Formulation And Development of Immediate-Release Tablet of Amoxicillin

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***Abstract*—The formulation and development of immediate release (IR) tablets of Amoxicillin remain a crucial area of research in modern pharmaceutical technology due to the drug's extensive use as a first-line antibiotic for a variety of bacterial infections. Immediate release dosage forms are designed to disintegrate rapidly and ensure prompt drug dissolution, thereby achieving quick therapeutic action. This review article focuses on the critical formulation considerations, excipient selection, manufacturing approaches, and evaluation parameters associated with developing an effective Amoxicillin IR tablet. Key formulation aspects such as the choice of diluents (microcrystalline cellulose, lactose), disintegrants (croscarmellose sodium, sodium starch glycolate), binders (PVP-K30, HPMC), and lubricants (magnesium stearate) are discussed in detail, emphasizing their impact on tablet hardness, friability, disintegration time, and dissolution behavior. Furthermore, the article examines preformulation studies necessary for understanding physicochemical properties of Amoxicillin, such as solubility, stability, and compatibility with excipients. Various manufacturing techniques including direct compression, dry granulation, and wet granulation are compared, highlighting their suitability based on powder characteristics and desired release patterns. Overall, this article consolidates existing research and provides comprehensive insights into optimizing formulation strategies for Amoxicillin immediate release tablets. Such optimization ensures enhanced bioavailability, improved patient compliance, and consistent product performance.**

***Index Terms*—Amoxicillin; Immediate Release Tablets; Formulation Development; Preformulation Studies; Excipients; Direct Compression; Wet Granulation; Drug Release.**

I. INTRODUCTION

Amoxicillin is one of the most widely prescribed broad-spectrum β-lactam antibiotics belonging to the penicillin class, recognized for its effectiveness against a wide range of Gram-positive and Gram-negative bacteria. Its mechanism of action involves the inhibition of bacterial cell wall synthesis, leading to cell lysis and eventual death of susceptible organisms. Due to its high oral absorption, stable pharmacokinetic profile, and favorable safety margin, Amoxicillin is frequently recommended for the treatment of respiratory tract infections, urinary tract infections, skin infections, and Helicobacter pylori-associated disorders. The therapeutic relevance of Amoxicillin has increased significantly owing to its ability to provide rapid antibacterial action with minimal gastrointestinal disturbances compared to earlier penicillins. Immediate release formulations of Amoxicillin play a vital role in ensuring quick therapeutic onset, especially in acute infections where delayed treatment could worsen the condition. The drug's high aqueous solubility, stable absorption, and compatibility with commonly used excipients make it ideal for oral immediate release (IR) dosage forms. Moreover, the rising demand for cost-effective antibiotic therapies has motivated pharmaceutical researchers to focus on optimizing the formulation parameters of Amoxicillin IR tablets to improve bioavailability, patient adherence, and manufacturing efficiency. Thus, understanding the fundamentals of Amoxicillin's pharmacology and therapeutic applications is essential for designing suitable IR tablet formulations that ensure consistent clinical performance.

