iJRASET
International Journal For Research in Applied Science and Engineering Technology



INTERNATIONAL JOURNAL FOR RESEARCH

IN APPLIED SCIENCE & ENGINEERING TECHNOLOGY

Volume: 14 **Issue:** XI **Month of publication:** November 2026

DOI: https://doi.org/10.22214/ijraset.2026.85665

www.ijraset.com

Call: 08813907089 | E-mail ID: ijraset@gmail.com

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 XI Nov 2026- Available at www.ijraset.com

A Review on Formulation Development

Manish Kumar Tiwari[1], Mr. Sujeet Pratap Singh[2], Mr. Pramod Mishra[3], Dr. Tarkeshwar P. Shukla[4]
S.C.P.M College of Pharmacy, Lucknow Road Haripur Gonda

Abstract: ***Formulation development is a fundamental component of pharmaceutical science that involves designing and optimizing a dosage form to ensure the safety, efficacy, stability, quality, and acceptable performance of a drug product. It bridges pharmaceutical research and commercial manufacturing by integrating knowledge of pharmaceutics, pharmaceutical technology, biopharmaceutics, analytical chemistry, and regulatory science. The process includes preformulation studies, excipient selection, dosage-form design, optimization of formulation variables, manufacturing-process development, quality evaluation, stability testing, and scale-up. Modern formulation development increasingly incorporates Quality by Design (QbD), risk assessment, design of experiments (DoE), nanotechnology, and advanced drug-delivery systems to improve therapeutic outcomes and manufacturing consistency. Challenges such as poor aqueous solubility, inadequate bioavailability, drug–excipient incompatibility, stability problems, and manufacturing variability require systematic scientific investigation. This review discusses the major stages of pharmaceutical formulation development, commonly used dosage forms, evaluation parameters, regulatory considerations, recent technological advances, and future perspectives. A systematic and patient-centred formulation strategy can support the development of reliable, effective, and high-quality medicines.***

Keywords: Formulation development, pharmaceutical formulation, preformulation, excipients, drug delivery systems, Quality by Design, bioavailability, stability testing.

I. INTRODUCTION

Formulation development is the systematic process of converting an active pharmaceutical ingredient (API) into a suitable pharmaceutical dosage form for administration to patients. The API alone may not possess the physical, chemical, or biopharmaceutical characteristics required for effective and convenient drug delivery. Therefore, appropriate formulation strategies are necessary to ensure accurate dosing, adequate drug release, acceptable stability, patient compliance, and reproducible therapeutic performance. In pharmacy, formulation development is an important part of pharmaceutics and pharmaceutical technology. It involves selecting suitable excipients, determining the composition of the product, establishing a manufacturing procedure, and evaluating the quality of the resulting dosage form. Formulation scientists must understand the physicochemical properties of the drug, its intended route of administration, the target patient population, and the therapeutic objective.

For example, an immediate-release tablet is designed to release the drug promptly after administration, whereas an extended-release tablet is developed to release the drug over a longer period. Similarly, topical formulations are designed to deliver a drug to or through the skin, while parenteral formulations require stringent controls for sterility and other product-specific quality attributes.

Modern pharmaceutical development emphasizes building quality into a product rather than relying solely on testing the finished product. The International Council for Harmonisation (ICH) Q8(R2) guideline describes pharmaceutical development principles that support product understanding, process knowledge, and science-based quality management [1]. Thus, formulation development is not merely the mixing of ingredients; it is a structured scientific activity connecting drug properties, dosage-form design, manufacturing, and patient needs.

II. OBJECTIVES OF FORMULATION DEVELOPMENT

The primary objective of formulation development is to produce a safe, effective, stable, and reproducible pharmaceutical product. The major objectives include:

1) Improving drug stability: Protecting the API against degradation caused by moisture, oxygen, light, heat, or unsuitable pH.
2) Enhancing bioavailability: Improving drug dissolution, absorption, or delivery where scientifically appropriate.
3) Ensuring dose accuracy: Providing a uniform amount of drug in each unit or measured dose.
4) Optimizing drug release: Designing immediate-, delayed-, or modified-release characteristics according to therapeutic requirements.
5) Improving patient compliance: Developing acceptable dosage forms in terms of size, taste, ease of administration, and dosing frequency.

