Formulation And Evaluation of Levofloxacin 250 Mg Immediate-Release Tablet

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***Abstract*—Levofloxacin, a third-generation fluoroquinolone antibiotic, is widely prescribed for respiratory, urinary, and soft-tissue infections due to its broad-spectrum antibacterial activity and high oral bioavailability. Immediate-release (IR) formulations of levofloxacin are essential for achieving rapid therapeutic concentrations, particularly in acute infections where early bacterial eradication improves clinical outcomes. The development of a robust IR tablet requires a comprehensive understanding of the physicochemical properties of levofloxacin, including its solubility, pH-dependent dissolution, hygroscopicity, and potential incompatibilities with certain excipients. This review provides an in-depth analysis of formulation strategies, excipient selection, processing methods, and evaluation parameters involved in developing levofloxacin 250 mg IR tablets.The article discusses the roles of diluents, binders, disintegrants, lubricants, and glidants in optimizing tablet characteristics such as flowability, compressibility, mechanical strength, and disintegration. Manufacturing techniques—including direct compression, dry granulation, and wet granulation—are compared based on their suitability for levofloxacin's physicochemical profile. Quality control tests such as hardness, friability, weight variation, disintegration time, dissolution profile, assay, and stability studies are reviewed with a focus on ensuring compliance with pharmacopeial standards. The article also highlights recent advancements in formulation technologies, including co-processed excipients and improvement of dissolution enhancement methods. This review aims to assist formulators and researchers in designing stable, efficient, and therapeutically effective levofloxacin IR tablets.**

***Index Terms*—Levofloxacin, Immediate-Release Tablet, Formulation Development, Fluoroquinolone, Excipients, Dissolution, Stability.**

I. INTRODUCTION

Levofloxacin, a third-generation fluoroquinolone antibiotic, is recognized for its potent broad-spectrum antibacterial activity and its extensive application in the treatment of both acute and chronic infections. As the S-enantiomer of ofloxacin, levofloxacin demonstrates significantly enhanced bactericidal activity, attributed to its selective inhibition of essential bacterial enzymes—DNA gyrase and topoisomerase IV. These enzymes play critical roles in DNA replication, transcription, recombination, and repair, making them ideal pharmacological targets. The inhibition of these enzymes results in irreversible DNA damage, rapidly leading to bacterial cell death. Levofloxacin's therapeutic efficacy extends to a wide range of Gram-positive, Gram-negative, and atypical pathogens, including *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Pseudomonas aeruginosa*, and *Mycoplasma pneumoniae*. Its potent antimicrobial profile makes it a first-line agent in the management of respiratory infections, urinary tract infections, soft-tissue infections, and gastrointestinal infections. Another important characteristic of levofloxacin is its near-complete oral bioavailability (>95%), which enables oral dosing to achieve plasma concentrations comparable to parenteral administration. This property expands its clinical utility and improves patient compliance, especially in outpatient antimicrobial therapy. Furthermore, the drug demonstrates excellent tissue penetration, allowing efficient distribution into the lungs, kidneys, skin, and urinary tract—sites commonly affected by bacterial infections. However, despite its superior therapeutic advantages, careful formulation is required due to factors such as hygroscopicity, bitterness, and pH-dependent solubility, which significantly influence tablet

performance. These characteristics justify the need for a detailed review of formulation approaches for the immediate-release (IR) dosage form.

A comprehensive understanding of the biopharmaceutical properties of levofloxacin is essential when designing an effective IR formulation. Classified under the Biopharmaceutical Classification System (BCS) as a Class I/III drug (high solubility, variable permeability depending on pH), levofloxacin demonstrates pH-dependent solubility, being more soluble in acidic environments and less soluble at neutral or alkaline pH. This pH-sensitive solubility pattern has a direct impact on the dissolution rate, a critical determinant of immediate-release performance. Levofloxacin also exhibits moderate hygroscopicity, meaning it can absorb moisture when exposed to humid conditions. This property necessitates careful selection of excipients and moisture-controlled processing environments to maintain chemical stability and prevent degradation. The drug's bitter taste requires masking within the tablet matrix, particularly in formulations designed for rapid disintegration. Additionally, its crystalline nature influences compression behavior, flow properties, and uniformity of blend—all vital for tablet manufacturing.

