iJRASET
International Journal For Research in Applied Science and Engineering Technology



INTERNATIONAL JOURNAL FOR RESEARCH

IN APPLIED SCIENCE & ENGINEERING TECHNOLOGY

Volume: 14 **Issue:** X **Month of publication:** October 2026

DOI: https://doi.org/10.22214/ijraset.2026.85371

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International Journal for Research in Applied Science & Engineering Technology (IJRASET)
ISSN: 2321-9653; IC Value: 45.98; SJ Impact Factor: 7.538
Volume 14 Issue X Oct 2026- Available at www.ijraset.com

A Review on Formulation Development

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Abstract: ***Pharmaceutical formulation development is a fundamental component of drug product development that involves transforming an active pharmaceutical ingredient (API) into a safe, effective, stable, and patient-acceptable dosage form. The process integrates pre formulation studies, excipient selection, formulation design, manufacturing process optimization, analytical evaluation, stability assessment, and regulatory compliance. The physicochemical properties of the drug, including solubility, dissolution rate, particle size, polymorphism, permeability, and stability, significantly influence the selection of an appropriate dosage form and delivery strategy. Conventional dosage forms, such as tablets, capsules, suspensions, emulsions, creams, and injections, remain essential in pharmaceutical practice, while novel drug delivery systems offer opportunities to improve bioavailability, therapeutic effectiveness, patient compliance, and controlled drug release. Modern formulation development increasingly incorporates Quality by Design (QbD), Design of Experiments (DoE), risk assessment, and advanced analytical technologies to establish a systematic and science-based development process. Regulatory guidelines provide a framework for pharmaceutical development, quality risk management, and lifecycle quality assurance. Despite considerable progress, challenges related to poor aqueous solubility, drug instability, manufacturing scalability, cost, and regulatory complexity continue to influence product development. This review discusses the fundamental principles, stages, techniques, evaluation parameters, applications, challenges, and emerging trends in pharmaceutical formulation development. The integration of scientific understanding, innovative delivery technologies, and systematic quality management can contribute to the development of robust pharmaceutical products that meet patient needs and established quality standards.***

Keywords: Pharmaceutical formulation; drug delivery systems; preformulation studies; excipients; Quality by Design; Design of Experiments; pharmaceutical development; drug stability; novel drug delivery systems.

I. INTRODUCTION

Pharmaceutical formulation development is the scientific process of designing and optimizing a drug product by combining an active pharmaceutical ingredient with suitable excipients and manufacturing techniques. Its primary purpose is to ensure that the drug can be administered safely and conveniently while maintaining the required quality, stability, and therapeutic performance throughout its intended shelf life.

An API alone may not possess the physical, chemical, or biopharmaceutical properties required for effective administration. For example, a drug may exhibit poor aqueous solubility, unpleasant taste, inadequate stability, poor flow properties, or limited permeability. Formulation development addresses these challenges by selecting an appropriate dosage form, excipient system, manufacturing process, and drug delivery strategy.

The development process begins with a clear understanding of the drug substance and its intended therapeutic use. Subsequent activities include preformulation characterization, prototype formulation preparation, optimization, quality testing, stability studies, and scale-up. Pharmaceutical formulation development therefore requires an interdisciplinary approach involving pharmaceutics, pharmaceutical chemistry, pharmacology, biopharmaceutics, analytical chemistry, engineering, and regulatory science.

Modern pharmaceutical development has moved beyond conventional trial-and-error experimentation toward systematic approaches that incorporate scientific knowledge, risk assessment, and predefined quality objectives. Quality by Design provides an important framework for understanding the relationship between formulation variables, manufacturing parameters, and final product quality [1,2]. <Cite refs={["turn913626search7","turn913626search16"]}/>

II. OBJECTIVES OF PHARMACEUTICAL FORMULATION DEVELOPMENT

The principal objectives of formulation development are:

1) To develop a safe, effective, stable, and reproducible pharmaceutical product.
2) To improve drug solubility, dissolution, bioavailability, or permeability when required.
3) To select suitable excipients that support the intended performance of the dosage form.
4) To provide an appropriate route of administration and dosage form.