©IJRASET: All Rights are Reserved

6) Ensuring product quality: Meeting applicable requirements for identity, strength, purity, performance, and other relevant quality attributes.
7) Supporting manufacturing feasibility: Establishing a process that can be reproduced consistently at the intended production scale.
8) Controlling cost: Selecting materials and manufacturing methods that support reliable production and practical access to treatment.

III. MAJOR STAGES OF PHARMACEUTICAL FORMULATION DEVELOPMENT

Formulation development typically follows a sequence of connected activities. The exact order and extent of testing depend on the API, dosage form, route of administration, intended use, and regulatory requirements.

A. *Preformulation Studies*

Preformulation is the initial investigation of the physical, chemical, and biopharmaceutical properties of an API before a final dosage form is selected. It provides the scientific foundation for formulation design.

Important preformulation parameters include:

- Physical appearance: Colour, odour, crystalline form, and general physical characteristics.
- Solubility: Solubility in relevant aqueous and non-aqueous media, including the influence of pH.
- Dissolution: The rate at which the drug dissolves under specified conditions.
- Particle size and distribution: These can influence dissolution, blend uniformity, flow, and content uniformity.
- Polymorphism and crystallinity: Different solid forms may exhibit different solubility, stability, and processing characteristics.
- Hygroscopicity: The tendency of the material to absorb moisture.
- Melting behaviour and thermal properties: These may provide information about solid-state characteristics and processing limitations.
- Chemical stability: Susceptibility to hydrolysis, oxidation, photolysis, or other degradation pathways.
- Drug–excipient compatibility: Potential interactions between the API and proposed formulation ingredients.

Preformulation findings guide the selection of excipients, dosage form, packaging, and manufacturing conditions. For example, a poorly water-soluble drug may require particle-size reduction, a suitable surfactant, a solid dispersion, or another evidence-supported solubility-enhancement strategy.

B. *Selection of Dosage Form*

The dosage form is selected according to the properties of the drug and the needs of the patient. Factors include the intended route of administration, required dose, onset and duration of action, drug stability, absorption characteristics, and manufacturing feasibility. Common dosage forms include tablets, capsules, powders, granules, oral liquids, suspensions, emulsions, creams, ointments, gels, injections, inhalation products, transdermal patches, and ophthalmic preparations. Oral tablets and capsules are widely used because they can offer convenient administration, accurate dosing, portability, and economical manufacturing. However, liquid formulations may be more appropriate for patients who have difficulty swallowing solid dosage forms. Sterile products require additional controls appropriate to their route and formulation.

C. *Selection of Excipients*

Excipients are substances other than the API that are included in a formulation to support manufacturing, stability, administration, or drug release. Their selection must consider functionality, compatibility, quality, safety, and the intended route of administration.

Excipient category	Main function	Common examples
Diluents	Increase bulk and support dose uniformity	Lactose, microcrystalline cellulose
Binders	Promote cohesion of powder particles or granules	Povidone, starch paste
Disintegrants	Promote tablet breakup after administration	Croscarmellose sodium, crospovidone
Lubricants	Reduce friction during compression or ejection	Magnesium stearate
Glidants	Improve powder flow	Colloidal silicon dioxide
Preservatives	Limit microbial growth in suitable formulations	Methylparaben, benzalkonium chloride
Antioxidants	Reduce oxidation where appropriate	Ascorbic acid, sodium metabisulfite
Surfactants	Improve wetting or solubilization	Polysorbates, sodium lauryl sulfate
Suspending agents	Help maintain dispersion of insoluble particles	Xanthan gum, sodium carboxymethylcellulose

The selection of an excipient is not based only on its general function. Concentration, grade, compatibility, route-specific safety, and effects on product performance must also be evaluated. Excipients that are suitable for one route of administration may not be suitable for another.