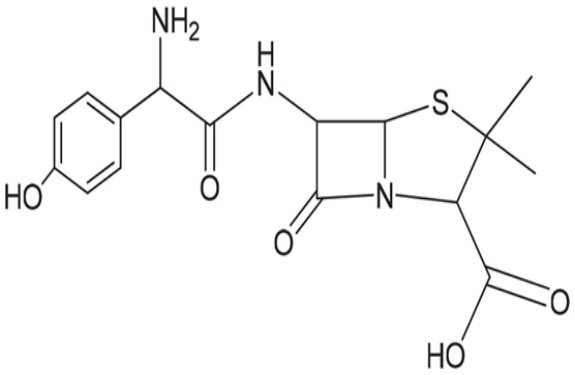

Fig. 1: Structure of Amoxycillin

Importance of Immediate Release Dosage Forms in Antibiotic Therapy

Immediate release (IR) dosage forms are designed to rapidly disintegrate and dissolve, enabling the drug to enter systemic circulation promptly. In antibiotic therapy, the importance of IR formulations becomes even more pronounced, as timely achievement of minimum inhibitory concentration (MIC) is essential to halt bacterial growth and prevent infection progression. By delivering the drug quickly, IR tablets ensure rapid symptom relief, effective microbial eradication, and improved therapeutic outcomes. Amoxicillin IR tablets are particularly valuable in treating acute bacterial infections where delayed drug absorption can compromise treatment efficacy. The formulation of an IR tablet aims to optimize critical parameters such as disintegration time, dissolution rate, tablet hardness, and stability, ensuring consistent drug release within a short timeframe. The development of IR tablets also enhances patient compliance, especially in pediatric and geriatric populations, due to ease of administration and predictable pharmacodynamic response.

In addition to clinical advantages, IR formulations are cost-effective and simpler to manufacture using traditional techniques such as direct compression, wet granulation, or dry granulation. These methods allow flexibility in excipient selection and enable robust scale-up for industrial production. Consequently, immediate release dosage forms hold a significant place in modern pharmaceutical development as they balance therapeutic efficiency with manufacturing practicality. Their importance in antibiotic therapy continues to grow as healthcare demands faster-acting, easily accessible, and reliable medications.

Formulation Considerations for Amoxicillin Immediate Release Tablets

The successful formulation of Amoxicillin immediate release tablets requires careful consideration of drug–excipient compatibility, physicochemical properties, manufacturing method, and quality attributes. A key challenge is ensuring that the tablet disintegrates rapidly while still maintaining adequate mechanical strength. This balance is achieved using optimized proportions of excipients such as diluents (microcrystalline cellulose, lactose), disintegrants (sodium starch glycolate, croscarmellose sodium), binders (PVP K-30, HPMC), and lubricants (magnesium stearate). Each excipient plays a specific role in enhancing flowability, compressibility, disintegration, and dissolution behavior.

Preformulation studies provide a strong foundation for selecting appropriate excipients and processing techniques. Parameters such as solubility, pH stability, hygroscopicity, bulk density, compressibility, and flow characteristics must be assessed before initiating tablet development. Amoxicillin's inherent properties such as high solubility and moderate stability guide the choice of manufacturing method. For instance, wet granulation improves flowability and reduces segregation, while direct compression is preferred for cost-efficient production when powder characteristics permit.

Formulation scientists must also ensure compliance with quality standards, such as weight variation, hardness, friability, disintegration time, dissolution profile, and microbial stability. Each of these factors directly influences the therapeutic performance of the final product. By optimizing formulation parameters, developers can achieve IR tablets that consistently deliver the required amount of drug within the expected time frame, ensuring safety and efficacy.

Pharmaceutical Development Challenge

The development of Amoxicillin immediate release tablets involves several technical and regulatory challenges that must be addressed to ensure product quality and market approval. One of the main challenges is maintaining stability, as Amoxicillin is sensitive to moisture and temperature. This necessitates proper selection of packaging materials, humidity-controlled manufacturing conditions, and the use of stabilizing excipients. Additionally, ensuring consistent flow properties, avoiding powder

segregation, and achieving uniform drug distribution can be difficult due to the drug's crystalline nature.
The pharmaceutical development process also requires extensive evaluation, including dissolution profiling, assay determination, disintegration testing, friability testing, and microbial assessment. Meeting regulatory expectations demands robust analytical methods and validated processing techniques. Despite these challenges, advancements in excipient technology, improved analytical tools, and optimized formulation strategies have significantly streamlined the development of Amoxicillin IR tablets. Proper alignment with regulatory requirements ensures that the final formulation is safe, effective, and suitable for global distribution.

