Formulation and Development of Paracetamol IP 75 mg Immediate Release Tablet Using Wet Granulation Technique

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Abstract: The present study focuses on the formulation and development of Paracetamol IP 75 mg immediate-release tablets using the wet granulation technique, with the objective of achieving rapid drug release, optimal mechanical strength, and batch-to-batch uniformity. Paracetamol, a widely used analgesic and antipyretic agent, requires precise dosing and consistent bioavailability, particularly in low-dose formulations intended for pediatric and geriatric use. Wet granulation was selected to overcome flowability and compressibility challenges commonly associated with fine Paracetamol powder. Various excipients—including diluents, binders, disintegrants, and lubricants—were evaluated to determine their influence on granule characteristics and final tablet performance. The process involved preparing granules using an appropriate binder solution, followed by drying, sizing, lubrication, and compression. Formulated batches were assessed for pre-compression parameters such as moisture content, angle of repose, bulk density, and compressibility index. Post-compression evaluation included weight variation, hardness, friability, disintegration time, drug content uniformity, and in-vitro dissolution studies. Among the formulations tested, the optimized batch demonstrated satisfactory granule flow properties and produced tablets with adequate hardness, low friability, and rapid disintegration within the pharmacopeial limits. The dissolution profile indicated that more than 80% of the drug was released within the first 30 minutes, confirming the immediate-release nature of the formulation. Overall, the study highlights the effectiveness of the wet granulation technique in producing a stable, uniform, and fast-acting Paracetamol IP 75 mg tablet suitable for clinical use.

Keywords - Paracetamol IP 75 mg; Immediate-release tablet; Wet granulation; Formulation development; Pre-compression studies; Post-compression evaluation; Dissolution profile; Disintegration; Tablet optimization.

I. INTRODUCTION

Paracetamol, also known as *Acetaminophen*, is one of the most widely used *analgesic* and *antipyretic* agents across the globe due to its proven safety profile, favorable tolerability, and effectiveness in managing mild to moderate pain and fever. Unlike non-steroidal anti-inflammatory drugs (*NSAIDs*), Paracetamol lacks significant anti-inflammatory properties and does not exhibit adverse effects such as *gastrointestinal irritation*, *platelet dysfunction*, or *renal impairment* when used within therapeutic limits. These characteristics contribute to its widespread acceptance in *pediatric*, *geriatric*, and *sensitive patient populations* who require gentle yet effective symptom relief. The *75 mg strength* is particularly relevant for infants and young children, where accurate dosing is critical to prevent toxicity while achieving the desired therapeutic effect. The physicochemical properties of Paracetamol, including its *poor flowability*, *brittleness*, and *compressibility issues*, present challenges in the formulation of low-dose tablets, especially for achieving weight uniformity and mechanical strength. These limitations often necessitate the incorporation of suitable *excipients* and an appropriate manufacturing method capable of ensuring consistent quality. Therefore, the adoption of the *wet granulation technique* becomes an essential strategy to improve particle size distribution, enhance flow characteristics, and produce tablets with optimal *hardness*, *friability*, and *disintegration time*. Understanding the therapeutic importance of Paracetamol and the need for accurate low-dose formulations sets the foundation for developing an

effective *immediate-release (IR) tablet* that delivers rapid onset of action and high patient acceptability.

Rationale for Developing an Immediate-Release Paracetamol 75 mg Tablet

Immediate-release (*IR*) dosage forms are designed to ensure that the active drug becomes *bioavailable* within a short period after administration. In the case of Paracetamol, rapid absorption from the gastrointestinal tract is essential to provide quick *analgesic* and *antipyretic* effects, especially in acute conditions such as fever spikes or sudden onset of pain. The development of an *immediate-release Paracetamol IP 75 mg tablet* aims to deliver fast therapeutic action while maintaining dosing precision for vulnerable populations. For pediatric patients, where swallowing capabilities and physiological parameters differ significantly from adults, the use of a small, accurately formulated IR tablet supports both safety and compliance.

