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A Review on Formulation Development

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Abstract: *Formulation development is the scientific process of combining an active pharmaceutical ingredient (API) with inactive ingredients (excipients) to create a safe, stable, and effective patient dosage form. Drug formulation is the science of designing drug compositions that deliver active pharmaceutical ingredients safely and effectively. This discipline combines chemistry, biology, and engineering to optimize bioavailability, stability, and patient compliance, ensuring medications achieve their intended therapeutic outcomes while meeting regulatory standards. Drug formulation is an essential step in drug development, as it directly impacts the safety, efficacy, and patient experience of taking a drug. A well-crafted formulation ensures the APIs are delivered as intended, helping to optimize their therapeutic efficacy while minimizing side effects. Additionally, drug formulation helps to address practical concerns like patient compliance, making medications easier to administer, and increasing adherence to prescribing protocols. Additionally, it also plays a vital role in obtaining regulatory approval and patent protection, which underlines its significance in bringing new and improved therapies to market. In essence, the formulation process serves to bridge the gap between scientific breakthroughs and real-world applications, ultimately determining the impact of pharmaceutical interventions*

Keywords: *Formulation development, pharmaceutical ingredient*

I. INTRODUCTION

Formulation development is the process of creating a finished drug product by combining an active pharmaceutical ingredient (API) with inactive ingredients, or excipients. The goal is to produce a safe, effective, stable, and manufacturable product that can be reliably administered to patients.



The fundamental principles of pharmaceutical formulation





The process is a critical part of drug development that determines a product's patentability, shelf-life, and overall success. The formulation development is a crucial component of pharmaceutical development and important for therapeutic and commercial achievement of product by delivering quality, safety and efficiency. The main parts of formulation development are product development methods like drug discovery, research etc. It is an essential factor not only in the starting stage of drug development, but also in later marketing success of drug product. It is the exploration of a new drug substance to the successful development of a drug product. Formulation can determine patentability, lifecycle the success of a pharmaceutical product.

It is the process of combining an active pharmaceutical ingredient (API) with various inactive ingredients (excipients) to produce a final, safe, effective, stable, and patient-friendly drug product. It links the discovery of a new drug substance to the successful development of a commercial medicine.

A. Core Goals

The primary goals of formulation development are to:

- 1) Ensure Efficacy: Guarantee the drug delivers the desired therapeutic effect efficiently.
- 2) Maximize Stability & Shelf Life: Create a product that is chemically and physically stable throughout its storage and usage life.

- 3) Optimize Bioavailability: Ensure the drug is absorbed by the body at the optimal rate and amount.
- 4) Enhance Patient Acceptability: Develop user-friendly dosage forms (e.g., tablets, capsules, injections, creams) that improve patient compliance.
- 5) Ensure Manufacturability: Design a process that can be reliably scaled up for large-scale production and commercialization.
- 6) Meet Regulatory Standards: Ensure the final product adheres to all quality and safety standards required for regulatory approval.

B. Key Stages in the Process

The formulation development process typically involves several sequential stages:

- 1) Pre-formulation Studies: This initial stage involves a thorough physical and chemical characterization of the API. Key properties like solubility, particle size, polymorphism, and stability under different conditions (pH, temperature, light) are assessed to provide a scientific basis for later formulation decisions.
- 2) Analytical Method Development: Validated analytical methods are developed to test and characterize the API and the formulated product at various stages of development.
- 3) Excipient Screening and Dosage Form Development: Appropriate inactive ingredients (binders, fillers, disintegrants, etc.) are selected based on compatibility with the API. A suitable dosage form (e.g., tablet, liquid suspension, injectable) and delivery system are determined.
- 4) Prototype Formulation: Several prototype formulations are created and tested on a small scale to identify the most promising candidates.
- 5) Stability Testing: The stability of the chosen prototypes is rigorously tested under various environmental conditions (e.g., accelerated and long-term studies) to determine the product's shelf life and appropriate storage conditions.
- 6) Process Optimization and Scale-up: The manufacturing process for the selected formulation is refined and scaled up to prepare materials for clinical trials and eventual commercial production.
- 7) Regulatory Submissions and Clinical Trials: Data from the formulation development process is compiled for inclusion in regulatory applications (e.g., IND, NDA) to gain approval for clinical trials and market authorization.

