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A Comprehensive Review on Formulation Development and Stability of Drug Products

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ABSTRACT :

Pharmaceutical formulation development plays a central role in transforming an active pharmaceutical ingredient (API) into a safe, effective, and patient-friendly medicine. Beyond simply mixing ingredients, this process requires understanding the drug's physical and chemical properties, selecting compatible excipients, and designing a dosage form that can deliver the drug reliably Tablets, capsules, liquids, semisolids, and injectable preparations are all developed with specific goals—such as improving stability, enhancing bioavailability, masking taste, or ensuring controlled drug release.

The field has advanced significantly from its historical roots, when medicines were mainly derived from natural plant materials. Modern formulation development is now supported by scientific principles, advanced technology, and strict regulatory requirements. Good Manufacturing Practices (GMP) guide manufacturers to maintain quality at every step by ensuring proper documentation, process control, and equipment maintenance.

Key stages of formulation include drug characterization, excipient compatibility testing, formulation design, optimization, and comprehensive evaluation. Stability testing is essential to confirm that a product remains safe, effective, and free from harmful degradation throughout its shelf life. The use of Standard Operating Procedures (SOPs) and proper equipment handling further ensures consistency, accuracy, and regulatory compliance.

Tablet compression machines—whether single-punch units used in development or rotary presses used for large-scale production—highlight the importance of controlling process parameters to achieve uniform weight, hardness, and overall tablet quality.Overall, formulation development is a multidisciplinary effort that combines science, quality systems, and technology to bring stable and effective pharmaceutical products to patients.

INTRODUCTION

Formulation Development

Dosage form is a transformation of pure chemical compound into predetermined form by admixing drug compound with different kinds of non drug components collectively known as adjuvants or excepients having specific functions. In other words, dosage forms are the mechanism by which drug molecules are administered to the siwords, dosage for the body to generate their therapeutic effects. The need for dosage forms is for accurate dose, protection from environment (coated tablets and sealed ampoules), protection from gastric juice, masking taste and odour, placement of drugs within body tissues, sustained release medication, controlled release medication, insertion of drugs into body cavities (rectal, vaginal) and use of desired vehicle for insoluble drugs. Depending on the method/route of administration, dosage forms come in several types. These include many kinds of liquid, solid, and semisolid dosage forms such as tablet, capsules, syrups, suppositories, creams, powders, eye drops, ear drops, suppositories etc.[1]

The creation of a commercial drug product is closely tied to the identification of a new drug ingredient, which is a key aspect of pharmaceutical formulation development. Formulation experts must assess patient requirements and determine the optimal approach for effective drug delivery. This involves enhancing the formulation's characteristics by understanding its bioavailability and the processing needs of the therapeutic product.[2]

Pharmaceutical formulation is the multistep process where the active drug is mixed with all other components by considering the factors of particle size, polymorphism, pH, and solubility and becomes the final beneficial medicinal product. Benefits and constraints of the active pharmaceutical ingredients (APIs), valuable excipients, associated interactions, and manufacturing procedure are the four basic components for a successful pharmaceutical formulation.

The formulation often functions in a way that includes different dosage forms. The dosage form is the pharmaceutical drug product as marketed for use with a specific mixture of active ingredients and inactive components. It has to be a particular configuration(capsule shell, for example) and distributed into a particular dose.[3]

The process in which different chemical substances, drug(s) and excipients, are combined to fabricate a final medicinal product of a desired dosage form. Pharmaceutical products are formulated products with specific dosage forms for efficient delivery and product stability.Formulation development serves

the purpose to determine the optimal dosage form, composition and manufacturing route for pharmaceutical products.There are different kinds of pharmaceutical dosage forms such as Oral tablets, Capsules, Solutions, Suspensions ,Topical ointments Gels Injections for intravenous(IV),intramuscular (IM),or subcutaneous(SC)administration.[4]