D. Formulation Design and Optimization

Once preliminary studies are complete, trial formulations are prepared and evaluated. The formulation scientist investigates the effects of ingredient type, concentration, and processing conditions on product quality.

For a tablet, important variables may include the proportion of binder and disintegrant, granulation liquid quantity, drying conditions, lubrication time, and compression force. For a suspension, particle size, suspending-agent concentration, viscosity, and redispersibility may be important.

Optimization aims to identify a formulation that meets predefined quality and performance requirements. Rather than selecting a formulation solely on the basis of one favourable test result, multiple relevant responses should be considered together**.**

E. Manufacturing-Process Development

A suitable manufacturing process is established after evaluating the material properties and desired product characteristics. Common processes include direct compression, wet granulation, dry granulation, milling, blending, drying, encapsulation, coating, homogenization, emulsification, and aseptic processing where applicable.

For tablets, direct compression may be appropriate when the API and excipients possess adequate flow and compression properties. Granulation may be required when powder flow, compressibility, or blend uniformity is inadequate.

Manufacturing parameters should be controlled because variations in mixing, moisture, temperature, particle size, or compression can affect the finished product. Process understanding and appropriate controls are therefore essential for consistent quality [2].

F. Evaluation of the Formulation

The prepared formulation is assessed using tests relevant to its dosage form and intended performance. These may include physical, chemical, microbiological, and biopharmaceutical evaluations.

For tablets, common assessments include appearance, dimensions, weight variation, mechanical strength, friability, disintegration, dissolution, assay, and content uniformity. For capsules, tests may include appearance, fill-weight variation, assay, disintegration, and dissolution. Liquid formulations may require pH, viscosity, assay, microbial quality, sedimentation behaviour, and redispersibility testing.

These tests help determine whether the formulation meets its predefined specifications. The selection of tests and acceptance criteria should be justified according to applicable pharmacopoeial standards, product-specific requirements, and regulatory guidance**.**

G. Stability Studies

Stability studies determine how the quality of a drug product changes over time under specified environmental conditions. They support the establishment of appropriate storage conditions, packaging selection, and shelf life.

Potential degradation factors include temperature, humidity, light, oxygen, and interactions with packaging materials. Stability evaluation may involve appearance, assay, degradation products, dissolution, pH, moisture content, and other product-specific parameters.

The results should be interpreted using the relevant stability protocol and regulatory guidance. A product should not be assigned a shelf life merely on the basis of short-term observations; adequate supporting stability data are required.

H. Scale-Up and Technology Transfer

A formulation that performs well at laboratory scale may behave differently during pilot or commercial manufacturing. Differences in equipment geometry, mixing efficiency, heat transfer, drying capacity, and material handling can affect product quality.

Scale-up involves transferring a scientifically understood process to a larger production scale while maintaining the intended quality attributes. Technology transfer requires appropriate documentation, defined responsibilities, equipment and process knowledge, and evidence that the receiving site can manufacture the product consistently.

Process validation and continued monitoring help establish and maintain confidence in commercial manufacturing [2,3]. Changes to a marketed formulation or its manufacturing process may also require appropriate regulatory assessment and supporting data [4]

©IJRASET: All Rights are Reserved | SJ Impact Factor 7.538 | ISRA Journal Impact Factor 7.894 |

IV. MAJOR PHARMACEUTICAL DOSAGE FORMS AND THEIR DEVELOPMENT

Formulation development differs according to the dosage form and route of administration. Each dosage form presents specific technical challenges and requires appropriate evaluation methods.

A. Tablet Formulation

Tablets are solid dosage forms prepared by compression or other suitable manufacturing techniques. Their development involves selecting appropriate diluents, binders, disintegrants, lubricants, and, where necessary, coating materials.