C. Key objectives

- 1) Improve stability and shelf life: Protects the drug from degradation by light, heat, or moisture to ensure it remains effective for its intended shelf life.
- 2) Enhance bioavailability: Ensures the drug is absorbed by the body at the correct rate and time to produce the desired therapeutic effect.
- 3) Improve patient compliance: Creates user-friendly dosage forms, such as those that are easier to swallow or have better taste.
- 4) Ensure manufacturability: Develops a formulation that can be reliably and repeatedly produced on a small or large industrial scale.
- 5) Optimize therapeutic efficacy: Balances the chemical properties of the API and excipients to improve the overall effectiveness of the drug.

The formulation development process

- Pre-formulation studies: This initial phase involves a thorough analysis of the drug substance's (API) physicochemical properties, including its solubility, particle size, polymorphism, and stability.
- Excipient screening and compatibility: Scientists select the appropriate inactive ingredients (e.g., binders, fillers, and preservatives) and test their compatibility with the API. This ensures the excipients do not cause degradation or interfere with the drug's effectiveness.
- Dosage form design and development: Based on the drug's properties and patient needs, a dosage form is chosen. Common options include:
 - Solid: Tablets, capsules, or powders.
 - Liquid: Solutions or suspensions.
 - Parenteral: Injectable formulations.
 - Topical: Creams or ointments.

- **Analytical method development:** Robust testing methods are developed to accurately measure the drug's concentration, identify impurities, and ensure the product meets quality standards.
- **Formulation optimization:** Using techniques like Quality by Design (QbD), the formulation's composition is fine-tuned to achieve the desired critical quality attributes, such as stability and dissolution rate.
- **Stability testing:** The finished product is tested under various conditions (temperature, humidity, light) to determine its shelf life and identify the optimal storage conditions.
- **Manufacturing process development and scale-up:** A repeatable and robust manufacturing process is designed, and production is scaled up from laboratory batches to larger industrial-scale production. This involves testing critical process parameters to ensure consistent quality.
- **Package and delivery system selection:** The final packaging and delivery device are selected to protect the product and ensure effective administration.

D. Process development and optimization

Once a prototype is selected, the manufacturing process is refined for consistency and efficiency.

- 1) **Process scale-up:** The formulation moves from small, laboratory-sized batches to commercial-scale manufacturing, a phase known as "tech transfer".
- 2) **Manufacturing methods:** The process is optimized using principles like Quality by Design (QbD) to ensure consistent product quality, even with large-scale production.

E. Stability testing

This is a critical phase to ensure the drug product remains stable and potent throughout its shelf life.

- 1) **Accelerated stability testing:** The formulation is subjected to elevated temperatures and humidity to predict its long-term stability and shelf life.
- 2) **Long-term stability testing:** The product is monitored under recommended storage conditions to confirm its stability over an extended period.

F. Clinical evaluation and regulatory submission

The final formulation undergoes rigorous testing before it can be approved for public use.

- 1) **Clinical trials:** The drug's safety, efficacy, and dosage are confirmed in human trials.
- 2) **Regulatory approval:** Data on the formulation, manufacturing, safety, and efficacy are compiled into a submission for regulatory bodies like the FDA.

Common challenges in formulation development

Formulation scientists often face complex challenges during the development process.

- **Poor solubility:** Many new APIs are poorly soluble, which limits the body's ability to absorb them. Innovative approaches like micronization and nanosuspensions are often needed to overcome this.
- **Stability issues:** The API can be sensitive to light, heat, or moisture, which can degrade its effectiveness. The use of antioxidants, protective coatings, and specialized packaging is crucial for protection.
- **Taste and palatability:** Especially for oral medications, taste-masking techniques are required to make the drug acceptable, particularly for pediatric patients.
- **Regulatory hurdles:** Ensuring the formulation and manufacturing processes comply with stringent international standards is a continuous and complex challenge.