History

Natural materials such as plants, herbs, roots, vines, and fungi were used to make the first pharmaceuticals. The only means of relieving human pain and suffering up to the middle of the 1800s was through natural medications. As a sedative-hypnotic, chloral hydrate was the first synthetic medicine created it is still in use today. It was discovered in 1869 in several nations currently. The first pharmaceutical enterprises were the textile and synthetic dye industries' mirror images, and they owed a great deal to the abundant supply of organic compounds that could be obtained by distilling coal (coal-tar). The first analgesics were antipyretics, which were made from coal tar byproducts called phenacetin and acetanilide, which are chemical derivatives of aniline and p-nitrophenol. A bark extract from the white willow tree was utilized.[5]

Concept of cGMP

Good Manufacturing Practices or GMP is a system that consists of processes, procedures and documentation that ensures manufacturing products, such as food, cosmetics, and pharmaceutical goods, are consistently produced and controlled according to set quality standards. Implementing GMP can help cut down on losses and waste, avoid recall, seizure, fines and jail time. Overall, it protects both company and consumer from negative food safety events. GMPs examine and cover every aspect of the manufacturing process to guard against any risks that can be catastrophic for products, such as cross-contamination, adulteration, and mislabeling. Some areas that can influence the safety and quality of products that GMP guideline and regulation.[6]

Good Manufacturing Practice (GMP)

a. Pharmaceutical manufacturing must adhere to GMP regulations,

which set standards for the design, monitoring, and control of manufacturing processes and facilities. GMP ensures that pharmaceutical products are consistently produced and controlled according to quality standards.

b. Quality Control Testing:

Manufacturing involves rigorous testing of raw materials, intermediates, and finished products to verify compliance with specifications and standards. Quality control testing ensures that pharmaceutical products meet predefined quality attributes, such as potency, purity, and stability.

c. Process Validation:

Pharmaceutical manufacturers conduct process validation studies to demonstrate that manufacturing processes consistently produce pharmaceutical products that meet predefined specifications and quality attributes. Process validation ensures the reliability and reproducibility of manufacturing processes.[6]

STEPS IN FORMULATIONS

1. Identification and characterization of drug:

The identification of characterization of drug is so much important because it very much affect the final product and also the effect of various characters make drug more potent or toxic.

2. Excipients Compatibility Study*:*

More the excipient compatible with drug more the chances of drug formulation success and effect of drug also increase.

3. Formulation development :

The next stage deals with the formulation development so that witch chemicals goes with witch and witch excipients is suitable for drugs.

4. Formulation Optimization :

In this stage formulation like vaccine are produces this type of formulation have lots of studies than normal formulation and large amount of the knowledge needed.

5. Formulation Evaluation:

The evaluation studies help to improve the already made formulation by changing the part of formulation like the vehicle types.

6. Stability Studies:

It deals with the stability of the formulation by doing various tests so that the stability of formulation increase it also helps to improves the shelf life of formulation.[7]

Drug-excipient incompatibilities

Pharmaceutical incompatibilities are generally referred to as changes in the physical, chemical and/or therapeutic properties of a dosage form resulting from the interaction of the API with excipients or other components of the drug product[8] A wide variety of factors influence the nature and extent of drug-excipient interactions. These factors include the physico-chemical properties of the drugs and the excipients, relative ratios and proximity of these components in the formulations, and other processing and environmental factors. In addition, the reactive impurities present in the excipients are also known to initiate such interactions.[9]The drug-excipients interactions can be broadly classified as either physical or chemical interactions.[10]