From a formulation standpoint, achieving immediate drug release requires careful selection of *disintegrants*, *binders*, and *diluents*, each contributing to tablet performance and dissolution behavior. The rapid breakdown of the tablet matrix into smaller particles enhances gastric solubility and absorption, meeting pharmacopeial requirements for IR dosage forms. The challenge, however, lies in achieving this rapid release without compromising *mechanical integrity*, such as hardness and friability. Low-dose formulations, particularly those containing Paracetamol, face additional hurdles due to the drug's inherent *poor compressibility* and *tendency to cap or laminate* during compression. Thus, developing an effective IR tablet involves a delicate balance between *formulation science* and *process optimization*. The study emphasizes a systematic approach to excipient selection, granule modification, and tablet evaluation to ensure that the final product meets the desired specifications for quick onset of action and reliable therapeutic performance.

Importance of Wet Granulation in Tablet Formulation

The *wet granulation technique* is one of the most widely used and reliable methods for producing high-quality tablets, especially when dealing with active pharmaceutical ingredients (*APIs*) that exhibit poor *flowability* and *compressibility*. Paracetamol, being a crystalline and cohesive powder, tends to produce irregular flow, leading to numerous tableting challenges such as *weight variation*, *content inconsistency*, and *tablet defects* like capping or chipping. Wet granulation provides a solution by transforming fine powders into larger, more uniform *granules* that possess improved handling characteristics. The process typically involves the addition of a *binder solution* to powder blends, forming wet masses that are subsequently dried and sized. This modification enhances interparticle bonding, resulting in granules with superior *bulk density*, *flow properties*, and *compressibility*. For an immediate-release formulation, the technique also allows controlled incorporation of *superdisintegrants* and other functional excipients, ensuring that tablets disintegrate rapidly upon contact with gastric fluids. Additionally, wet granulation improves the uniform distribution of Paracetamol within the tablet matrix, which is crucial for low-dose formulations like *75 mg tablets* where even minor deviations can affect therapeutic outcomes.

By enabling better powder handling, enhancing mechanical strength, and facilitating predictable dissolution profiles, wet granulation serves as a cornerstone in the development of a stable, safe, and fast-acting IR Paracetamol tablet. Its effectiveness in overcoming physicochemical and processing challenges underscores the importance of this technique in modern pharmaceutical manufacturing.

II. OBJECTIVES

- To formulate and develop Paracetamol IP 75 mg immediate-release tablets using the wet granulation technique, ensuring rapid drug release, uniformity, and mechanical stability suitable for clinical use.
- To evaluate the physicochemical properties of Paracetamol and excipients used in the formulation.
- To prepare granules using wet granulation and assess pre-compression parameters such as angle of repose, bulk density, and compressibility index.
- To compress the granules into tablets and evaluate post-compression parameters including weight variation, hardness, friability, disintegration time, and content uniformity.

- To study the in-vitro dissolution profile of the formulated tablets and compare with pharmacopeial standards.
- To optimize the formulation by selecting the most suitable combination of binder, diluents, and disintegrants for immediate-release characteristics.

III. IMPORTANCE OF EXCIPIENTS IN WET GRANULATION METHOD

Excipients form the backbone of a tablet formulation and significantly influence its manufacturability and performance. In direct compression, excipients must possess appropriate particle size, bulk density, and flow properties to ensure uniform die filling and consistent weight variation during compression.

- Diluents or Fillers such as microcrystalline cellulose (MCC), lactose monohydrate, and mannitol provide bulk to the formulation and enhance compressibility.
- Binders such as povidone (PVP) and hydroxypropyl cellulose (HPC) ensure adequate cohesion between particles.
- Disintegrants, including crospovidone, croscarmellose sodium, and sodium starch glycolate, facilitate the breakup of tablets into smaller fragments upon contact with aqueous fluids, promoting rapid dissolution.
- Lubricants like magnesium stearate and talc prevent adhesion to punches and dies, enhancing the manufacturing process.

The proportion and compatibility of these excipients must be carefully optimized to ensure desirable tablet hardness, friability, disintegration time, and drug release profile.

The present review aims to provide an in-depth understanding of the formulation and development of Paracetamol IP 75 mg immediate release tablets utilizing the wet granulation method. It focuses on the rationale behind the selection of excipients, the optimization of formulation parameters, and the evaluation techniques necessary to achieve an ideal immediate release profile. Furthermore, this article discusses the scientific principles, advantages, and practical challenges associated with the direct compression process, offering insights into how formulation scientists can develop cost-effective, stable, and therapeutically efficient Paracetamol tablets.