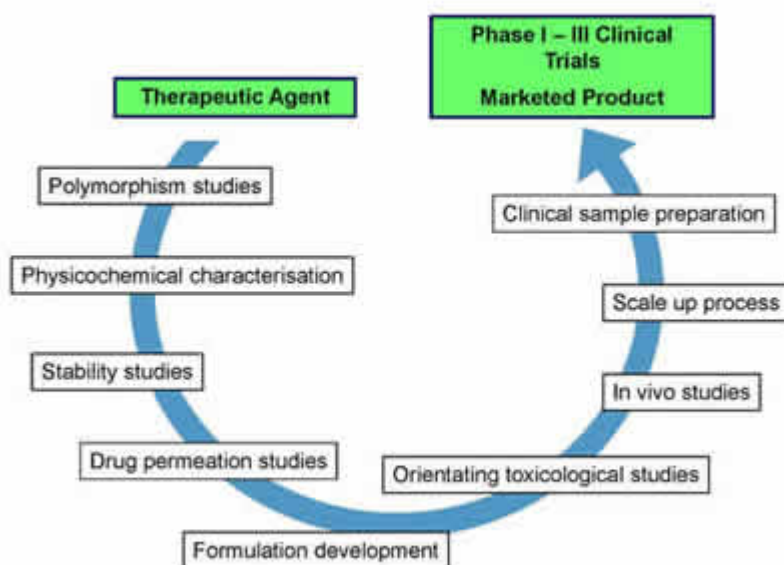
II. PHARMACEUTICAL FORMULATION DEVELOPMENT

Pharmaceutical formulation development is the process of creating a safe, effective, and stable final drug product by combining an active pharmaceutical ingredient (API) with inactive substances, known as excipients. This process transforms a potential drug candidate into a usable medicine that ensures the correct dosage reaches the target area of the body.

A successful formulation optimizes several critical factors, including:

- 1) **Bioavailability:** The proportion of a drug that enters the bloodstream and becomes available to produce its effect.

- 2) **Stability:** Protecting the drug from degradation caused by environmental factors like light, temperature, and moisture, which ensures a longer shelf life.



- 3) **Patient compliance:** Creating a dosage form that is easy and acceptable for the patient to use, such as a palatable syrup or an easy-to-swallow tablet.
- 4) **Controlling drug release:** Designing formulations that deliver a drug to the body at a desired rate, from immediate release to slow, sustained release.

The formulation development process

The process is a multi-stage, interdisciplinary effort that begins early in drug development.

- **Pre-formulation studies:** Before combining ingredients, scientists thoroughly analyze the physicochemical properties of the API. This includes evaluating its:
 - **Solubility:** How well the drug dissolves in different solvents.
 - **Polymorphism:** The different crystal forms of the drug, which can affect its solubility and stability.
 - **Particle size:** The size and shape of the drug particles, which influence dissolution and absorption.
 - **Compatibility:** How the API might interact with potential excipients.
- **Formulation design:** Using the pre-formulation data, scientists select the most appropriate excipients and determine the best dosage form. This involves creating various prototypes to test and evaluate.
- **Formulation optimization:** Through techniques such as Design of Experiments (DoE), the formula and manufacturing process are refined to ensure consistency, reproducibility, and optimal performance.
- **Process scale-up:** The manufacturing process is transitioned from a small, laboratory-scale batch to a larger, commercial-scale production, ensuring product consistency is maintained.
- **Stability testing:** The drug product is subjected to various conditions (e.g., different temperatures, humidity levels) to determine its shelf life and appropriate storage conditions.
- **Regulatory submission:** The final formulation and manufacturing data are compiled for submission to regulatory bodies like the FDA, demonstrating the drug's safety, efficacy, and quality.

Common dosage forms

Formulations are tailored for different routes of administration and patient needs, resulting in a variety of dosage forms:

- **Oral:** Tablets, capsules, syrups, suspensions, and powders. These are the most common and convenient.
- **Parenteral:** Injections and infusions (intramuscular, subcutaneous, or intravenous). These bypass the digestive system and are used for rapid effect or for drugs that are not absorbed orally.

- Topical: Creams, ointments, gels, and patches applied to the skin for local or systemic delivery.
- Inhalation: Inhalers and nebulizers that deliver drugs directly to the lungs for respiratory conditions.
- Novel delivery systems: Advanced systems like nanoparticles and liposomes are used for targeted drug delivery and to improve a drug's effectiveness.

