanding these variations helps optimize drug performance and stability. Techniques like X-ray diffraction and thermal analysis are used to characterize these forms and ensure consistent drug quality[12,13].

Crystalline solids are divided into following types:-

Polymorphism:-

It refers to the existence of a substance in multiple crystalline forms, each having distinct physical and chemical characteristics such as solubility and melting point. These different forms can significantly affect a drug's bioavailability and stability. Polymorphism also influences how drugs compress during tablet formation; for example, paracetamol exhibits

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polymorphism with monoclinic and orthorhombic forms, where the orthorhombic variety has better compression qualities.

Amorphous:-

Amorphous drugs have atoms or molecules arranged without a fixed or regular structure. Amorphous form possesses high thermodynamic energy compared to crystalline forms, resulting in greater solubility and faster dissolution rates. Because of this disordered arrangement, amorphous drugs often dissolve more quickly and can enhance bioavailability more effectively than their crystalline counterparts.

2. Hygroscopicity:-

Hygroscopicity means to the ability of a substance to absorb moisture from the surrounding environment. For example, water vapor can be physically adsorbed on the surface and within the pores of a porous material like activated carbon, forming a thin liquid layer. It often begins at specific "active sites" and spreads from there. In other materials, such as silica gel, moisture uptake may involve not only physical adsorption but also weak chemical interactions. Many natural materials, including hair, cotton, and wool, are hygroscopic—they absorb water and undergo changes in their physical size. This property plays an important role in how these materials behave and can be utilized accordingly[14,15].

3. Characterization of fine particles[16,17]:-

1. Microscopy

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2. Microscopy on a hot stage

3. Thermo graphic analysis

4. Diffraction of X-rays

5. Infrared spectroscopy (IR)

6. Proton magnetic resonance (PMR) for detecting protons

7. Nuclear Magnetic Resonance (NMR) (NMR)

4. Flow properties of powder :-

Particle size, shape, density, and moisture content greatly affect powder flow. To assess flow, common tests include measuring the angle of repose, calculating Carr's compressibility index and Hausner ratio, observing flow through an orifice, and performing shear cell analysis. These methods help understand and optimize powder behavior during manufacturing.

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Angle of repose is the steepest angle between the surface of a powder pile and flat horizontal surface. It is calculated using the formula tan □□ = ^{h}, h is the height and □□ is the base radius of

□□

pile. Rougher, irregular particles create a larger angle. A lower angle of repose indicates higher powder flowability[18,19].

Compressibility is determined using two main tests: Carr’s compressibility index and Hausner ratio. These methods evaluate how much a powder's volume decreases under pressure, indicating its flow and compaction behavior. Lower values in both tests generally mean better powder flow, while higher values suggest poor flow properties.

Carr's index (%) = Tapped density – Bulk density x100 / Tapped density

Hausner's ratio = Tapped density X 100 / Bulk density

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5. pKA ionization constant:-

The pKa value indicates how easily a molecule with acidic or basic groups ionizes, which affects its solubility in water. Compounds are more soluble when ionized compared to their neutral form, so the solution's pH influences the solubility of ionizable substances. Understanding pKa helps predict how a molecule behaves in different pH environments[22].

PH = pKa + log ([ionized drug] / [un-ionized drug])

PH = pKa + log ([un-ionized drug] / [ionized drug]

6. Solubility profile at pH:-

The rate of drug release into the dissolving media and thus the therapeutic efficacy of the pharmaceutical product, is affected by drug solubility, which is an essential physicochemical attribute.

Rules of thumb –

1. polar liquids are dissolves in polar solutes.

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2. non-polar liquids are dissolves in non-polar.

7. Ksp (common ion action):-

It explaions the reduction in the solubility of an ionic compound when another substance containing the same ion is introduced into the solution. This phenomenon occurs due to Le Chatelier's principle, which governs the balance between ionic association and dissociation. It is most often observed in the decreased solubility of salts or weak electrolytes. When the concentration of a shared ion is increased, more of the salt tends to precipitate out, reducing

the levels of both ions in the solution until the system reaches equilibrium. This happens because the added compound and the original salt share a common ion within the mixture[24].

8. Thermal Effect:-

When a drug dissolves in a solvent, heat is may absorbed or released during the process that heat is known as heat of solution. its happening due to the energy requirement to break apart the bonds in the drug particles, while energy is also released when solvent reacts with particles. If the need of

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energy to break the bond is greater, the process absorbs heat (endothermic), meaning warmer temperatures can help the drug dissolve more easily and if more energy is released during the bond formation, heat is given off (exothermic). Knowing how temperature affects this heat exchange is the main aspect to understand about how well a drug dissolves, which is crucial for developing effective medicines[25].