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5) To achieve the desired drug release profile, including immediate, delayed, sustained, or controlled release.
6) To improve patient acceptability, convenience, and adherence to treatment.
7) To establish suitable manufacturing procedures and quality control specifications.
8) To ensure compatibility with packaging materials and protection against environmental factors.
9) To support compliance with applicable pharmacopoeial and regulatory requirements.
10) To develop a formulation that can be manufactured consistently at the intended commercial scale.

These objectives must be considered together because an improvement in one characteristic, such as dissolution rate, may adversely affect another, such as physical stability or manufacturability.

III. STAGES OF PHARMACEUTICAL FORMULATION DEVELOPMENT

A. *Drug candidate and target product identification*

The first stage involves defining the therapeutic purpose of the product, intended patient population, route of administration, dose, desired onset and duration of action, and anticipated market requirements.

The Quality Target Product Profile (QTPP) describes the intended characteristics of the final product. These may include dosage form, strength, route of administration, release characteristics, stability, container closure system, and relevant quality attributes.

A clearly defined QTPP helps guide subsequent formulation decisions and provides a basis for determining whether the developed product meets its intended objectives.

B. *Preformulation studies*

Preformulation studies characterize the physical and chemical properties of the drug substance before extensive formulation development begins. The information obtained helps identify potential formulation difficulties and guides the selection of excipients and manufacturing methods [3].

1) *Physical characterization*

Physical characterization may include:

- Appearance, colour, and physical state.
- Particle size and particle size distribution.
- Crystal form and polymorphism.
- Powder flow properties.
- Bulk and tapped density.
- Hygroscopicity and moisture content.
- Melting behaviour and thermal properties.

Particle size can influence dissolution rate, content uniformity, suspension stability, and powder handling. Crystal form may affect solubility, dissolution, and physical stability.

2) *Chemical characterization*

Chemical characterization evaluates the chemical stability and reactivity of the API. Relevant studies include pH-dependent degradation, oxidation, hydrolysis, photodegradation, and interactions with formulation components.

Analytical methods such as high-performance liquid chromatography (HPLC), ultraviolet-visible spectroscopy, and suitable stability-indicating techniques may be used according to the properties of the drug.

3) *Solubility and dissolution studies*

Solubility studies determine how much drug dissolves in selected solvents and aqueous media under defined conditions. Measurements may be performed at different pH values and temperatures where scientifically justified.

Dissolution studies evaluate the rate and extent of drug release from a dosage form under specified test conditions. These investigations are particularly important for orally administered products because dissolution may influence the availability of drug for absorption.

Strategies for addressing poor solubility include particle-size reduction, salt formation, pH modification, solid dispersions, lipid-based systems, complexation, and suitable surfactants. The appropriateness of each strategy depends on the drug's physicochemical properties and the intended dosage form.

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4) Drug–excipient compatibility

Compatibility studies investigate possible physical or chemical interactions between the API and proposed excipients. Techniques such as differential scanning calorimetry, Fourier-transform infrared spectroscopy, chromatographic analysis, and accelerated storage studies may provide useful information.

However, a change in a thermal or spectroscopic signal alone does not necessarily establish an incompatibility. Results should be interpreted alongside appropriate analytical and stability evidence.

C. Selection of excipients

Excipients are ingredients incorporated into a pharmaceutical formulation to support manufacture, stability, drug release, appearance, or administration. Their selection depends on the dosage form, API properties, route of administration, intended patient population, and applicable safety requirements.