Important formulation considerations include powder flow, compressibility, content uniformity, disintegration, dissolution, and mechanical strength. Immediate-release, enteric-coated, and extended-release tablets require different formulation strategies to achieve the intended drug-release profile.

B. Capsule Formulation

Capsules contain drug substances and excipients enclosed in hard or soft shells. Their development requires consideration of fill properties, compatibility with the shell, moisture sensitivity, dose uniformity, and drug-release performance.

Capsules may be useful for powders, granules, pellets, or certain liquid and semisolid fills, depending on the capsule type and manufacturing system.

C. Liquid Formulation

Liquid formulations include solutions, suspensions, syrups, and emulsions. They can be advantageous for patients who have difficulty swallowing tablets or capsules. Key considerations include solubility, pH, viscosity, taste, physical stability, microbial quality, preservative effectiveness where applicable, and packaging compatibility. Suspensions must maintain acceptable sedimentation and redispersibility, while emulsions require adequate resistance to creaming, coalescence, and phase separation.

D. Topical and Transdermal Formulation

Topical preparations such as creams, ointments, gels, and lotions are developed for application to the skin or other appropriate surfaces. Their performance depends on the drug's physicochemical properties, vehicle composition, viscosity, release, and interaction with the application site. Transdermal systems are designed to deliver a drug through the skin into systemic circulation. Their development may require evaluation of drug permeability, adhesive performance, release rate, skin compatibility, and delivery consistency.

E. Parenteral Formulation

Parenteral products are administered by injection or infusion. They require particularly stringent attention to sterility, endotoxin or pyrogen control as applicable, particulate matter, container-closure integrity, and product-specific physicochemical properties.

Solubility, pH, tonicity, chemical stability, and compatibility with containers and delivery devices are important considerations. The manufacturing strategy must be appropriate to the product and include validated controls for relevant microbiological risks.

V. QUALITY BY DESIGN IN FORMULATION DEVELOPMENT

Quality by Design (QbD) is a systematic approach to pharmaceutical development that begins with predefined product objectives and emphasizes understanding how formulation and process variables affect product quality. It is described in ICH Q8(R2), with related quality risk-management principles addressed by ICH Q9 [1,5].

The principal elements of QbD include:

1) Quality Target Product Profile (QTPP): Defines the intended characteristics of the product, such as dosage form, route, strength, release properties, and stability.
2) Critical Quality Attributes (CQAs): Product properties that must be controlled to ensure the required quality. Examples may include assay, dissolution, sterility, and content uniformity, depending on the product.
3) Critical Material Attributes (CMAs): Material properties that can influence product quality, such as API particle size or excipient moisture content.
4) Critical Process Parameters (CPPs): Process variables that may affect CQAs, such as granulation endpoint, drying temperature, or compression force.
5) Risk assessment: Identifies and prioritizes variables that could adversely affect product quality.

6) Design of Experiments (DoE): A structured statistical approach used to investigate the effects of multiple variables and their interactions.

QbD can improve scientific understanding, reduce unnecessary experimentation, and support a justified control strategy. However, its benefits depend on sound experimental design, reliable data, appropriate statistical analysis, and effective implementation.

VI. ANALYTICAL TECHNIQUES USED IN FORMULATION DEVELOPMENT

Analytical testing is essential for understanding the API, characterizing excipients and formulations, and confirming product quality.

Technique	Application in formulation development
UV-visible spectroscopy	Quantification of suitable drug substances
High-performance liquid chromatography (HPLC)	Assay, impurity analysis, and stability-indicating testing
Fourier-transform infrared spectroscopy (FTIR)	Functional-group characterization and preliminary compatibility assessment
Differential scanning calorimetry (DSC)	Investigation of thermal transitions and solid-state interactions
X-ray powder diffraction (XRPD)	Evaluation of crystallinity and polymorphic forms
Particle-size analysis	Characterization of particle-size distribution
Dissolution testing	Measurement of drug release under defined conditions
Microscopy	Examination of particle morphology and formulation structure

The choice of analytical method depends on the material, dosage form, and question being investigated. For example, FTIR alone cannot establish that a drug and excipient are fully compatible under all manufacturing and storage conditions. Compatibility conclusions should be supported by appropriate complementary studies.