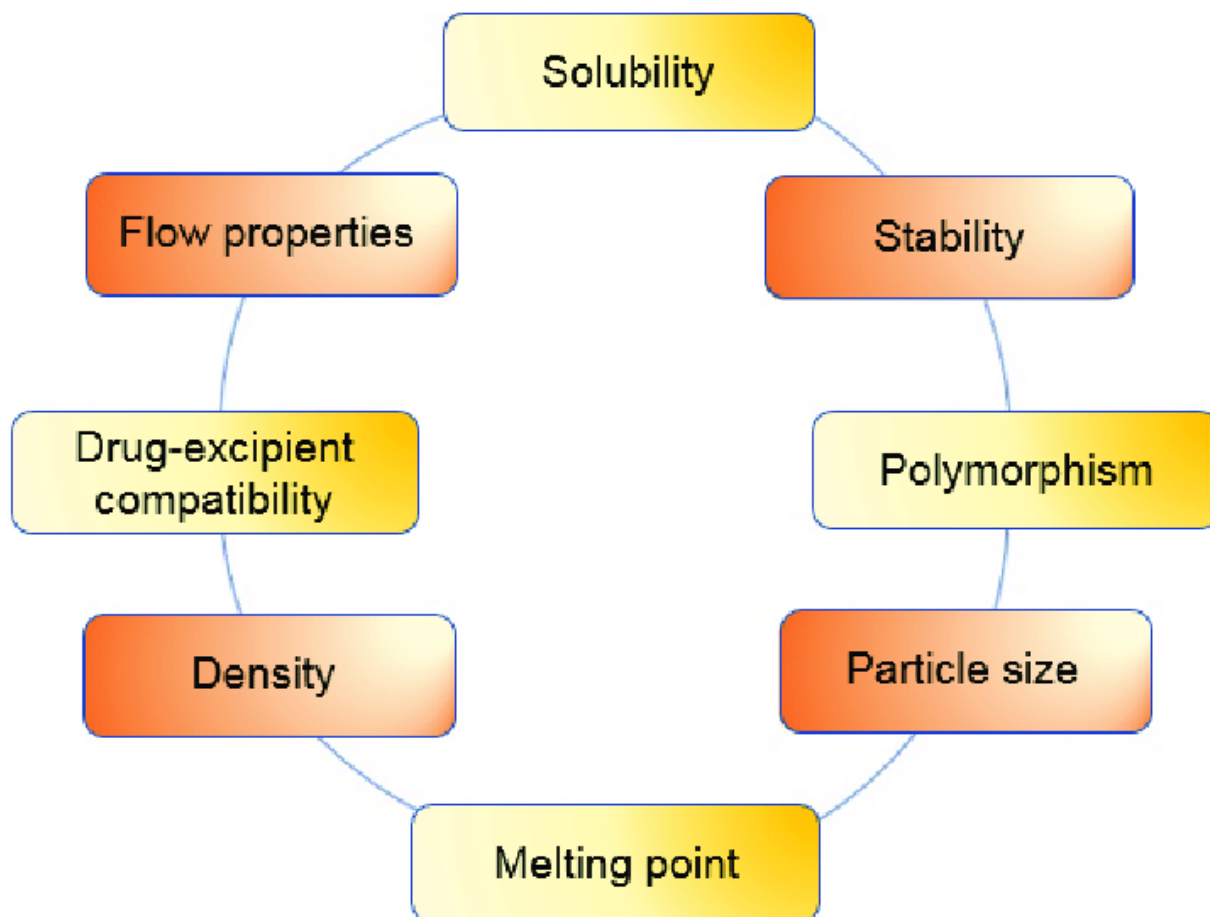
PRE-FORMULATION STUDIES

Preformulation studies can be defined as laboratory studies to determine the characteristics of active substance and excipient that may influence formulation and process design and performance. The preformulation is a group of studies that emphasize the physicochemical properties of new drug candidate and combination with the excipient that affect drug performance.^[6,7]

III. OBJECTIVES

- 1) To develop the stable, effective and safer dosage form.
- 2) To provide useful information to design a new drug delivery system with better Bioavailability
- 3) To establish the physicochemical parameter of new drug.
- 4) To generate useful data needed in developing a safe dosage form that can be manufactured on a commercial scale.