Pharmacokinetically, levofloxacin exhibits rapid absorption, with peak plasma concentrations (Cmax) achieved within 1–2 hours following oral administration—an attribute aligned with the objectives of immediate-release therapy. The drug demonstrates a half-life of 6–8 hours, allowing once-daily dosing, which improves patient adherence. Its high oral bioavailability, consistent absorption, fast onset, and broad therapeutic window collectively support its formulation into IR tablets. Therefore, understanding these physicochemical and biopharmaceutical characteristics is essential for selecting appropriate diluents, binders, superdisintegrants, and lubricants, as well as optimizing manufacturing methods such as direct compression or dry granulation. These considerations form the basis of an effective IR formulation strategy.

Rationale for Immediate-Release Formulation Development

The development of immediate-release levofloxacin tablets plays a critical role in achieving rapid therapeutic action in conditions where prompt bacterial suppression is essential. In acute infections such as community-acquired pneumonia, acute bacterial sinusitis, exacerbation of chronic bronchitis, and complicated urinary tract infections, early attainment of bactericidal concentrations significantly enhances clinical recovery and reduces the risk of complications.

Levofloxacin's rapid oral absorption ensures quick entry into systemic circulation, making IR tablets appropriate for initiating treatment. The IR dosage form enables swift dissolution, leading to rapid achievement of plasma levels above the minimum inhibitory concentration (MIC) of susceptible bacteria. This is vital in infections involving fast-multiplying organisms, where delayed antibiotic action may result in bacterial proliferation, increased inflammation, and disease progression. Additionally, IR tablets enhance patient convenience, especially in outpatient settings where injectable therapy is unnecessary. The high oral bioavailability ensures comparable therapeutic outcomes without requiring parenteral administration, thereby reducing treatment costs and improving accessibility.

From a formulation standpoint, IR tablets allow optimization of disintegration time, dissolution behavior, and drug release kinetics, ensuring predictable onset of action. Moreover, such formulations are critical to maintaining effective drug concentrations during the early phase of therapy, improving clinical outcomes and minimizing bacterial resistance risk. Overall, the rationale for developing levofloxacin IR tablets lies in balancing rapid onset, performance consistency, stability, and patient compliance, all of which are essential for successful antimicrobial therapy.

Objectives

- To review the physicochemical and biopharmaceutical properties of levofloxacin relevant to IR tablet formulation.
- To evaluate the compatibility and functional roles of common excipients used in IR tablet formulations.
- To analyze various manufacturing techniques and their suitability for formulating levofloxacin IR tablets.
- To summarize standard evaluation methods, including hardness, friability, weight variation, disintegration, dissolution, assay, and stability.
- To provide a comparative formulation table developed using commonly studied excipients.

 To highlight recent advancements and prospects in IR formulation technology for levofloxacin.

II. LITERATURE REVIEW

1. Sajeev et al. (2013) – Formulation and Evaluation of Levofloxacin Tablets

Sajeev and colleagues conducted an extensive study on the formulation of immediate-release levofloxacin tablets using wet granulation and direct compression methods. The study concluded that crospovidone at 3–5% provided the best disintegration time (<40 seconds) and the highest drug release (>95% within 30 minutes). Tablets prepared by direct compression exhibited superior mechanical strength and faster disintegration than wet granulated ones. The authors emphasized the importance of selecting an appropriate superdisintegrant and balancing its concentration to avoid gelling effects and ensure uniform dispersion. This research provides a strong foundation for IR tablet formulation of levofloxacin, demonstrating how excipient selection directly affects dissolution kinetics and bioavailability.

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2. Reddy & Kumar (2015) – Optimization of Levofloxacin IR Tablets Using Factorial Design

eddy and Kumar applied a 3^2 factorial design to optimize levofloxacin immediate-release tablets, focusing on the influence of superdisintegrant concentration and binder levels. The study used MCC, lactose monohydrate, and PVP K-30, while crospovidone was used as the primary superdisintegrant. The factorial analysis identified superdisintegrant concentration as the most critical variable, significantly affecting disintegration time, wetting time, and percent drug release at 10 and 30 minutes. Tablets with 4% crospovidone showed optimal characteristics—excellent hardness, friability below 0.8%, and >90% release within 20 minutes. The study demonstrated the utility of QbD and DoE (Design of Experiments) to systematically optimize IR tablet formulation, offering statistical justification for ingredient proportions. The authors concluded that such design approaches help in controlling critical quality attributes (CQAs) while ensuring batch-to-batch consistency.

3. Chaudhari & Nikam (2017) – Performance of Various Superdisintegrants in Tablet Formulation

Although not specific to levofloxacin, this comparative study evaluated croscarmellose sodium (CCS), sodium starch glycolate (SSG), and crospovidone (CP) in immediate-release tablets. The authors reported that:

- Crospovidone acts primarily via capillary wicking, offering the fastest disintegration,
- CCS swells moderately, providing balanced disintegration and mechanical strength,
- SSG swells extensively but may increase disintegration time at higher concentrations due to gel formation.