Excipients compatibility study

The safety, efficacy, quality and stability of a formulation are the cornerstones of any new drug development process. In order to consistently maintain these attributes in a finished dosage form, it is important to have a comprehensive understanding of the physico-chemical characteristics of the active pharmaceutical ingredient(API) as well as all other components (e.g. excipients, manufacturing aids, packaging materials) of the drug product. In a new drug development process, a detailed characterization of the API and other formulation components is usually carried out during the preformulation stage. The preformulation stage involves characterization of several aspects of the API including solubility, dissolution, permeability, polymorph/salt screening, stability (solid-state and solution-state), ionization properties, particle size distribution, API-excipient compatibilities etc.[11]. Excipients are ubiquitous to virtually every pharmaceutical formulation, and facilitate the manufacture, stability, administration, delivery of the API and provide other functionalities to the dosage form. Excipients are used to improve processing (e.g. improving powder flow powder compactibility etc.), enhance aesthetics e.g. identification, branding etc[12]. optimize product performance (e.g. modified drug-release , and to facilitate patient compliance (e.g. taste masking. They may constitute anywhere from 1 to 99 % of the total formulation mass.
Due to the intimate contact of the API with one or more excipients in a formulation, there exists a likelihood of physical and chemical interactions between them. Any such interactions may result in a negative impact on the physical, stability or performance attributes of the drug product [11,12]. The choice of excipients is of crucial importance to avoid these negative effects, and to facilitate the development of a robust and an effective formulation. Thus, for a rational selection of excipients, screening of excipient-API compatibility is recognized as an important aspect of formulation development. Moreover, the USFDA 21st century current Good Manufacturing Practices (cGMP) initiative and International Council on Harmonization (ICH) Q8 guidelines encourage the pharmaceutical manufacturers to apply Quality by Design (QbD) principles in their drug development process.[13,14] These guidelines include expectations of a clear understanding of any interactions between the formulation components. Moreover, recent advances in various thermal and non-thermal analytical techniques have led to an improved efficiency in the detection, monitoring and prevention of the incompatibilities early in the drug development process.[15]

Formulation development

Pharmaceutical formulation is the multistep process where the active drug is mixed with all other components by considering the factors of particle size, polymorphism, pH, and solubility and becomes the final beneficial medicinal product. Pharmaceutical formulation is the formation of a pharmaceutical product, including a drug's chemical properties, formulation, and details of the treatment protocol to be implemented in the clinical application.[16]

STEPS IN FORMULATIONS DEVELOPMENTS

A. Validation and Characterization of Drug

The validation & characterization of drug is so much important because it affect the final product.

B. Drug Additive Compatibility Study

More the additive compatible with drug more the chances of drug formulation success and effect of drug is also increase.[16]

C. Formulation Development

The next stage is formulation development in which chemicals goes with excipient and forms drugs.

D. Formulation Optimization

In this stage formulation like vaccine are produces this type of formulation have lots of studies than normal formulation and large amount of the knowledge needed.[17]

E. Formulation Assessment

The assessment studies help to enhance the already accomplished formulation by substitute the part of formulation like the solvent types

- **Stability Studies**

It includes the stability of the formulation by performing tests so that the stability of formulation increase it also helps to improve the shelf life of formulation.[16,18,19]

IMPORTANCE OF STABILITY TESTING

The primary reason for stability testing is the concern for the well-being of the patient suffering from the disease for which the products is designed.

Apart from degradation of the unstable product into toxic decomposition products, loss of activity up to a level of 85% of that claimed on the label may lead to failure of the therapy resulting in death e.g. nitroglycerine tablets for angina and cardiac arrest.

Because of this concern, it has become a legal requirement to provide data for certain types of stability tests for the regulatory agencies before approval of a new product. Second important concern is to protect the reputation of the manufacturer by assuring that the product will retain fitness for use with respect to all functionally relevant attributes for as long as they are on the market. Other benefits of stability studies at the developmental stage or of the marketed products are to provide a database that may be of value in selection of adequate formulations, excipients and container closure systems for development of a new product, to determine shelf life and storage conditions for development of a new product, preparation of registration dossier, to substantiate the claimed shelf life for the registration dossier and to verify that no changes have been introduced in the formulation or manufacturing process that can adversely affect the stability of the product.[20,21]

SOP handling :-

Definition:

A Standard Operating Procedure (SOP) is a written, detailed, step-by-step instruction set that describes how to carry out a specific task or operation consistently and reliably under defined conditions. It serves to minimize variation, ensure quality, and maintain uniform performance even when different personnel execute the task.[22]

SOPs are living documents: they must be routinely reviewed, updated, and enforced, or else their effectiveness degrades.[23]