IV. PRE-FORMULATION PARAMETER



Capsules differ from tablets in that tablets are compressed forms of a medication, while capsules contain a drug by putting active pharmaceutical ingredients and excipients inside a capsule. There are a number of different capsule dosage forms, each with its distinctive advantages, strengths, and weaknesses. They include dosage forms in which drug substance is enclosed within hard or soft soluble shell. The shells are generally formed from gelatin.

Capsules are of two types 1. Hard gelatin capsules 2. Soft gelatin capsules. Capsules are tasteless, odourless and can easily be administered. Combination of powders we can use. There are attractive in appearance. The drugs having un-pleasant odour and taste are enclosed in a tasteless shell. They can be filled quickly and conveniently. Physician can change the dose and combination of drug according to patient requirement. They are economical. They are easy to handle and carry. Hygroscopic are not suitable for filling into capsules, because they absorb water present in capsule shell makes shell very brittle and ultimately lead to crumble into pieces. The concentrated solutions which require previous dilution are unsuitable for capsules because if administered as such lead to irritation into stomach. For human use, empty capsules ranging in size from 000 the largest to 5 the smallest. Generally, hard gelatin capsule is used to encapsulate between 65 mg to 1 gram.



Gelatin is heterogeneous product derived by hydrolytic extraction of animal's collagen. The sources of gelatin including animal bones, hide portions and frozen pork skin.

There are two basic types of gelatin TYPE A Derived from acid treated precursor that exhibits an iso electric point at pH-9. It is manufactured mainly from pork skin. TYPE B Derived from alkali treated precursor that exhibits an iso electric point at pH-4.7. It is manufactured mainly from animal bones.

Steps involved in making empty gelatin capsules- 1.Dipping2.Spinning3.Drying4.Stripping5.Trimming and Joining 6.Polishing
Manufacturing of hard gelatin capsules

- Dipping - Pairs of the stainless steel pins are dipped into the dipping solution to simultaneously form the caps and bodies. The dipping solution is maintained at a temperature of about 500 C in a heated, jacketed dipping pan.
- Spinning - The pins are rotated to distribute the gelatin over the pins uniformly and to avoid the formation of a bead at the capsule ends.
- Drying -The gelatin is dried by a blast of cool air to form a hard shell. The pins are moved through a series of air-drying kilns to remove water
- Stripping - A series of bronze jaws strip the cap and body portions of the capsules from the pins
- Trimming and joining- The stripped cap and body portions are trimmed to the required length by stationary knives. After trimming to the right length, the cap and body portion are joined and ejected from the machine.
- Polishing -Acela-cota pan is used to dust and polish. Cloth Dusting Capsule are rubbed with cloth. Brushing Capsule are feed under soft rotating brush.

➤ Preparation of filled hard gelatin capsules:

In large scale or small preparations of filled hard gelatin capsules divided into the following general steps: Developing and preparing formulation. Filling the capsule shell Capsule sealing Cleaning and polishing the filled capsules.

➤ Developing and preparing the formulation

- o Diluents and fillers: lactose, microcrystalline cellulose, starch.
- o Disintegrants: sodium starch glicolate, pregelatinised starch
- o Gligants and lubricants: silicon dioxide, magnesium stearate, calcium stearate
- o Wetting agents: SLS

V. FILLING OF HARD GELATIN CAPSULES

Hand Operated methods. ex: Feton capsule filling machine

Semi-Automatic Capsules Devices.

Automatic filling machine. ex: Osaka capsule filling machine, macofar capsule filling machine

HAND OPERATED CAPSULE FILLING MACHINE- It is having following parts-

- a) Bed having 200-300 holes.
- b) Loading tray having 200-300 holes.
- c) Powder tray.
- d) Pin Plate having 200-300 pins.
- e) Sealing plate having rubber top.
- f) Lever
- g) Cam handel

Capsule may also be sealed through a heat welding process that fuse capsule cap to the body. Lightly coating the inner surface of the cap with a warm gelatin solution immediately prior to placement on the filled capsule body. Soft Gelatin capsules are one piece, hermetically sealed, soft gelatin shells containing a liquid, a suspension, or a semisolid. Soft gelatin is mainly composed of gelatin, plasticizers, preservative, colouring and opacifying agents, flavoring agents and sugars.