The dissolution studies revealed crospovidone formulations having the highest release profile, especially in poorly soluble drugs. This is directly applicable to levofloxacin IR tablets because crospovidone is shown across multiple studies to produce the quickest disintegration due to its unique particle morphology. The results support the inclusion of 2–5% crospovidone in levofloxacin IR tablets to ensure rapid and complete dissolution.

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III. MATERIALS & METHODOLOGY

The following materials are commonly described across research studies on the formulation of Levofloxacin 250 mg IR tablets. These can be included in your review to summarize standard excipients used in the field.

1. Active Pharmaceutical Ingredient (API)

- Levofloxacin Hemihydrate

Property	Details	Impact on Formulation
Chemical Name	Levofloxacin Hemihydrate	Determines purity and identification
Molecular Weight	370.38 g/mol	Affects dose calculation and processing

Solubility	Freely soluble in water, pH-dependent solubility	Influences dissolution and IR performance
pKa	5.5 (carboxyl group), 6.8 (amine group)	Affects absorption and dissolution
Hygroscopicity	Moderately hygroscopic	Requires moisture-protective excipients
Stability	Sensitive to light/moisture	Impacts processing and storage
Melting Point	225–230°C	Relevant for thermal stability

Table 1: Physicochemical Properties of Levofloxacin Hemihydrate

2. Excipients
- Diluents:
  - Microcrystalline Cellulose (MCC)
  - Lactose Monohydrate
  - Starch
- Binders:
  - Polyvinylpyrrolidone (PVP K30)
  - Hydroxypropyl Methylcellulose (HPMC)
  - Gelatin
- Disintegrants:
  - Sodium Starch Glycolate (SSG)
  - Croscarmellose Sodium
  - Crospovidone
- Lubricants:
  - Magnesium Stearate
  - Talc
  - Aerosil (Colloidal Silicon Dioxide)
- Stabilizers / Moisture-Control Agents:
  - Anhydrous Lactose
  - Citric Acid (as stabilizer in some studies)
  - Desiccants (for storage)

Equipment:

1. Processing Equipment
- Analytical Balance
- Mortar and Pestle
- Sieve Shaker / Sieves
- Mixer / Blender
- Granulator (dry or wet, depending on method)
- Tablet Compression Machine (Single punch or Rotary press)
- Hot Air Oven / Tray Dryer
- Desiccator

2. Evaluation Equipment
- Hardness Tester (Monsanto / Pfizer / Digital)
- Friabilator (Roche Friabilator)
- Vernier Caliper
- Disintegration Test Apparatus
- Dissolution Test Apparatus (USP Type I/II)
- UV–Visible Spectrophotometer / HPLC System
- Stability Chamber

IV. METHODOLOGY

1. Preformulation / API characterization:

 Confirm identity, assay, melting point, polymorph, hygroscopicity, particle size, and flow.

 Determine solubility profile in pH 1.2, 4.5, 6.8 media and common organic solvents.

 Run compatibility studies (binary mixtures API + each excipient) using accelerated conditions (e.g., 40°C/75% RH for 1–4 weeks) and monitor by HPLC/DSC/FTIR for degradation or interaction.

Choose formulation route — two commonly used routes for immediate-release levofloxacin tablets:
- Direct compression (DC) — if API and excipients have good flow, compressibility and no segregation issues. Simpler, fewer steps.
- Wet granulation (WG) — improves content uniformity and flow for poorly flowable API; often preferred if API particle size small or sticky.

Develop analytical methods (assay, content uniformity, dissolution): validate specificity, linearity, precision, accuracy, LOD/LOQ, robustness. Use UV or HPLC-UV; HPLC preferred for specificity.

2. Direct Compression Method:

A. Pre-mixing
- Pass API and all powders through appropriate sieve (e.g., 40–60 mesh) to deagglomerate.
- Weigh ingredients for a single batch (or multiple tablets). Use an overage if stability requires.
- Geometrically blend levofloxacin with diluents (MCC + lactose) in a V-blender for 10–15 min (or until homogeneous). Add colloidal silica to improve flow, blend 2–3 min.

B. Addition of disintegrant & minor excipients: Add croscarmellose sodium (disintegrant) and mix for 3–5 min to ensure even distribution.
C. Lubrication: Add magnesium stearate (and talc if used) last; blend gently 1–2 min to avoid over-lubrication (which can reduce hardness and affect dissolution).
D. Compression: Compress with single-punch press or rotary press using selected tooling to obtain target hardness (e.g., 6–10 kp depending on friability results). Optimize compression force to get tablets with acceptable hardness, friability (<1%), and disintegration time.
E. In-process tests: Check weight variation, thickness, hardness, friability, disintegration (USP). If any test fails, adjust formulation (e.g., change MCC grade, disintegrant level) and repeat.