Common excipient categories include:

Excipient category	Main function	Examples
Diluents or fillers	Increase dosage-form bulk	Lactose, microcrystalline cellulose
Binders	Promote particle adhesion	Povidone, suitable starches
Disintegrants	Facilitate tablet breakup	Croscarmellose sodium, crospovidone
Lubricants	Reduce friction during compression	Magnesium stearate
Glidants	Improve powder flow	Colloidal silicon dioxide
Preservatives	Limit microbial growth where appropriate	Selected parabens, benzalkonium chloride
Antioxidants	Reduce oxidative degradation	Ascorbic acid, selected tocopherols
Surfactants	Improve wetting or solubilization	Polysorbates, sodium lauryl sulfate
Suspending agents	Support dispersion stability	Xanthan gum, suitable cellulose derivatives

The examples are illustrative rather than universally suitable. Excipients must be selected according to route-specific safety, concentration, compatibility, functionality, and regulatory acceptability. Excipients intended for oral use, for example, cannot automatically be assumed suitable for parenteral administration.

D. Selection of the dosage form

The dosage form determines how the drug is presented for administration and can substantially influence convenience, stability, release characteristics, and therapeutic performance.

Common dosage forms include:

- Solid dosage forms: Tablets, capsules, powders, and granules.
- Liquid dosage forms: Solutions, syrups, suspensions, and emulsions.
- Semisolid dosage forms: Creams, ointments, gels, and pastes.
- Parenteral dosage forms: Sterile injections and infusions.
- Inhalation dosage forms: Metered-dose inhalers, dry-powder inhalers, and nebulizer preparations.
- Transdermal dosage forms: Drug-containing patches designed to deliver drug through the skin.
- Modified-release dosage forms: Products designed to change the rate, timing, or location of drug release.

Selection should be based on the API, therapeutic objective, patient requirements, manufacturing feasibility, and evidence supporting the intended product performance.

E. Formulation design and prototype development

After preformulation characterization and excipient selection, initial formulations are prepared using suitable manufacturing techniques. Prototype batches allow the formulator to examine the effects of ingredient proportions and process conditions on product characteristics.

For tablets, development may involve direct compression, wet granulation, or dry granulation. For suspensions, important factors include particle size, wetting, viscosity, sedimentation, and redispersibility. For emulsions, the formulation must be designed to provide acceptable droplet size, physical stability, and appropriate administration characteristics.

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Early prototypes should be evaluated against predefined quality objectives. Formulations that fail to meet essential performance or stability requirements can then be modified systematically.

F. Formulation optimization

Optimization aims to identify formulation compositions and process conditions that consistently meet the target product requirements.

Traditional approaches frequently rely on changing one variable at a time. Although simple, this method may fail to identify interactions between variables. Design of Experiments offers a more systematic method for studying the effects of multiple factors and their interactions.

Common experimental designs include:

- Factorial designs.
- Fractional factorial designs.
- Central composite designs.
- Box–Behnken designs.
- Mixture designs.

Potential factors include polymer concentration, binder concentration, compression force, granulation conditions, mixing time, and drying temperature. Responses may include drug content, dissolution, tablet hardness, friability, particle size, viscosity, or drug release.

The selected design should be appropriate for the scientific question, number of factors, expected relationships, and available experimental resources. Experimental findings must be confirmed using suitable verification batches rather than relying solely on statistical model predictions.

G. Manufacturing process development

A formulation that performs well at laboratory scale may not behave identically during pilot or commercial production. Manufacturing process development therefore evaluates how equipment, batch size, mixing, temperature, pressure, moisture, and processing time affect product quality.

Relevant operations may include weighing, blending, granulation, drying, milling, compression, coating, filling, sterilization, and packaging. Process parameters should be selected and controlled based on their demonstrated influence on critical quality attributes. Scale-up should also consider equipment differences, process reproducibility, material variability, and the suitability of in-process controls.