The shape of soft gelatin capsule are round, oval, oblong, tube.

1) Composition of the shell

The basic component of soft gelatin shell is gelatin; however, the shell has been plasticize .The ratio of dry plasticizer to dry gelatin determines the “hardness” of the shell and can vary from 0.3-1.0 for very hard shell to 1.0-1.8 for very soft shell Up to 5% sugar may be included to give a “chewable” quality to the shell .The residual shell moisture content of finished capsules will be in the range of 6-10%.

2) Formulation: □

Formulation for soft gelatin capsules involves liquid, rather than powder technology. Materials are generally formulated to produce the smallest possible capsule consistent with maximum stability, therapeutic effectiveness and manufacture efficiency. The liquids are limited to those that do not have an adverse effect on gelatin walls. Emulsion can not be filled because water will be released that will affect the shell . The pH of the liquid can be between 2.5 and 7.5.

Soft gelatin is manufactured by four methods

- Plate process
- Rotary die process
- Reciprocating die
- Accogel machine

vehicles used in soft gelatin capsules: Two main groups :1.Water immiscible, volatile or more likely more volatile liquids such as vegetable oils, mineral oils, medium-chain triglycerides and acetylated glycerin. 2.Water miscible, nonvolatile liquids such as low molecular weight PEG have come in to use more recently because of their ability to mix with water readily and accelerate dissolution of dissolved or suspended drugs. All liquids used for filling must flow by gravity at a temperature of 350 C or less. The sealing temperature of gelatin films is 37-400 C

HARD GELATIN CAPSULES 1) Two piece (large body & short cap)

2) Cylindrical shape.

3) Powder drug or pallets coated with drug are encapsulated.

4) Gelatin in Hard form is used.

5) Capsules are sealed after they are filled to ensure that the medicaments may not come out of the capsule due to rough handling.

6) 8 different type of sizes are available.

SOFT GELATIN CAPSULES

1) One piece & hermetically sealed.

2) Available in round, oval & tube-like shapes.

3) Liquid & Semi liquid fill & unstable substances are encapsulated.

4) Molten gelatin is used.

5) Filling & sealing of soft gelatin capsules are done in a combined operation on machine. 6) No specific sizes are available.

Evaluation of capsule drug products

Drug product testing is generally divided into three stages:

- In-process testing, during the manufacture of the drug product. These batteries of tests are carried out at predefined intervals during the product manufacturing, by the manufacturing personnel, and their results recorded on the batch record. Adverse findings in these tests can be used as a guide to alter the manufacturing-process parameters.
- Finished product testing, after the whole batch has been manufactured. These tests help identify whether the batch is acceptable for marketing or its intended usage.
- Shelf-life testing, after the whole batch has been packaged. These tests are frequently carried out after defined periods of storage at predetermined conditions. They help to assign and verify the shelf life and usability of the drug product.

➤ In-process tests

Visual inspection of soft gelatin capsules is done to ensure absence of clearly malformed, damaged, or improperly filled capsules. During the encapsulation of soft gelatin capsules, the following parameters are usually closely monitored and controlled:

- Gel ribbon thickness and uniformity across the ribbon
- Seal thickness
- Weight of the capsule fill and its variation from capsule-to-capsule
- Weight of the capsule shell and its variation from capsule-to-capsule
- Moisture level of the capsule shell before and after drying

➤ Finished product quality control tests

○ Permeability and sealing

Soft gelatin capsules are tested for physical integrity (absence of leakage) by visual inspection. Similarly, hard gelatin capsules are tested for any breach of physical integrity (breakage or opened cap and body).

○ Potency and impurity content

All capsules are tested for drug content (potency, as a percent of label claim). In addition, most drug products are tested for the related substances or impurities. These must meet predefined specifications for a batch to be acceptable.