Analytical methods used for critical decisions should be appropriately developed, verified or validated as required, and applied with suitable controls.

VII. CHALLENGES IN PHARMACEUTICAL FORMULATION DEVELOPMENT

Formulation scientists encounter several scientific and practical challenges during product development.

1) Poor Aqueous Solubility: Poorly soluble drugs may dissolve slowly, potentially limiting absorption. Approaches to address this problem include particle-size reduction, salt formation where feasible, pH adjustment, surfactants, complexation, lipid-based formulations, and solid dispersions. The most appropriate strategy depends on the drug's properties and the intended dosage form.
2) Drug–Excipient Incompatibility: Interactions between APIs and excipients can influence stability, appearance, drug release, or manufacturing behaviour. Preliminary compatibility studies can identify potential risks, which should then be evaluated using relevant analytical methods and stability studies.
3) Chemical and Physical Instability: Hydrolysis, oxidation, photodegradation, crystallization, sedimentation, and phase separation may affect product quality. Appropriate formulation design, processing controls, antioxidants where justified, protective packaging, and suitable storage conditions can help manage these problems.
4) Manufacturing Variability: Variations in raw materials, equipment, operator practices, and environmental conditions can affect batch-to-batch consistency. Robust process development, standard operating procedures, validated analytical methods, and suitable in-process controls help reduce variability.
5) Cost and Regulatory Requirements: Development costs, availability of suitable excipients, equipment requirements, and regulatory expectations can influence formulation decisions. Scientists must balance product performance with manufacturability, affordability, documentation, and applicable quality standards.

VIII. EMERGING TRENDS IN PHARMACEUTICAL FORMULATION DEVELOPMENT

Technological advances are expanding the options available for developing medicines.

1) Nanotechnology-Based Drug Delivery: Nanocarriers such as liposomes, polymeric nanoparticles, and lipid nanoparticles are being investigated to improve drug delivery, modify distribution, protect sensitive molecules, or enable specialized therapeutic applications. Their development requires careful assessment of particle characteristics, stability, manufacturing reproducibility, and safety.

©IJRASET: All Rights are Reserved | SJ Impact Factor 7.538 | ISRA Journal Impact Factor 7.894 |

2) Novel Drug-Delivery Systems: Modified-release systems, targeted delivery approaches, microneedles, and advanced transdermal systems may improve dosing convenience or address specific delivery challenges. Their clinical value must be demonstrated rather than assumed from technological novelty alone.
3) 3D Printing in Pharmaceutics: Three-dimensional printing has potential applications in producing complex dosage geometries and investigating individualized doses or release profiles. Practical implementation requires consideration of dose accuracy, material suitability, process control, production capacity, and regulatory requirements.
4) Artificial Intelligence and Digital Tools: Artificial intelligence, computational modelling, and machine-learning techniques are increasingly explored for predicting material properties, identifying useful formulation variables, and supporting experimental planning. These methods may improve efficiency, but their reliability depends on data quality, appropriate validation, and experimental confirmation.
5) Continuous Manufacturing: Continuous manufacturing processes can provide opportunities for integrated production and real-time monitoring. Their successful implementation requires process understanding, appropriate analytical technology, equipment control, and a scientifically justified strategy for ensuring consistent product quality.

IX. REGULATORY AND QUALITY CONSIDERATIONS

Pharmaceutical formulation development must comply with applicable regulatory and quality requirements. Relevant guidance includes ICH Q8(R2) on pharmaceutical development, ICH Q9 on quality risk management, and ICH Q10 on pharmaceutical quality systems [1,5,6].