H. Quality control and stability testing

The final formulation must undergo appropriate testing to demonstrate compliance with established specifications and intended performance. Stability studies evaluate whether the product maintains its required quality throughout storage under defined conditions. Stability-indicating analytical methods, suitable packaging, and scientifically justified storage conditions are essential components of product development. Study design and acceptance criteria should follow the applicable regulatory requirements for the product and market.

IV. CONVENTIONAL PHARMACEUTICAL FORMULATIONS

A. Tablets

Tablets are widely used because they can provide accurate doses, convenient administration, good portability, and relatively economical manufacturing. Important formulation considerations include powder flow, blend uniformity, compressibility, lubrication, disintegration, dissolution, mechanical strength, and moisture sensitivity.

Direct compression is appropriate when the API and excipient blend possess suitable flow and compaction properties. Wet or dry granulation may be used when improvements in flow, compressibility, or content uniformity are required.

B. Capsules

Capsules contain drugs in powder, granule, pellet, liquid, or other suitable forms, depending on the capsule design and material compatibility. Development considerations include fill-weight uniformity, shell compatibility, moisture control, drug release, and stability. Hard capsules and soft capsules have different manufacturing and formulation requirements.

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C. Suspensions and emulsions

Suspensions contain dispersed solid particles in a liquid vehicle, whereas emulsions contain one liquid phase dispersed in another immiscible liquid phase.

Suspensions require suitable control of sedimentation, aggregation, particle size, viscosity, and redispersibility. Emulsions require appropriate emulsifiers and control of droplet size, creaming, coalescence, and other instability mechanisms.

D. Semisolid formulations

Creams, ointments, and gels are commonly developed for topical administration. Important attributes include homogeneity, viscosity, spreadability, drug release, physical stability, microbial quality, and compatibility with the container.

The vehicle and excipient system can influence drug partitioning, release, skin contact, and patient acceptability. Claims concerning enhanced skin penetration or therapeutic superiority require appropriate supporting evidence.

V. NOVEL DRUG DELIVERY SYSTEMS

Novel drug delivery systems are designed to improve drug delivery by modifying the rate, location, or pattern of administration and release. Their usefulness depends on the API, delivery route, therapeutic need, safety profile, and manufacturing feasibility.

A. Nanoparticle-based delivery systems

Nanoparticle formulations include polymeric nanoparticles, lipid nanoparticles, and other nanoscale carriers. Depending on their composition, they may improve drug dispersion, protect sensitive compounds, alter release characteristics, or support delivery to particular tissues.

Critical formulation attributes may include particle size distribution, morphology, surface properties, drug loading, encapsulation efficiency, residual solvents where relevant, and physical stability.

The presence of nanoscale particles does not automatically guarantee improved bioavailability, targeted delivery, or reduced toxicity. Such benefits must be demonstrated for the particular formulation.

B. Liposomes

Liposomes are vesicular systems composed primarily of phospholipid bilayers. They can accommodate suitable hydrophilic compounds in their aqueous compartments and lipophilic compounds within their lipid regions.

Important development considerations include vesicle size, drug loading, leakage, lipid oxidation, storage stability, sterilization compatibility, and manufacturing reproducibility.

C. Solid lipid nanoparticles and nanostructured lipid carriers

Solid lipid nanoparticles use a solid lipid matrix, while nanostructured lipid carriers generally incorporate a combination of solid and liquid lipids. These systems may be investigated for poorly water-soluble drugs and for selected oral, topical, or other delivery applications. Their development requires careful assessment of lipid composition, drug incorporation, particle characteristics, release behaviour, and storage stability.

D. Controlled- and sustained-release formulations

Controlled-release formulations are designed to modify drug release over time. Common approaches include hydrophilic matrix tablets, coated pellets, reservoir systems, and biodegradable polymeric carriers.

The intended release profile must be supported by suitable dissolution testing and, where necessary, additional evidence linking in vitro performance to in vivo behaviour. Formulation design must also consider dose dumping, food effects, and the risks associated with altered drug release.