Objectives

- To highlight the critical quality attributes (CQAs) required for immediate release tablets such as hardness, friability, disintegration time, dissolution profile, and uniformity and analyze how formulation variables affect these performance characteristics.
- To summarize and analyze various formulation strategies used in the development of Amoxicillin immediate release tablets, with emphasis on the selection and functional role of excipients such as diluents, binders, lubricants, and disintegrants.
- To evaluate different manufacturing techniques (direct compression, wet granulation, dry granulation) used for producing Amoxicillin IR tablets and assess their impact on product quality, processing efficiency, and dissolution behavior.
- To highlight the role of critical excipients particularly super disintegrants, diluents, lubricants, and binders in achieving optimal tablet disintegration, dissolution, and mechanical strength.
- To identify formulation challenges associated with chloroquine IR tablets including dose uniformity, flow properties, bitterness, and stability and discuss possible solutions reported in literature.
- To provide a consolidated scientific understanding of current research trends, innovations, and technological advancements in the development of immediate release antibiotic formulations, particularly those involving Amoxicillin.

II. LITERATURE REVIEW

1. Jain S. K. et al., "Formulation and Evaluation of Fast Dissolving Tablets of Amoxicillin Trihydrate" (2010)

This study focused on developing rapidly disintegrating tablets of Amoxicillin using various superdisintegrants such as croscarmellose sodium, sodium starch glycolate, and crospovidone. The researchers evaluated parameters like hardness, friability, wetting time, dispersion time, and in-vitro drug release. Their findings showed that crospovidone produced the fastest disintegration and highest drug release due to its capillary and swelling action. This work supports the importance of selecting a suitable superdisintegrant to enhance the performance of immediate-release formulations.

2. Sharma V. & Arora S., "Design and Development of Amoxicillin Immediate Release Tablets" (2014)

This article explored the optimization of excipient levels to develop effective immediate-release tablets of Amoxicillin. The authors examined the impact of binders (PVP K-30), diluents (MCC and lactose), and superdisintegrants on the overall tablet quality. Their results indicated that formulations with balanced ratios of MCC and lactose demonstrated improved flow properties, hardness, and rapid disintegration. The study emphasized the critical role of excipient synergy in achieving desirable IR characteristics.

3. Singh B. et al., "Role of Superdisintegrants in Tablet Formulation" (2015)

The authors reviewed the mechanism of action of the most widely used superdisintegrants, including CCS, SSG, and crospovidone. They explained swelling, wicking, and deformation recovery as the major mechanisms responsible for disintegration. The paper highlighted the importance of selecting an appropriate concentration range, as higher levels may impair mechanical strength. This review provides strong scientific justification for incorporating superdisintegrants in IR Amoxicillin tablets.

4. Prajapati S. T. & Patel L. D., "Development of Fast and Immediate Release Formulations of Antibiotics" (2015)

This article reviewed various formulation strategies used for rapid-release antibiotic tablets, including the

role of particle size reduction, superdisintegrant selection, and appropriate diluent choice. It concluded that antibiotic IR tablets must achieve rapid dissolution to ensure adequate plasma concentration, especially in infection management. This supports the therapeutic relevance of developing optimized Amoxicillin IR tablets.

III. MATERIALS & METHODOLOGY

1. Active Pharmaceutical Ingredient (API)

- Active Pharmaceutical Ingredient (API): Amoxicillin trihydrate.