○ Average weight and weight variation

Ten hard gelatin capsules are usually weighed individually and the contents are removed. The emptied shells are individually weighed and the net weight of the contents is calculated by subtraction. The content of active ingredient in each capsule may be determined by calculation based on the percent drug content in the formulation for high drug load formulations.

For soft gelatin capsules, the gross weight of 10 gelatin capsules is determined individually. Then each capsule is cut open, and the contents are removed by washing with a suitable solvent (that dissolves the fill but not the shell). The solvent is allowed to evaporate at room temperature, followed by weighing of the individual washed shells. The net contents are calculated by subtraction and the content of active ingredient in each of the capsules can be determined by calculation based on the percent drug content in the formulation

○ Uniformity of content

Uniformity of content of the active ingredient can be determined by weight variation of the fill of hard or soft gelatin capsules for high drug load (API $\geq 25\%$ w/w of the total fill weight), high fill-weight (250 mg/capsule) formulations. For low drug load and low fill-weight formulations, each capsule must be analyzed individually by the potency method for the content of the active ingredient. The uniformity of content is assured if predetermined criteria for the range and variation in the content of the active ingredient are met.

○ Disintegration

Disintegration of hard and soft gelatin capsules is evaluated to ensure that the drug substance is fully available for dissolution and absorption from the GI tract. The disintegration media varies depending on the type of capsules to be tested.

○ Dissolution

Drug absorption and physiological availability depend on the drug substance being in the dissolved state at the site of drug absorption, viz. the GI fluids. The rate and extent of dissolution of the drug from the capsule dosage form is tested by a dissolution test. Dissolution test provides means of quality control in ensuring that (a) different batches of the drug product have similar drug release characteristics and (b) that a given batch has similar dissolution as the batch of capsules that was shown initially to be clinically effective.

○ Moisture content

Water content of the entire capsule or the capsule contents are determined by Karl Fisher titrimetric to enable the correlation of water content with the degradation profile or drug-release characteristics of capsules.

o Microbial content

The capsules are tested to ensure lack of growth of bacteria and mold by microbiological tests. These tests are usually carried out by incubation of the capsule contents in a growth medium and counting the colonies formed after a predefined period of time. Selection of the growth medium and duration of the test, as well as maintenance of aseptic conditions during the testing, are critical to successful assessment of microbial contamination by this method.

o Shelf-life tests

Stability testing of capsules is performed to determine the physicochemical stability of the active drug molecule in the finished drug product under specified package and recommended storage conditions. Shelf-life tests are usually same as the finished product tests. Since the shelf life of the product at recommended storage conditions can be long, the product is often subjected to accelerated (higher than normal levels of environmental conditions) storage for predicting shelf life under recommended storage conditions. These storage conditions that are accelerated for stability testing include temperature, humidity, and light.

For example, for a product intended for sale in the United States with recommended storage at room temperature and ambient humidity, real-time stability is carried out at 25°C and 60% relative humidity (RH) with periodic testing up to the recommended shelf life, for example, 2 years. Accelerated stability testing on such a product is usually carried out at 40°C and 75% RH for a limited duration of time, for example, 3 months. The exact conditions for real-time and accelerated storage testing depend on the geographic and climatic region where the drug product is intended to be manufactured and marketed