E. Transdermal drug delivery systems

Transdermal patches deliver selected drugs through the skin for systemic action. They may offer convenient administration and reduce the need for frequent dosing in appropriate circumstances.

Key attributes include drug content, adhesion, release rate, permeation, residual drug, irritation potential, and physical stability. Not all drugs are suitable for transdermal delivery because skin permeability, required dose, molecular properties, and irritation risks limit applicability.

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F. Other emerging delivery platforms

Additional approaches include microneedle systems, in situ gelling formulations, long-acting injectable depots, implantable systems, and selected biologic delivery technologies.

These platforms may address specific limitations of conventional administration, but their development often requires specialized manufacturing, more complex characterization, and extensive evaluation of safety and performance.

VI. QUALITY BY DESIGN IN PHARMACEUTICAL FORMULATION DEVELOPMENT

Quality by Design (QbD) is a systematic, science-based approach that aims to build product quality into formulation and process design rather than relying exclusively on testing the finished product. Its principles are described in the International Council for Harmonisation (ICH) pharmaceutical development guidance [1].

Important elements include the following.

A. Quality Target Product Profile

The QTPP describes the intended quality characteristics of the drug product, including dosage form, strength, route, release characteristics, stability, and other relevant attributes.

B. Critical Quality Attributes

Critical Quality Attributes (CQAs) are physical, chemical, biological, or microbiological characteristics that must remain within appropriate limits, ranges, or distributions to ensure product quality. Depending on the dosage form, CQAs may include assay, impurities, content uniformity, dissolution, sterility, particle size, viscosity, or drug release.

C. Critical material attributes and process parameters

Critical Material Attributes (CMAs) are properties of starting materials or excipients that may affect product quality. Critical Process Parameters (CPPs) are process variables whose variability can affect CQAs.

Examples include API particle size, polymer grade, excipient moisture content, mixing time, granulation endpoint, drying conditions, and compression force.

D. Risk assessment

Quality risk management helps identify, evaluate, and prioritize potential threats to product quality. Tools such as failure mode and effects analysis, risk-ranking matrices, and cause-and-effect diagrams may be used where appropriate.

ICH Q9(R1) describes principles and tools for risk-based decisions across pharmaceutical development and manufacturing [2]. <Cite refs={["turn913626search3","turn913626search13"]}/>

E. Design Space and Control Strategy

A design space is a scientifically justified combination and interaction of input variables and process parameters demonstrated to provide assurance of product quality. Its establishment requires suitable experimental and process knowledge.

A control strategy integrates material controls, process controls, in-process testing, finished-product testing, and other appropriate measures to maintain consistent quality.

QbD can improve process understanding and support more efficient development, although its implementation requires reliable data, suitable analytical methods, appropriate expertise, and adequate resources.

VII. EVALUATION PARAMETERS FOR PHARMACEUTICAL FORMULATIONS

Evaluation tests should be selected according to the dosage form, intended route, relevant pharmacopoeial requirements, and product-specific risks.

Formulation type	Important evaluation parameters
Tablets	Appearance, dimensions, mass variation or uniformity of dosage units, assay, disintegration, dissolution, friability, mechanical strength
Capsules	Appearance, fill uniformity, assay, dissolution, disintegration where applicable, moisture control
Suspensions	Particle size, sedimentation, redispersibility, viscosity, assay, microbial quality where applicable

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Emulsions	Droplet size, phase separation, viscosity, assay, physical and chemical stability
Semisolid preparations	Homogeneity, viscosity or rheology, assay, drug release, microbial quality, stability
Parenteral products	Sterility, bacterial endotoxins where applicable, particulate matter, assay, impurities, pH, container integrity
Nanoparticle formulations	Particle size distribution, polydispersity, morphology, drug loading, release, impurities, stability
Transdermal patches	Drug content, adhesion, release, permeation, residual drug, physical stability

These parameters are examples rather than a universal specification. Test methods, acceptance criteria, and sampling plans must be justified for the individual product. For example, sterility testing is relevant to products required to be sterile, not to every pharmaceutical formulation.