Ultimately, the review emphasizes the importance of formulation design, quality assurance, and regulatory compliance in ensuring that the final product meets both pharmacopoeial requirements and therapeutic expectations.

IV. LITERATURE REVIEW AND DATA COLLECTION

1. Evaluation of Directly Compressible Cellulose Derived from Cassava Waste

Eraga et al. evaluated the direct compression suitability of microcrystalline cellulose (MCC) obtained from cassava fermentation waste in the formulation of Paracetamol tablets. The MCC produced locally demonstrated excellent flowability, low moisture content, and good compressibility, comparable to commercially available MCC (Avicel PH 102). Tablets prepared using this excipient showed acceptable hardness (4–5 kg/cm²), low friability (<1%), and fast disintegration (<5 min).

Relevance: The study confirms the feasibility of direct compression for Paracetamol using eco-friendly and cost-effective excipients, reinforcing that properly engineered cellulose derivatives can maintain tablet integrity and rapid drug release.

2. Formulation and Evaluation of Paracetamol Tablets Using Natural Binders

Kulkarni and co-researchers formulated Paracetamol immediate release tablets using natural binders such as coconut oil and compared them with conventional binders (e.g., PVP K-30). The results demonstrated that natural binders provided adequate tablet hardness and content uniformity, while maintaining a disintegration time of under 5 minutes. Dissolution studies showed that more than 90% of Paracetamol was released within 25 minutes, confirming immediate release characteristics.

Relevance: This study highlights the role of binder optimization in balancing tablet strength with rapid drug release, directly aligning with the objectives of developing an efficient Paracetamol IP 75 mg immediate release tablet.

3. Impact of Material Properties on wet granulation of Tablet Quality

A 2023 study reported on the impact of material properties and process parameters on tablet quality during continuous direct compression manufacturing. Parameters such as particle size distribution, moisture content, and lubrication level significantly affected tablet weight variation, hardness, and dissolution performance. The study emphasized the importance of excipient functionality and powder rheology in maintaining batch consistency.

Relevance: These findings are vital to understanding the critical quality attributes (CQAs) and critical process parameters (CPPs) that influence Paracetamol tablet quality in the direct compression process. It underscores the need for quality-by-design (QbD) approaches in formulation development.

V. METHODOLOGY / MATERIALS AND METHODS

Material

A. Active Pharmaceutical Ingredient (API):

The primary drug used in this formulation is Paracetamol IP, a white crystalline powder with slightly bitter taste and odorless nature. It is freely soluble in ethanol, sparingly soluble in water, and practically insoluble in ether and chloroform. The drug exhibits a melting point range of 169–172°C and belongs to Biopharmaceutical Classification System (BCS) Class I, characterized by high solubility and high permeability. This makes Paracetamol an ideal candidate for immediate release formulations, as it can be rapidly absorbed in the gastrointestinal tract following disintegration.

B. Exipients:

The choice of excipients is critical in direct compression formulations since they must impart adequate flowability, compressibility, and disintegration efficiency. The commonly used excipients in this formulation include:

1. Diluents / Fillers:

- Microcrystalline Cellulose (MCC PH 102): Improves compressibility, flow properties, and tablet strength.
- Lactose Monohydrate: Provides bulk, enhances mouthfeel, and assists in tablet uniformity.
- Mannitol: Used for its cooling sensation and non-hygroscopic nature, improving patient acceptability.

2. Disintegrants:

- Crospovidone and Sodium Starch Glycolate (SSG) promote rapid tablet disintegration by swelling and wicking mechanisms.
- Croscarmellose Sodium may be used alternatively for enhancing break-up efficiency in gastric fluids.

3. Binders:

- Povidone (PVP K-30) or Hydroxypropyl Cellulose (HPC) help in maintaining tablet integrity without compromising disintegration.

4. Lubricants and Glidants:

- Magnesium Stearate acts as a lubricant, reducing friction during tablet ejection.
- Talc or Colloidal Silicon Dioxide improves flowability and prevents sticking to punches and dies.

All excipients used should comply with pharmacopoeial standards (IP/BP/USP) and be of analytical grade.