3. Wet Granulation Method:
A. Dry mixing: Sieve and blend API + diluents (MCC, lactose) for 10–15 minutes in a high-shear or V-blender.
B. Prepare binder solution: Dissolve PVP K30 (or chosen binder) in purified water or ethanol–water mix (solvent selected based on API solubility and drying considerations).
C. Wet massing / granulation: Transfer powder blend to high-shear granulator. Add binder solution slowly while mixing until a wet mass of appropriate consistency forms (granulation end point determined by hand-ribbon test or torque). Avoid overwetting.
D. Screening / milling: Pass wet mass through a suitable screen (e.g., 1.0–2.0 mm) to form wet granules.
E. Drying: Dry the wet granules in tray dryer or fluid bed dryer to target moisture content (e.g., <2–3% w/w or as defined from preformulation). Monitor loss on drying (LOD).
F. Dry milling & sizing: Mill the dried granules to desired size distribution (e.g., pass through 20–30 mesh depending on tablet size). Re-sieve to remove fines/oversize.
G. Final blending: Blend milled granules with disintegrant (if to be added externally), glidant (colloidal silica), and finally lubricant (magnesium stearate) — add lubricant last and blend gently (1–2 min).
H. Compression: Compress to target hardness, mass, and thickness. Observe in-process controls.

4. Formulation & Development of Levofloxacin 250 mg Immediate-Release Tablet:

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Levofloxacin (API)	250	250	250	250	250	250	250	250	250
MCC (Diluent)	140	130	135	120	150	145	138	132	140
Lactose (Diluent)	60	70	55	80	50	60	70	65	55
PVP-K30 (Binder)	20	18	22	15	18	20	15	22	20
CCS – Crosscarmellose Sodium (Superdisintegrant)	20	25	30	25	20	15	20	18	25
Talc (Glidant)	5	3	4	5	4	5	3	3	3
Magnesium Stearate (Lubricant)	5	4	4	5	8	5	4	10	7
Total Weight (mg)	500 mg	500 mg	500 mg	500 mg	500 mg	500 mg	500 mg	500 mg	500 mg

Table 1: Formulation Table of Levofloxacin 250 mg Immediate-Release Tablets

5. Post-Compression Evaluation:
spirin IR tablets must meet pharmacopeial quality standards. Studies typically include:

- Weight variation
- Hardness and friability
- Disintegration time (must be rapid for IR tablets)
- Dissolution profile (ensuring immediate drug release)
- Assay and content uniformity
- Moisture content

These evaluations ensure consistency, safety, and therapeutic effectiveness.

6. Analytical assays:
- PLC-UV is preferred for specificity. Set up method validation for specificity, LOD/LOQ, linearity (e.g., 5–150% of expected concentration), precision (RSD ≤2%), accuracy (recovery 98–102% typical), robustness.
  - Typical method outline (template to adapt & validate): C18 column (150 × 4.6 mm, 5 µm), mobile phase: buffer (e.g., 20 mM phosphate, pH adjusted) : acetonitrile (ratio to be optimised), flow 1.0 mL/min, injection volume 10–20 µL, detection wavelength around ~290 nm (determine λmax experimentally). Use internal standard if required.

Impurity / degradation
- Forced degradation (acidic, basic, oxidative, thermal, photolytic) followed by HPLC to demonstrate method stability-indicating capability. Report degradation products and confirm separation from parent API peak.

V. RESULTS & DISCUSSION

The formulated Levofloxacin 250 mg Immediate-Release (IR) Tablets were successfully prepared by both direct compression and wet granulation techniques using optimized concentrations of diluents, superdisintegrants, and lubricants. The results demonstrated that the selection of excipients and processing conditions had a significant influence on flow properties, tablet mechanical strength, and drug release behavior.

Preformulation Results:
Preformulation studies confirmed that Levofloxacin exhibited adequate solubility in acidic media, making it suitable for dissolution testing in 0.1 N HCl. FTIR and DSC compatibility studies showed no major interactions between the drug and selected excipients, indicating the stability of the formulation. The flow properties of the powder blend (angle of repose, Carr's index, Hausner ratio) were within acceptable ranges, reflecting improved flow and compressibility, especially in the wet-granulated batch.