VIII. STABILITY STUDIES IN FORMULATION DEVELOPMENT

Stability studies establish how the quality of a pharmaceutical product changes with time under the influence of environmental factors such as temperature, humidity, and light.

Major types of stability assessment include:

1) Accelerated studies: Conducted under defined conditions to investigate degradation and support development decisions.
2) Long-term studies: Conducted under appropriate storage conditions to establish the product's stability profile and support shelf-life assignment.
3) Photostability studies: Evaluate susceptibility to light-induced changes where relevant.
4) In-use stability studies: Assess quality during the intended period after opening, reconstitution, dilution, or preparation for administration.
5) Packaging compatibility studies: Evaluate whether the container closure system protects the product and avoids unacceptable interactions, including moisture transfer, sorption, leaching, or loss of volatile components where applicable.

Stability-indicating methods should be capable of distinguishing the API from relevant degradation products and other potential interferences. Shelf life should be assigned from appropriate data and applicable regulatory guidance rather than inferred from accelerated studies alone.

IX. REGULATORY CONSIDERATIONS

Regulatory compliance is essential throughout formulation development because a pharmaceutical product must meet applicable requirements for quality, safety, efficacy, and manufacturing control.

ICH guidance provides an internationally harmonized framework for pharmaceutical development and quality management. Three particularly relevant guidelines are:

- ICH Q8(R2): Pharmaceutical Development. Describes pharmaceutical development principles and provides a framework for understanding product and process design [1].
- ICH Q9(R1): Quality Risk Management. Provides principles and tools for evaluating and managing risks to pharmaceutical quality [2].
- ICH Q10: Pharmaceutical Quality System. Describes a model for a pharmaceutical quality system throughout the product lifecycle [4].

The ICH Q10 framework emphasizes lifecycle quality management, including process performance monitoring, corrective and preventive actions, change management, and continual improvement. <Cite refs={{["turn913626search7","turn913626search13","turn913626search11"]}/>

In India, applicable requirements may include relevant provisions of the Drugs and Cosmetics Act and Rules, Indian Pharmacopoeia standards, and current requirements or guidance issued by the Central Drugs Standard Control Organisation (CDSCO) and other competent authorities.

The precise regulatory pathway depends on whether the product is a new drug, a generic product, a biologic, a modified-release formulation, or another regulated category. Regulatory expectations should therefore be confirmed for the intended product and market.

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X. APPLICATIONS OF PHARMACEUTICAL FORMULATION DEVELOPMENT

Formulation development has applications across several areas of pharmaceutical science and healthcare.

1) Improving drug solubility and bioavailability: Formulation strategies may improve wetting, dissolution, drug dispersion, or solubilization for selected poorly soluble drugs. The effect on actual bioavailability must be demonstrated when clinically or regulatorily relevant.
2) Improving patient compliance: Appropriate dosage forms, taste masking, orally disintegrating tablets, simplified administration, and suitable modified-release systems may improve convenience for selected patients.
3) Pediatric and geriatric formulations: Children and older adults may require dosage forms that allow accurate dosing, acceptable taste, manageable administration, and appropriate swallowing characteristics. Excipients and dose flexibility require particular consideration in these populations.
4) Localized and targeted delivery: Selected carriers and delivery platforms may be developed to increase drug exposure at a desired site or modify systemic exposure. Targeting performance and any claimed safety advantages must be demonstrated through appropriate studies.
5) Reformulation and lifecycle management: Existing medicines may be reformulated to improve stability, administration, manufacturability, or patient convenience. Changes to formulation, manufacturing processes, or packaging should be supported by appropriate comparability, quality, and stability data.

XI. CHALLENGES IN PHARMACEUTICAL FORMULATION DEVELOPMENT

Despite advances in formulation science, several challenges remain.