C. Equipment Used:

The following instruments and apparatus are typically utilized in the formulation and evaluation of Paracetamol tablets using direct compression:

- Analytical Balance – for accurate weighing of materials.
- Sieve Shaker – for particle size reduction and uniformity.
- Blender or Double Cone Mixer – for homogeneous powder mixing.
- Planetary Mixer / Tumbling Mixer / V-Blender: Ensures uniform mixing of Paracetamol with excipients before wetting & Promotes homogeneity, reducing risk of content variability.
- Granulator Bowl / High-Shear Mixer: For wet massing when binder solution is added & High-shear mixers improve granule uniformity and cohesiveness, essential for good flow and compressibility.
- Lender / Octagonal Blender: Used to blend dried granules with lubricants (e.g., magnesium stearate) and remaining disintegrants & Prevents

over-lubrication, which can affect tablet hardness and dissolution.

- Hardness Tester – to determine mechanical strength.
- Friability Tester – to assess tablet resistance to abrasion.
- Disintegration Test Apparatus – to measure tablet disintegration time.
- Dissolution Test Apparatus (USP Type II – Paddle) – for in vitro drug release studies.
- UV-Visible Spectrophotometer – for quantitative drug analysis.
- Digital Vernier Caliper – for thickness and diameter measurements.

Methodology

A. Preformulation Studies:

Preformulation studies are performed to evaluate the physicochemical compatibility of the API with selected excipients:

- Drug-Excipient Compatibility Studies:
  1. Conducted using Fourier Transform Infrared Spectroscopy (FTIR) and Differential Scanning Calorimetry (DSC) to detect chemical interactions.
- Micromeritic Properties of Powder Blend:
  1. Angle of Repose: Determines powder flowability.
  2. Bulk and Tapped Density: Used to calculate Carr's Index and Hausner Ratio for compressibility assessment.
  3. Moisture Content: Critical for granulation efficiency and stability.

B. Wet Granulation Process

Wet granulation is chosen to overcome flow and compressibility challenges of fine Paracetamol powder. The process involves:

- Weighing and Mixing:
  1. Paracetamol is blended with diluents and part of the disintegrant to form a uniform powder mixture.
- Binder Addition:
  1. A binder solution (PVP K30 in water or starch paste) is added gradually to form a wet mass with sufficient cohesiveness.
- Granulation:
  1. The wet mass is passed through a sieve to produce uniform granules.
- Drying:
  1. Granules are dried in a hot air oven at 50–60°C until moisture content is within acceptable limits.
- Sizing and Lubrication:
  1. Dried granules are sieved to ensure uniform particle size.
  2. Lubricants and remaining disintegrants are added to improve flow and compressibility before tableting.

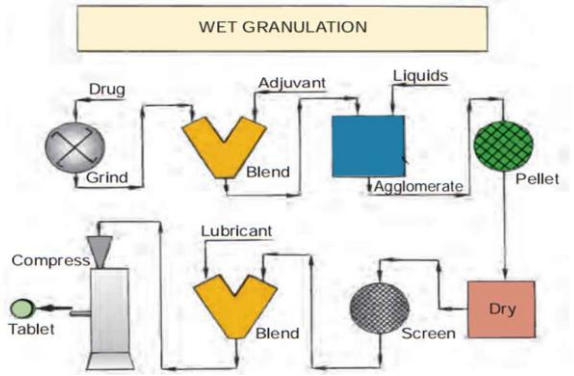

Fig. 1: Methodology of the Wet Granulation Method

C. Evaluation of Tablets:

After compression, the prepared tablets undergo pharmacopoeial quality control tests to ensure compliance with IP standards.

1. Physical Evaluation

- General Appearance: Tablets are inspected for color, shape, surface texture, and uniformity.
- Weight Variation: Twenty tablets are weighed individually and collectively; average weight and deviation are calculated as per IP guidelines.
- Thickness and Diameter: Measured using a digital Vernier caliper to ensure uniformity in dimensions.
- Hardness Test: Determines the mechanical strength using a Monsanto or Pfizer hardness tester.
- Friability Test: Conducted using a Roche friabilator at 25 rpm for 4 minutes; weight loss below 1% is acceptable.