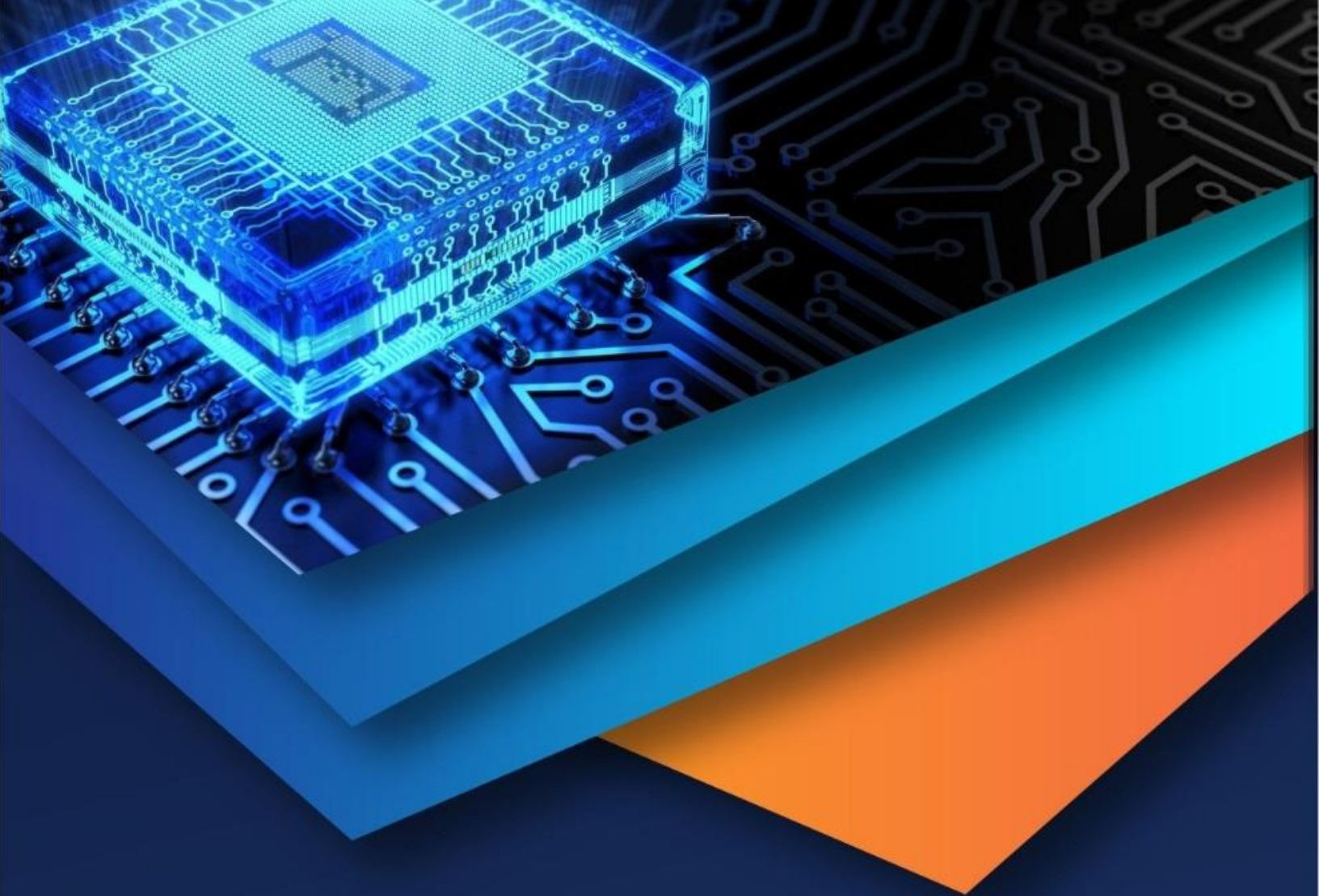
VI. CONCLUSION

Formulation development's conclusion is that it is a critical, multifaceted process integral to pharmaceutical success, transforming active drug molecules into safe, effective, and patient-friendly treatments. Through meticulous design, testing, stability studies, and scale-up, it bridges the gap from concept to patient, influencing quality, efficacy, safety, and market viability. Advances in technology and a deep understanding of physicochemical properties are vital for overcoming challenges and ensuring successful, accessible, and innovative healthcare solutions. The formulation development studies along with the pre-formulation studies include the various tests, research & the S.O.P handling. These are the important parameter of the pharmaceutical industries without these pharmaceutical industries does not conduct properly and the quality efficiency. New problems arise during development and it cannot be solve until required efforts with knowledge not met. Formulation development's conclusion is that it is a critical, multifaceted process integral to pharmaceutical success, transforming active drug molecules into safe, effective, and patient-friendly treatments. Through meticulous design, testing, stability studies, and scale-up, it bridges the gap from concept to patient, influencing quality, efficacy, safety, and market viability. Advances in technology and a deep understanding of physicochemical properties are vital for overcoming challenges and ensuring successful, accessible, and innovative healthcare solutions

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