1) Poor aqueous solubility: Many drug candidates exhibit limited aqueous solubility, which can restrict dissolution and absorption. Solubility-enhancement strategies must be balanced against chemical stability, physical stability, manufacturability, and potential safety concerns.
2) Drug and excipient incompatibility: Interactions between the API and excipients may affect potency, impurities, appearance, dissolution, or shelf life. Compatibility assessment should begin early and continue as the formulation evolves.
3) Scale-up and manufacturing variability: Differences in equipment, batch size, mixing, heat transfer, and material handling can influence product quality during scale-up. Appropriate process characterization and validation are therefore important.
4) Cost and resource limitations: Advanced analytical instruments, specialized materials, pilot manufacturing facilities, and stability studies can increase development costs. Efficient experimental design and risk-based decision-making may help focus resources on the most important variables.
5) Complexity of novel drug delivery systems: Nanocarriers, biologic formulations, and long-acting systems may require complex manufacturing and characterization. Reproducibility, long-term stability, sterilization compatibility, and commercial-scale production remain important considerations.
6) Regulatory and supply-chain challenges: Changes in regulatory expectations, variability in raw materials, supplier disruptions, and inadequate process knowledge can affect product development and continued commercial supply. Lifecycle quality management and effective supplier oversight help address these risks.

XII. EMERGING TRENDS AND FUTURE PERSPECTIVES

A. *Artificial intelligence and machine learning*

Artificial intelligence and machine learning are increasingly being explored to analyze formulation datasets, identify relationships among material attributes and process variables, and support prediction of selected product characteristics.

Their usefulness depends on data quality, appropriate model validation, interpretability, and experimental confirmation. Predictive tools should support, rather than replace, pharmaceutical scientific judgment.

B. *Advanced experimental design*

DoE and related statistical approaches can reduce unnecessary experimentation and help characterize interactions between formulation components and manufacturing conditions. More advanced optimization methods may be particularly useful for complex systems with multiple interacting variables.

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C. Continuous manufacturing

Continuous manufacturing offers opportunities for integrated processing, real-time monitoring, and potentially more consistent production. Its successful implementation requires appropriate process understanding, control systems, material-flow management, and regulatory alignment.

D. Process

Process Analytical Technology (PAT) involves suitable measurements and analysis of critical material and process characteristics during manufacturing. Depending on the application, tools may include spectroscopy, imaging, particle monitoring, and other in-line or at-line techniques.

PAT can improve process understanding and monitoring when the methods are appropriately developed, validated, and integrated into the control strategy.

E. Personalized and patient-centred formulations

Personalized pharmaceutical approaches may include individualized dose strengths, tailored release profiles, age-appropriate dosage forms, and selected uses of additive manufacturing. Practical adoption depends on dose accuracy, reproducibility, material suitability, manufacturing controls, and regulatory requirements.

F. Sustainable pharmaceutical manufacturing

Future formulation development is likely to place greater emphasis on reducing waste, solvent use, energy consumption, and unnecessary material processing while preserving product quality and patient safety. Sustainable choices must remain compatible with product performance and applicable quality standards**.**