2. Disintegration Test

The disintegration time of six tablets is determined using a disintegration test apparatus in 900 mL of distilled water maintained at 37 ± 0.5°C. For immediate release tablets, disintegration should occur within 15 minutes.

3. In Vitro Dissolution Study

Dissolution testing is performed using a USP Type II (paddle) dissolution apparatus containing 900 mL of phosphate buffer pH 5.8 at 37 ± 0.5°C and 50 rpm. Samples are withdrawn at regular intervals (e.g., 5, 10, 15, 20, and 30 minutes), filtered, and analyzed spectrophotometrically at λmax ≈ 243 nm using a UV-Visible spectrophotometer. The cumulative percentage of drug released is calculated and compared with IP specifications (usually ≥85% release within 30 minutes).

4. Drug Content Uniformity

Ten tablets are randomly selected, powdered, and dissolved in a suitable solvent. The solution is filtered, diluted, and analyzed spectrophotometrically. The drug content should fall within 95–105% of the labeled amount.

5. Stability Studies

To assess formulation stability, tablets are subjected to accelerated stability testing as per ICH guidelines (Q1A R2). The optimized batch is stored in high-density polyethylene (HDPE) containers at 40°C ± 2°C / 75% ± 5% RH for a period of 3 months. Samples are withdrawn at 0, 30, 60, and 90 days and evaluated for appearance, hardness, friability, disintegration, drug content, and dissolution profile. No significant changes in these parameters indicate a stable formulation.

6. Data Analysis and Optimization

Experimental results are analyzed statistically using Design of Experiments (DoE) tools such as factorial design or response surface methodology (RSM) to determine the influence of formulation variables (e.g., disintegrant concentration, binder ratio, and compression force) on critical quality attributes (CQAs) such as disintegration time, hardness, and drug release. The optimized formulation is selected based on desirability function and compliance with pharmacopoeial standards.

The direct compression approach simplifies the manufacturing process, minimizes environmental and processing stress, and enhances the reproducibility of Paracetamol IP 75 mg immediate release tablets. By employing a systematic formulation design, scientific excipient selection, and thorough evaluation, a robust, stable, and therapeutically efficient dosage form can be developed, ensuring rapid onset of action and patient compliance.

VI. RESULTS AND DISCUSSION

The results obtained from the formulation and evaluation of Paracetamol IP 75 mg immediate release tablets using the direct compression method are presented and discussed in this section. The findings include data from pre-compression studies, post-compression evaluation, in vitro dissolution analysis, and stability testing. These results help establish the relationship between formulation variables, tablet performance, and pharmacopoeial compliance.

A. Pre-Compression Studies

Pre-compression parameters were evaluated to determine the flow characteristics and compressibility of the powder blend. The results are summarized in Table 1.

Parameter	Observation	Inferred Property
Bulk Density (g/cm³)	0.45 ± 0.02	Acceptable for uniform die filling
Tapped Density (g/cm³)	0.52 ± 0.01	Indicates good packing ability
Carr's Index (%)	13.46 ± 0.45	Excellent flow (≤15%)
Hausner's Ratio	1.15 ± 0.02	Indicates good flow properties
Angle of Repose (°)	26.7 ± 0.4	Excellent flow (≤30°)

Table 1. Pre-Evaluation Parameters of the Powder Blend

The Carr's Index and Hausner's Ratio values confirm that the powder blend possessed good flowability and compressibility, which are essential for uniform tablet weight and content uniformity. The angle of repose further supports that the blend, ensuring consistent die filling during tableting. Proper powder flow and compressibility indicate successful excipient selection and effective pre-mixing.

B. Post-Compression Evaluation

The compressed tablets were evaluated for various physicochemical and mechanical properties, and the results are summarized in Table 2.

Parameter	Observed Value (Mean ± SD)	Pharmacopoeial Limit (IP)
Average Weight (mg)	175 ± 2.4	±7.5% deviation allowed
Thickness (mm)	3.12 ± 0.05	Uniform
Hardness (kg/cm²)	4.1 ± 0.3	3–5 kg/cm²
Friability (%)	0.42 ± 0.06	<1.0%
Disintegration Time (min)	4.2 ± 0.4	≤15 min
Drug Content (%)	99.1 ± 0.7	95–105%

Table 2. Post-Evaluation of Paracetamol 75 mg Immediate Release Tablets

The hardness and friability values indicate that the tablets had sufficient mechanical strength to withstand handling, packaging, and transportation. The low friability (0.42%) and uniform thickness suggest homogeneous compression and good die performance. The disintegration time of less than 5 minutes demonstrates the efficiency of superdisintegrants like crospovidone and sodium starch glycolate, ensuring the immediate-release nature of the formulation.