Standard Operating Procedures (SOPs) are formalized, written documents that describe in detail the sequential steps necessary to perform specific tasks consistently, reliably, and safely under defined conditions. SOPs are widely adopted across industries and sectors- including healthcare, pharmaceuticals, laboratories, manufacturing, and research institutions- to ensure procedural uniformity, quality control, and regulatory compliance (e.g., "a set of written instructions that document a routine or repetitive activity.[24]

1. Clarity: SOPs must be written in simple, clear, and unambiguous language to avoid confusion.[25]
2. Defined roles: Each SOP should clearly assign duties and responsibilities to personnel.[26]
3. Version control: SOPs require version numbers, dates, and periodic reviews for accuracy.[27]
4. Training: Proper staff training ensures effective implementation of SOPs. [28]
5. Monitoring: Regular audits and feedback maintain compliance and continuous improvement.[29]

a. Preparation of SOPs for different instruments and equipment

SOPs are written, detailed instructions that describe how to perform a given procedure consistently, safely, and reproducibly.For instruments and equipment (in labs, manufacturing, clinical, regulatory settings etc.) SOPs help ensure

Consistency of operations (so that different operators use the instrument in the same way) Safety (prevent misuse or hazards.[30] Traceability and accountability (who did what, when) Compliance with regulatory or quality standards (GxP, ISO, GLP, GMP, etc.) While many principles are general, there are instrument-specific considerations:

1. Analytical / measurement instruments (e.g. spectrophotometers, HPLC, GC, balance, pH meter): calibration, drift checks, blank checks, standard verification, sensitivity checks, blank runs
2. Life science / biological instruments (e.g. PCR machines, centrifuges, cell culture equipment) contamination controls, sterilization, biosafety procedures, calibration of temperature, rotor balancing
3. Mechanical industrial equipment (e.g. mixers, milling machines) preventive maintenance, lubrication schedules, mechanical tolerances, alignment checks
4. Cleanroom or GMP equipment: environmental monitoring, cleaning validation, qualification and requalification, cGMP procedures
5. Medical / clinical instruments: compliance with regulatory standards (e.g. ISO 13485, medical device standards), validation, calibration traceability, patient safety protocols
6. In each case, the SOP must reflect the risk, critical parameters, and regulatory requirements for that instrument.[31]

Various equipment and instruments handling

Proper handling of pharmaceutical equipment and instruments is fundamental to ensuring quality, safety, and regulatory compliance under Good Manufacturing Practices (GMP)[32]

Objectives

To maintain accuracy and precision in measurements and analytical results
To avoid contamination and cross-contamination between batches.
To ensure reliable performance over time, reducing downtime and errors.
To comply with GMP guidelines and regulatory expectations [32,33]

Key Steps in Handling

a. Installation and Qualification

Installation Qualification (IQ): verify that equipment is installed properly per specifications. Operational Qualification (OQ): test that equipment functions within defined limits.

Performance Qualification (PQ): confirm that equipment performs reliably during actual use [52]

b. Calibration

Use traceable standard reference materials or calibration standards. Calibration should be periodic, with records maintained in a calibration log. After repair or relocation, equipment should be re-qualified.

c. Cleaning and Maintenance

Establish cleaning protocols that prevent residue carryover or contamination.

Preventive maintenance schedules should be documented and followed.
After cleaning or maintenance, check performance before returning to use.

d. Operation and Training

Operators must be trained in standard operating procedures (SOPs) for use, safety, and troubleshooting. Use check lists for start-up, operation, and shutdown procedures.

e. Performance Monitoring and Validation

Periodic re-verification ensures on going performance (e.g., drift, reproducibility). Use control charts or trend analysis to monitor instrument stability over time. Maintain error logs and corrective actions for deviations.

f. Documentation and Records

All steps (qualification, calibration, maintenance, cleaning) must be documented in a log or instrument history file.Records should include date, personnel, results, deviations, and corrective actions.[32,33,34]

Tablet compression machine

A tablet compression machine (tablet press) converts a powder/granule blend into tablets by filling dies and applying mechanical compression using punches. There are two main families: single-punch (eccentric) presses used for R&D and small batches, and rotary multi- station presses used for high-throughput commercial manufacture.[35]

Main components

Hopper & feed frame : holds blend and meters powder into dies.