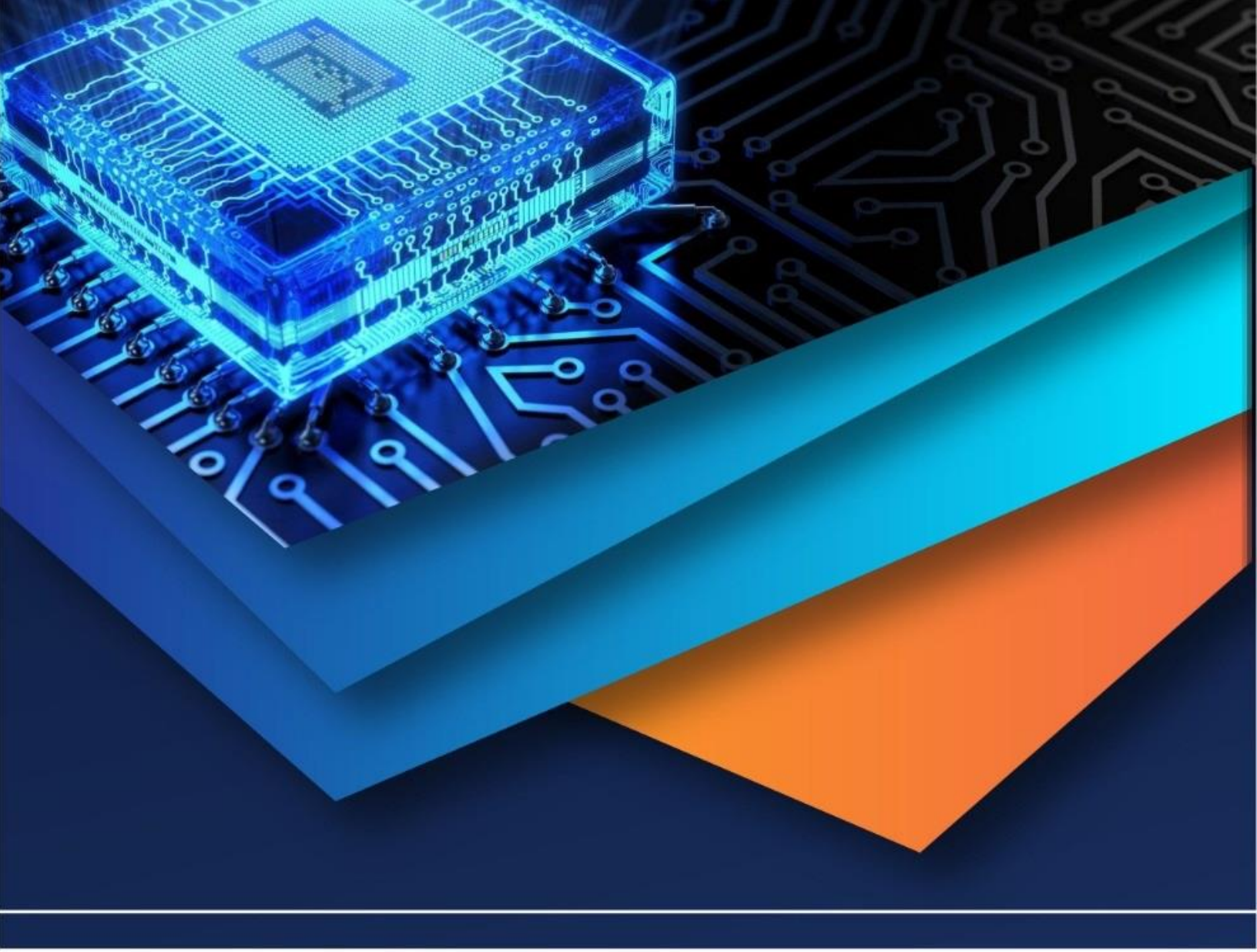
XIII. CONCLUSION

Pharmaceutical formulation development is essential for converting an active pharmaceutical ingredient into a suitable drug product that meets predefined quality requirements and patient needs. The process involves preformulation characterization, excipient selection, dosage-form design, manufacturing development, optimization, quality evaluation, stability assessment, and regulatory compliance. Conventional formulations continue to play a major role in healthcare, while novel drug delivery systems offer additional approaches for addressing selected limitations of drug administration and release. Quality by Design, Design of Experiments, and risk-based quality management provide systematic frameworks for improving process understanding and product consistency. Future progress will depend on integrating formulation science with reliable analytical methods, advanced manufacturing technologies, appropriate computational tools, and sustainable development practices. Ultimately, successful formulation development must be demonstrated through robust evidence that the finished product meets its intended quality, safety, and performance requirements.

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