Additionally, drug content uniformity was well within the IP-specified range, reflecting excellent blending efficiency and consistent dose accuracy. This uniformity is crucial for low-dose formulations, where even minor variations can impact therapeutic efficacy.

C. In Vitro Dissolution Studies

The dissolution profile was assessed using phosphate buffer pH 5.8 as the dissolution medium at 37 ± 0.5°C and 50 rpm. The results are tabulated below in Table 3.

Time (minutes)	% Drug Release (Mean ± SD)	Time (minutes)
5	45.6 ± 0.9	5
10	68.2 ± 1.1	10
15	82.7 ± 1.3	15
20	90.4 ± 0.8	20
30	96.8 ± 0.5	30

Table 3. In Vitro Drug Release Profile of Paracetamol 75 mg Tablets

The dissolution data demonstrate that the formulated tablets released more than 85% of the drug within 20 minutes, meeting the IP specification for immediate release formulations. The rapid dissolution can be attributed to the synergistic action of superdisintegrants (crospovidone and SSG), which facilitate quick tablet breakup and enhanced wetting of the drug particles.

The high surface area of Paracetamol particles and effective disintegration ensure faster dissolution and absorption, resulting in a rapid onset of analgesic and antipyretic activity. The observed dissolution kinetics were best described by the first-order model, indicating that the rate of drug release depended on the concentration of the remaining drug in the tablet.

D. Effect of Excipients on Tablet Properties

A detailed study of excipient impact revealed that:

- Microcrystalline Cellulose (MCC PH 102) significantly improved compressibility and tablet hardness due to its plastic deformation properties.

- Lactose Monohydrate acted as a diluent and enhanced tablet smoothness and mouthfeel.
- Crospovidone, due to its capillary and swelling mechanism, played a vital role in achieving rapid disintegration and faster dissolution.
- Magnesium Stearate at low concentration (≤1%) prevented sticking without hindering disintegration, confirming proper lubricant optimization.

Thus, the synergistic combination of excipients ensured mechanical stability along with rapid drug release, validating the efficiency of the wet granulation method.

E. Stability Studies:

The optimized formulation was subjected to accelerated stability testing under 40°C ± 2°C / 75% ± 5% RH for 3 months. The results are summarized in Table 4.

Parameter	Initial	1 Month
Appearance	White, smooth	No change
Hardness (kg/cm²)	4.1	4.0
Friability (%)	0.42	0.45
Disintegration Time (min)	4.2	4.3
Drug Content (%)	99.1	98.8
% Drug Release (30 min)	96.8	96.5

Table 4. Stability Study Results of Optimized Formulation

No significant changes were observed in physical appearance, hardness, or drug release profile over the 3-month testing period, confirming that the formulation was physically and chemically stable. The slight variations in hardness and friability were within acceptable limits, indicating no degradation or moisture absorption. Hence, the formulation complies with ICH Q1A(R2) stability requirements and can be considered stable under accelerated conditions.

Discussion:

The results collectively demonstrate that direct compression is a simple, economical, and reproducible technique for developing Paracetamol IP 75 mg immediate release tablets with desirable quality attributes. The flow and compressibility of the powder blend were excellent, ensuring uniform die filling and consistent tablet weights.

The final tablets exhibited good mechanical strength, rapid disintegration, and fast drug release, fulfilling pharmacopoeial standards. The optimized formulation maintained stability over the testing period, indicating robustness of formulation and process parameters.

The successful development of this dosage form highlights the efficiency of wet granulation method for producing low-dose immediate release tablets, ensuring fast therapeutic action, high patient acceptability, and cost-effective manufacturing. Furthermore, this formulation approach is industrially scalable and can be easily adapted for other analgesic–antipyretic combinations or low-dose APIs with similar properties.