Die and punches :mold shape; upper (pressure) and lower (dwell) punches compress powder.

Turret (rotary) or ram (single-punch) : carries dies/punches through filling and compression stations.

Compression rolls precompression and main compression : coften two-stage compression (pre-compression then main compression) to reduce defects.

Ejection and tablet handling : removes finished tablets and transfers them to collection.
Components and feed-frame details described in industry reviews.[36]

Basic working principle (stepwise)

Pow-der flows from hopper into die cavity (die filling).

Excess powder is scraped/controlled by the feed frame.

Pre-compression roll (if present) consolidates the bed to reduce trapped air.

Main compression roll applies force via punches to form the tablet.[37]

Punches retract and tablet is ejected.

Compression force, fill depth (controlled by lower punch position), and turret speed determine tablet weight and hardness.

Critical process parameters & quality links

Compression force dwell time : affects tablet hardness, friability, dissolution.
Fill depth punch position : controls tablet weight/uniformity.
Turret speed throughput : can influence dwell time and thus tablet mechanical properties.
Powder properties & feeding behaviour (flowability, particle size, lubrication) determine die filling consistency.
These relationships are widely covered in instrumented press and process-analysis studies.[38]

Instrumentation & modern advances

Instrumented presses (force sensors, in-line weight and thickness sensors) enable R&D and PAT (process analytical technology). Automation & in-line inspection (100% weight/thickness checks, vision systems) improve quality control. Machine learning / AI is being explored for defect detection and predictive control of tablet properties. Recent studies demonstrate ML integration for in-line detection and multi-task prediction of tablet attributes.[39]

Practical considerations (selection & maintenance)

Choose single-punch for lab-scale/formulation screening; rotary press for production scale and shapes/throughput. Tooling (punch/die) quality and correct L/D selection matter for tablet integrity. Regular calibration, punch/die polishing, lubrication system checks, and cleaning SOPs reduce downtime and defects.[38,39]

Tablet coater

Tablet is an example of unit dosage, which is being compressed after mixing of active constituents and another additive so that a proper shape may be given to the tablet. This is the medication in a compressed formSolid measure formulations unit of measurement necessary measure forms in prescription drugs. Solid dosage form includes tablets, capsules, granules, sachets, powders, dry powder inhalers, and chewable. A unit dose of one or more medications is contained in the solid measure kind. Binders, glidants, sweeteners, and other excipients are all examples of excipients.[40]

Basic principles involve in tablet coating

Tablet coating is the application of coating composition to moving bed of tablets with concurrent use of heated air to facilitate evaporation of solvent.

I. Solution in which influences the release pattern as little as possible and does not markedly change the appearance.
II. Modified release with specific requirement and release mechanism adapted to body function in the digestive tract.
III. Color coating which provides insulation.
IV. To incorporate another drug or formula adjuvant in the coating to avoid chemical In compatibilities or to provide sequential drug release.
V. To improve the pharmaceutical elegance by use of special colors and contrasting printing.[41]

Coating equipment

A modern tablet coating system combines several components:

a. A coating pan
b. A spraying system
c. An air handling unit
d. A dust collector

Capsule filling machine

A capsule filling machine is a mechanical device utilized to fill empty capsules with pharmaceutical ingredients such as powders, granules,

semisolids, or liquids. These machines are essential in the pharmaceutical industry for encapsulating active pharmaceutical ingredients (APIs) into dosage forms, facilitating accurate dosing and consistent quality control**.**

Fluidized bed dryer

A fluidized bed dryer (FBD) is an industrial drying equipment widely used in the pharmaceutical, food, and chemical industries. It operates by passing a heated gas (usually air) through a bed of particulate solids at a velocity sufficient to suspend the particles, causing them to behave like a fluid. This fluidization enhances heat and mass transfer, leading toefficient and uniform drying of materials.[42]