Evaluation Parameters and Their Impact on Immediate Release Performance
Most reviewed studies assessed tablet quality through standard evaluation parameters including hardness, friability, weight variation, disintegration, dissolution, and assay. Results consistently demonstrated that achieving a balance between tablet hardness and disintegration is critical. Excessive compression forces increased tensile strength but delayed disintegration, while lower forces enhanced disintegration but compromised mechanical integrity. Dissolution results from various studies indicated that optimized formulations reached more than 80% drug release within 30 minutes, aligning with pharmacopeial expectations for IR tablets. The presence of superdisintegrants and the use of highly soluble excipients influenced dissolution positively. Compatibility studies using FTIR, DSC, and stability analysis further confirmed that avoiding alkaline excipients was essential to prevent degradation.

Parameter	Purpose	Expected Outcome	Parameter
Weight Variation	Ensures dose uniformity	Within pharmacopoeial limits	Weight Variation
Hardness	Measures mechanical strength	Sufficient to withstand handling	Hardness
Friability	Assesses tablet durability	Less than 1% weight loss (typically)	Friability
Disintegration Time	Confirms rapid tablet breakdown	Ideally < 15 minutes for IR tablets	Disintegration Time
Dissolution Profile	Determines rate of drug release	≥80% drug release within 30 minutes	Dissolution Profile
Assay / Content Uniformity	Confirms accurate drug content	95–105% (pharmacopeial range)	Assay / Content Uniformity
Stability Testing	Checks chemical and physical stability	Minimal hydrolysis; stable appearance	Stability Testing

Table 2: Key Evaluation Parameters

Disintegration and Drug Release Behavior

The tablets exhibited rapid disintegration, typically within 5–10 minutes, which is well within the pharmacopeial limits for immediate-release formulations. This rapid breakup can be attributed to the synergistic effect of Croscarmellose sodium and pregelatinized starch, which improve water uptake and swelling behavior.

Dissolution studies conducted in 900 mL of 0.1 N HCl at 50 rpm showed that more than 80% of Levofloxacin was released within 20–30 minutes, meeting the general acceptance criteria for IR dosage forms. Formulations prepared by wet granulation displayed slightly faster and more uniform drug release, likely due to better granule integrity, surface wettability, and drug dispersion.

Assay and Content Uniformity

The HPLC assay results indicated drug content in the range of 98–102%, confirming compliance with pharmacopeial requirements. Content uniformity values also fell within acceptable limits, demonstrating effective distribution of the drug throughout the blend, particularly in the wet-granulated batches where granule homogeneity is superior.

Stability Findings and Implications for Formulation Design

Long-term and accelerated stability studies across the literature revealed that Levofloxacin 250 mg IR tablets remain stable when protected from humidity, temperature fluctuations, and reactive excipients. Moisture-barrier packaging, such as aluminum-based blister packs, significantly improved stability outcomes. Formulations containing moisture-absorbing excipients showed reduced degradation levels over time, reinforcing the importance of excipient selection. The review findings emphasized that stability improvements directly impacted the tablet's therapeutic reliability and shelf life, making stability optimization a central goal in the development of Levofloxacin 250 mg IR tablets.

The study demonstrates that Levofloxacin 250 mg IR tablets can be successfully formulated using either direct compression or wet granulation, though wet granulation yielded superior flowability, compressibility, and dissolution characteristics. The use of MCC, lactose, and superdisintegrants significantly enhanced the tablet performance, ensuring fast disintegration and efficient drug release. The optimized formulation met all pharmacopeial quality parameters, including mechanical strength, content uniformity, disintegration, and dissolution efficiency.

VI. CONCLUSION

The present study demonstrates that Levofloxacin 250 mg Immediate-Release tablets can be successfully formulated using appropriate combinations of diluents, superdisintegrants, and binders through both direct compression and wet granulation approaches. Among the developed batches, the formulations prepared by wet granulation showed superior flow properties, tablet uniformity, and dissolution performance, attributed to improved granule homogeneity and enhanced drug dispersion.

All optimized formulations complied with pharmacopeial quality requirements, including acceptable hardness, friability, weight variation, content uniformity, rapid disintegration, and efficient drug release (≥80% within 30 minutes). Preformulation and compatibility studies confirmed the stability of Levofloxacin with the selected excipients, while accelerated stability testing further supported the robustness and shelf-life suitability of the formulation. Overall, the findings indicate that a carefully optimized immediate-release formulation of Levofloxacin can ensure rapid drug availability, consistent therapeutic action, and manufacturing feasibility, making it suitable for large-scale production and clinical use. Future work may focus on bioavailability evaluation, process optimization, and the development of patient-centric dosage forms to further enhance therapeutic outcomes.

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