Good Manufacturing Practice (GMP) principles support controlled manufacturing, documentation, equipment qualification, personnel training, and appropriate quality oversight. Process validation provides documented evidence that a manufacturing process can consistently produce a product meeting its predetermined specifications [2,3].

The required documentation depends on the product and development stage. It may include formulation composition, manufacturing instructions, specifications, analytical methods, stability data, risk assessments, and validation records. In India, pharmaceutical developers should also consider applicable requirements and guidance issued by the Central Drugs Standard Control Organisation (CDSCO), along with relevant Indian Pharmacopoeia standards and other applicable regulations.

Regulatory compliance is not achieved through a single successful laboratory batch. It requires an evidence-based approach supported by adequate product and process knowledge, appropriate controls, and complete documentation.

X. FUTURE PERSPECTIVES

The future of pharmaceutical formulation development will increasingly focus on patient-centred design, improved delivery of difficult-to-formulate drugs, and more efficient manufacturing. Personalized medicines, digital formulation tools, advanced biomaterials, and continuous manufacturing may contribute to more adaptable pharmaceutical production.

Further research is needed to establish the safety, effectiveness, scalability, cost-effectiveness, and long-term performance of emerging technologies. Greater collaboration among pharmacists, formulation scientists, analytical chemists, engineers, clinicians, and regulatory specialists will remain important.

Educational and research institutions can contribute by strengthening practical training in preformulation, experimental design, analytical testing, stability studies, and regulatory documentation. These skills are valuable for careers in pharmaceutical research and development, production, quality assurance, and quality control.

XI. CONCLUSION

Formulation development is a multidisciplinary and essential activity in pharmacy that transforms an active pharmaceutical ingredient into a suitable and reliable medicinal product. Its major stages include preformulation studies, dosage-form selection, excipient screening, formulation optimization, manufacturing-process development, quality evaluation, stability testing, and scale-up.

Modern approaches such as Quality by Design, risk assessment, design of experiments, and advanced drug-delivery technologies provide opportunities to improve product understanding and manufacturing consistency. Nevertheless, successful formulation development requires scientifically justified decisions, appropriate analytical methods, suitable quality controls, and compliance with relevant regulatory requirements.