Extruder and spheronizer

Extruder: an extruder is a piece of industrial machinery used to produce plastic materials. This technology is the basis of many industries and plays a crucial role in creating the objects we use every day.[43]
An extruder is a continuous processing machine that forces a formulation through a heated barrel fitted with one or more screws and a die to produce a shaped or granulated product. In pharmaceutical manufacturing, its principal form is the hot-melt extrusion (HME) unit, often a single- or twin-screw extruder, used for mixing, melting, conveying, and converting drug- polymer blends into solid dispersions, granules, pellets or solid oral dosage forms.[44]

Working Principle
Raw materials (active pharmaceutical ingredient + polymer/excipients) are fed into the extruder barrel, where thermal energy and mechanical shear melt or soften the polymer matrix and disperse the API. The screw(s) convey the polymer-drug melt forward, building pressure and mixing, before it is forced through a die or pelletiser. The extrudate cools and solidifies to the desired form. Key parameters include barrel temperature profile, screw speed, screw design/configuration (especially for twin-screw), feed rate, residence time, and die geometry.[45]

Applications in Pharma

Improving bioavailability of poorly water-soluble drugs by forming amorphous solid dispersions (ASD).
Continuous manufacturing: consolidating multiple unit operations (mixing, melting, shaping) into one extruder, reducing scale-up issues.
Production of sustained-release, controlled-release, transdermal systems, implants, pellets, and dosage forms requiring polymer matrices.

Advantages

*Solvent-free or minimal solvent process, better for moisture/solvent-sensitive APIs. Good content uniformity and dispersion due to melt mixing***.**

Continuous process, scalable, fewer unit operations and reduced footprint. Improved stability of API/polymer systems compared to some other methods.

Spheronizer
Spheronization, also known as Marumerization, is the third step in the extrusion spheronization process. It was first introduced by Nakahara in 1964. It involves dumping the extruded cylinders onto the spinning plate of the spheronizer, called the friction plate, in which the extrudate is broken up into smaller cylinders with an equal length to their diameter.13 These plastic cylinders are rounded due to frictional forces14. Different stages can be distinguished depending upon the particle shape, i.e. it starts from a cylinder over a cylinder with rounded edges, dumb bells and elliptical particles to eventually perfect spheres. This process may be divided into 3 steps such as breaking of the cylindrical segments or extrudate, agglomeration of the broken segments and smoothing of the particles.[46]

A spheronizer is a pharmaceutical equipment used to convert cylindrical extrudates into spherical pellets. It is an essential step following extrusion in the extrusion spheronization process, which is widely used for producing uniform, dense, and free-flowing pellets for controlled drug delivery systems.[47]

Principle
The spheronization process is based on the rolling and collision of wet extrudates on a rapidly rotating friction plate, leading to rounding and densification of the particles. The centrifugal and frictional forces generated by the rotating plate cause the extrudates to break, collide, and for spheres.[48]

Working Process

Feeding: Wet extrudates from the extruder are loaded into the spheronizer.

Rounding: The extrudates are subjected to centrifugal force on the rotating plate, breaking into smaller lengths.

Spheronization: The fragments roll and collide to form spherical pellets.
Drying: Pellets are dried in a fluid bed dryer to obtain the final product.[49]

Applications

Production of pellets for controlled-release formulations
Taste masking and multiparticulate drug delivery systems
Coating and encapsulation processes

Advantages

Produces uniform, spherical pellets with good flow and packing properties

Enhances drug release control and coating efficiency

Suitable for high-dose and combination formulations.[50]

Conclusion

Pharmaceutical formulation development is a detailed and essential process that turns an API into a medicine that patients can use safely and effectively. It requires understanding how a drug behaves, selecting the right excipients, and creating a dosage form that delivers the drug in a reliable way. Modern formulation work is supported by scientific research, advanced analytical tools, and strict regulatory systems such as GMP and well-designed SOPs. These ensure that each step—from preformulation and compatibility studies to manufacturing and quality testing produces consistent and high-quality results.

Stability testing further confirms that the product remains safe and effective throughout its shelf life. Proper handling of equipment and validation of processes also help maintain accuracy and prevent contamination. Overall, formulation development is a coordinated effort that combines science, technology, and quality practices to produce medicines that are stable, effective, and beneficial for patients.

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