VII. CONCLUSION AND FUTURE SCOPE / RECOMMENDATIONS

Conclusion:

The present review successfully highlights the formulation and development of Paracetamol IP 75 mg immediate release tablets using the wet granulation method as an efficient, reliable, and industrially feasible manufacturing approach. The study confirms that through scientific excipient selection, process optimization, and comprehensive evaluation, an effective and pharmaceutically acceptable dosage form can be achieved.

The pre-compression studies indicated excellent flowability and compressibility of the powder blend, ensuring uniform die filling and content uniformity. The post-compression parameters such as tablet hardness, friability, thickness, and weight variation were found to be within acceptable Indian Pharmacopoeia (IP) limits, demonstrating the robustness of the direct compression process.

Moreover, the rapid disintegration time and enhanced dissolution rate confirmed the formulation's immediate release behavior, providing fast therapeutic onset, which is essential for analgesic and antipyretic

action. The use of superdisintegrants like crospovidone and sodium starch glycolate proved crucial in achieving the desired disintegration efficiency. The in vitro dissolution studies revealed that more than 85% of Paracetamol was released within 20 minutes, complying with the IP specifications for immediate release tablets.

The stability studies performed under accelerated conditions demonstrated that the optimized formulation retained its physical appearance, mechanical strength, drug content, and release characteristics throughout the testing period, confirming its chemical and physical stability.

Thus, it can be concluded that the wet granulation technique is a simple, cost-effective, and time-efficient method for producing Paracetamol IP 75 mg immediate release tablets with consistent quality, stability, and therapeutic efficacy. The developed formulation is suitable for mass production and offers excellent patient compliance, particularly in pediatric and geriatric populations requiring lower doses with quick onset of action.

Future Scope and Recommendations:

While the developed formulation meets the desired pharmacotechnical and biopharmaceutical criteria, there remains substantial scope for further research and industrial optimization. The following recommendations and future directions are suggested:

1. Scale-Up and Process Validation: Future studies should focus on the scale-up of the optimized formulation to pilot and industrial levels, validating process parameters such as mixing uniformity, compression pressure, and flow consistency to ensure reproducibility in large-scale production.
2. Advanced Disintegration and Dissolution Enhancement: Exploration of novel excipients or co-processed superdisintegrants could further enhance disintegration speed and drug release profile, reducing onset time and improving bioavailability.
3. Taste Masking and Palatability Improvement: For pediatric formulations, taste-masking strategies using flavoring agents, sweeteners, or film coatings can significantly improve patient acceptability and adherence to therapy.
4. Packaging and Moisture Protection: Since Paracetamol is moderately moisture-sensitive, employing desiccant-based packaging or blister packs can prolong shelf life and maintain formulation stability under varied environmental conditions.
5. In Vivo–In Vitro Correlation (IVIVC): Further work can be directed toward establishing a Level A IVIVC model to correlate in vitro dissolution data with in vivo plasma concentration profiles, thereby ensuring predictable therapeutic performance.
6. Incorporation into Fixed-Dose Combinations (FDCs): The developed direct compression approach may be extended to design FDCs containing Paracetamol with other APIs (e.g., caffeine or ibuprofen) for synergistic therapeutic effects, provided compatibility studies are satisfactory.
7. Regulatory and Quality by Design (QbD) Approach: Future formulation development should adopt Quality by Design (QbD) principles to identify Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs), ensuring consistent product quality and regulatory compliance under ICH and WHO guidelines.
8. Patient-Centric Formulation Research: Continued research can focus on orally disintegrating tablets (ODTs) or fast-melt formulations of Paracetamol 75 mg to cater to patients with swallowing difficulties, further improving convenience and adherence.

The findings of this review reaffirm that direct compression remains one of the most versatile and industry-friendly tablet manufacturing techniques, offering advantages in terms of simplicity, efficiency, and cost reduction. The successful formulation of Paracetamol IP 75 mg immediate release tablets through this method demonstrates that even low-dose formulations can achieve high uniformity, stability, and rapid drug release when designed using a rational, data-driven formulation strategy.

This work thus provides a strong foundation for future innovations in immediate release tablet development, encouraging further exploration into advanced excipient systems, QbD frameworks, and patient-focused formulation design.

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