9. Solubilization:-

Solubilization helps improve how well a poorly soluble drug dissolves by incorporating it into tiny structures called micelles, which create a stable solution. This happens once the amount of surfactant in the solution reaches a certain point—the critical micelle concentration—where micelles start to form and grow, trapping the drug inside. To develop a stable medicine that the body can absorb well and that delivers improved effectiveness, it’s important to understand how the drug behaves and dissolves across the different pH levels inside the digestive system. This knowledge is vital for drugs that don’t dissolve easily on their own, as using micelles can significantly boost their solubility and performance in the body[26].

10. Coefficient of partition:

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The ratio of the concentrations of the un-ionized form of a drug in two immiscible solvents— typically an organic phase like n-octanol and an aqueous phase like water—once equilibrium is reached. how much a compound prefers to dissolve in a fatty (organic) environment versus a watery (aqueous) one. Mathematically, it is expressed as[27]:

The knowledge of how drugs distribute between hydrophilic (water-loving) and lipophilic (fat- loving) phases is invaluable for formulators. This understanding helps in choosing suitable solvents for extracting drugs, conducting stability tests, and evaluating drug absorption from various dosage forms like ointment.

11. Toxicology formulations' stability:-

Toxicological studies usually begin early in drug development to ensure safety and test the stability and uniformity of toxicological preparations. Drugs can be administered orally through feed or as a solution or suspension via oral gavage. However, components like minerals, vitamins, enzymes, and other additives in the feed can reduce the drug’s shelf life, affecting its stability and effectiveness over time. This early testing is crucial for ensuring the drug remains safe and consistent throughout its use[28,29].

- Always use freshly prepared feed samples.

- Ensure that solutions or suspensions can be easily prepared.

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- Store samples in flame-sealed ampoules at different temperatures to maintain stability.

- Regularly shake the samples to check how well they disperse.

12. Stability of the solution:-

Experiments are conducted under extreme pH, including assay specificity and identifying maximum degradation rates. The entire pH-rate profile is analyzed to determine the pH where the drug is most stable. Aqueous buffers are used to create a wide range of drug concentrations, varying co-solvent levels, and different ionic strengths. these studies can be performed in physiological media to better mimic real biological environments, helping to understand the drug's stability under various conditions.

13. Bulk stability:-

During drug development, several bulk properties of the solid drug form are closely monitored as they can change. It contains particle size, bulk density, surface shape, flow properties,

compressibility, crystallinity, polymorphism, and hygroscopicity. Understanding and controlling these characteristics is crucial because they affect the drug's stability, solubility, manufacturability, and bioavailability. Proper evaluation helps in designing effective and consistent dosage forms,

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ensuring quality and therapeutic performance.

- Collect detailed information during the pre-formulation phase to help create a stable drug product.

- Determine the drug's maximum shelf life or expiration date to ensure safety and efficacy.

- Identify the best storage conditions to maintain drug's stability.

- Decide on the appropriate packaging materials and methods to protect the drug throughout its shelf life.

14. Compatibility:-

Understanding how drug and excipients interact is essential for selecting the right excipients in drug formulation. Pre-formulation screening typically involves mixing a small amount of drug (around 5 mg) with an equal amount of excipient to maximize the chances of detecting any interaction. During this process, physical and chemical properties such as the appearance of the mixture, drug assay results, and the formation of any degradation products are carefully evaluated to identify potential incompatibilities. This helps ensure that excipients does not produces opposite affect on the drug's stability, efficacy, or safety throughout the product's shelf life[30].

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DISCUSSION

1. Provide key information to help design stable and effective drug forms.

2. Check if the drug works well with common excipients to avoid problems [6].

3. Study the drug's behavior and stability in different conditions[7].

4. Understand the drug's physical and chemical traits before making a dosage form.

5. Improve how well the drug is absorbed by the body[8].

6. Help make drug forms that are safe and effective.

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CONCLUSION

Preformulation studies shows impact on the selection of the drug candidate, formulation components, API & drug product manufacturing processes, determining the most appropriate container closure system, development of analytical methods, API retest periods. Preformulation studies support the guidance's scientific foundation, provide regulatory release and save resources in the drug development and evaluation process, improve product quality, facilitate the implementation of new technologies. Preformulation studies are the crucial first steps in the developing any drug. They involve examining the drug’s physical and chemical characteristics to guide how the medicine should be formulated—this includes decisions about the drug’s form, the choice of inactive ingredients, and its overall composition and structure. These studies also help to understand how the drug acts on body its absorption and metabolism. Without these initial tests, creating an effective and stable medicine is not possible. Essentially, preformulation research provides the essential information needed to ensure that drug products are safe, effectfull and ready for further development.

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the author declared no abbreviations

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