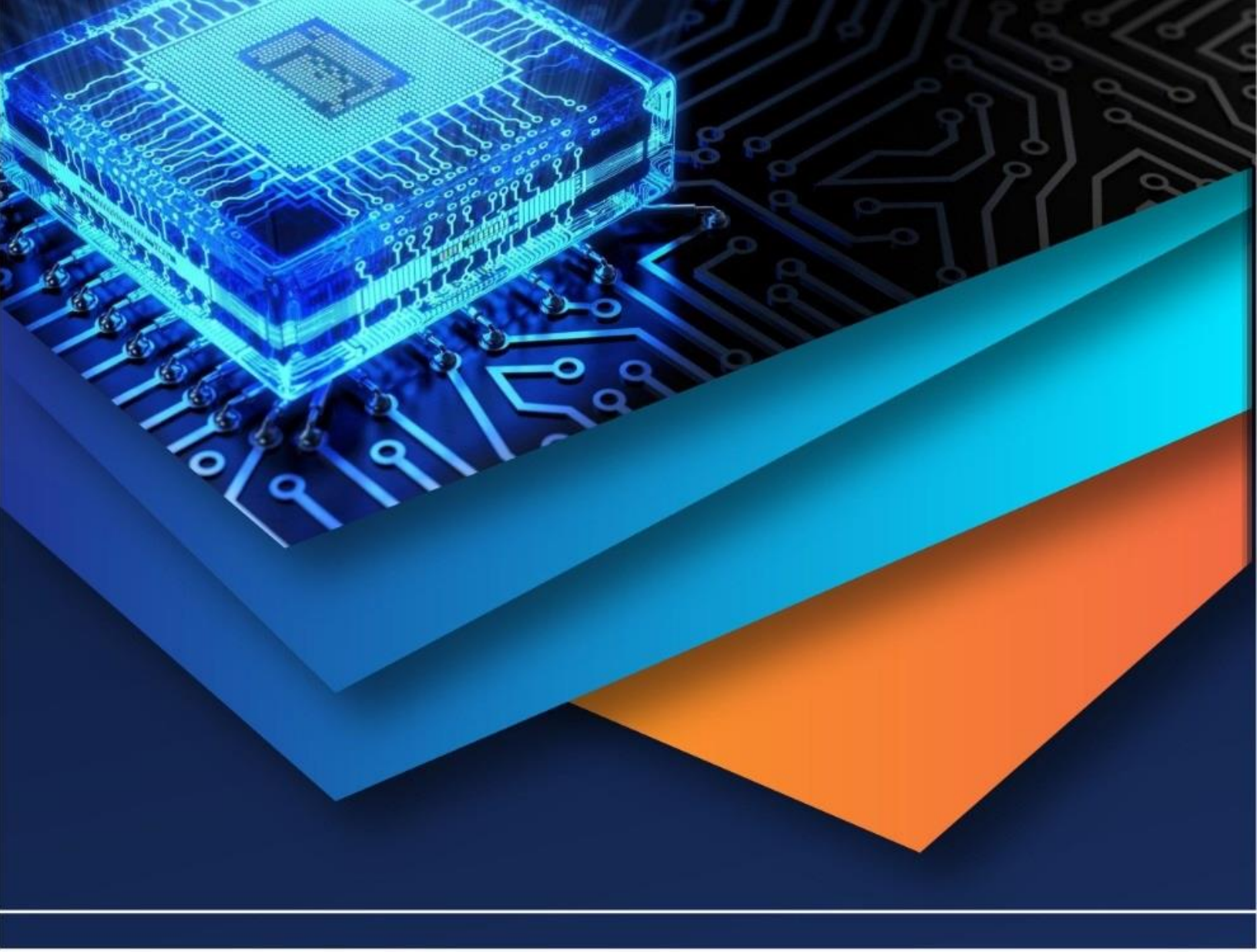
Ultimately, the goal is to develop pharmaceutical products that consistently meet their intended quality and performance requirements while addressing patient needs and practical manufacturing considerations.

©IJRASET: All Rights are Reserved | SJ Impact Factor 7.538 | ISRA Journal Impact Factor 7.894 |

REFERENCES

[1] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Q8(R2): Pharmaceutical Development. 2009. Available at: https://www.ich.org/page/quality-guidelines
[2] U.S. Food and Drug Administration. Process Validation: General Principles and Practices: Guidance for Industry. January 2011. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/process-validation-general-principles-and-practices
[3] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Q10: Pharmaceutical Quality System. 2008. Available at: https://www.ich.org/page/quality-guidelines
[4] U.S. Food and Drug Administration. SUPAC-IR: Immediate-Release Solid Oral Dosage Forms—Scale-Up and Post-Approval Changes. November 1995. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/supac-ir-immediate-release-solid-oral-dosage-forms-scale-and-post-approval-changes-chemistry
[5] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Q9(R1): Quality Risk Management. 2023. Available at: https://www.ich.org/page/quality-guidelines
[6] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Quality Guidelines: Q8, Q9 and Q10. Available at: https://www.ich.org/page/quality-guidelines

©IJRASET: All Rights are Reserved | SJ Impact Factor 7.538 | ISRA Journal Impact Factor 7.894 |



10.22214/IJRASET

45.98

IMPACT FACTOR: 7.129

IMPACT FACTOR: 7.429

INTERNATIONAL JOURNAL FOR RESEARCH

IN APPLIED SCIENCE & ENGINEERING TECHNOLOGY

Call : 08813907089 (24*7 Support on Whatsapp)