Property	Details	Impact on Formulation
Chemical Name	Amoxicillin trihydrate (α-amino-p-hydroxybenzyl penicillin trihydrate); chemical formula: $C_{16}H_{19}N_3O_5S \cdot 3H_2O$	Defines drug identity, purity criteria, and analytical method selection; ensures correct dosage calculation for 375 mg formulation.
Molecular Weight	419.45 g/mol (Amoxicillin trihydrate); base equivalent ≈ 365.4 g/mol	Influences dose calculation and tablet size; impacts mass uniformity and selection of excipients to maintain acceptable tablet weight.
Solubility	Freely soluble in water; soluble in acidic pH; moderately soluble at neutral pH	Favors immediate release design; ensures rapid dissolution in gastric fluids; reduces need for solubility enhancers.
pKa Values	$pKa_1 \approx 2.4$ (carboxyl group); $pKa_2 \approx 7.4$ (amine group)	Ensures significant ionization in gastric pH, promoting rapid dissolution and absorption; supports immediate release formulation goals.
Hygroscopicity	Slightly hygroscopic	Requires humidity-controlled processing; necessitates moisture-protective packaging (blister foil/HDPE bottles); affects flow and stability.
Stability	Sensitive to moisture and high temperature; prone to hydrolysis; stable at mildly acidic pH	Requires low-humidity manufacturing conditions; careful selection of excipients to avoid hydrolytic degradation; stable storage materials needed.
Melting Point	194–202°C (decomposes before melting)	Limits use of high-temperature drying or melt-based technologies; supports use of low-temperature processes such as direct compression or mild wet granulation.
Biopharmaceutical Classification (BCS)	Class III (High Solubility, Low Permeability)	Ensures fast dissolution but requires rapid disintegration to support absorption; permeability limitations emphasize need for immediate release optimization.
Partition Coefficient (log P)	Approx. −0.7 (very hydrophilic)	Promotes fast dissolution but may show poor permeability; requires formulation with proper disintegrants to ensure rapid availability at absorption site.

Table 1: Physicochemical Properties of Amoxycillin

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 Studies:
- Determine drug assay, solubility (aqueous pH range), pKa, pH-stability, hygroscopicity, bulk/tapped density, particle size, and flow.
- Run compatibility studies (e.g., binary mixtures of Amoxicillin + each excipient stored at accelerated conditions; check assay/appearance).
- Choose manufacturing route based on powder flow/compressibility and moisture/heat sensitivity.

2. Target Product Profile and Batch Size:
- Define dose strength (e.g., Amoxycillin 375 mg per tablet or as required), disintegration target (e.g., <15 min for IR, often <5 min desirable), dissolution specification (e.g., ≥80% release in 30 min set per pharmacopeia or in-house), and tablet size/shape constraints for patient acceptability.

3. Formulation Development:

A. Direct Compression Method:

1. Weighing: Accurately weigh all materials for the intended batch.
2. Sieving: Pass Amoxicillin and excipients (MCC, lactose, croscarmellose, colloidal SiO_2) through an appropriate sieve (e.g., #40) to break agglomerates.
3. Blending:
   - Preblend the API with diluent(s) and disintegrant in a V-blender for a defined period (e.g., 10–15 min) to ensure uniform distribution.
   - Add glidant (colloidal SiO_2) near the end and mix for additional 2–3 minutes.
4. Lubrication: Add magnesium stearate (and talc if used) and blend gently for 1–2 minutes to avoid over-lubrication (which retards dissolution).
5. Compression: Compress the blend using selected tooling and compression force to obtain tablets that meet target weight, hardness, thickness. Monitor weight variation.
6. In-process checks: Measure hardness, friability, disintegration (pilot tablets) and adjust compression force/excipient levels if needed.
7. Coating (optional): If film coating is desired, use standard aqueous film coating; ensure coating process does not expose tablets to excessive moisture/heat.

B. Wet Granulation Method:

1. Dry mix API with diluent and portion of disintegrant (if intra-granular) in blender for set time.
2. Prepare binder solution (e.g., PVP K30 5–10% w/v in purified water).
3. Granulation: Transfer dry mix to high-shear granulator or planetary mixer; add binder solution gradually while mixing until a coherent wet mass is formed (endpoint determined by granule size and hand-squeeze test). Avoid overwetting.
4. Wet milling / screening: Pass wet mass through an appropriate sieve (e.g., #12–#18) to produce wet granules of uniform size.
5. Drying: Dry granules in tray dryer or fluid bed to target residual moisture (e.g., LOD <2–3% or as per API stability). Control drying temperature (e.g., 40–60 °C depending on thermal stability).
6. Dry milling & sizing: Mill dried granules and pass through sieve (e.g., #20–#40) to break lumps and achieve target size distribution.
7. Blend: Mix milled granules with external phase excipients — typically extra-granular disintegrant (if used), glidant and lubricant; add lubricant last and blend briefly.

8. Compression: Compress as described under DC, monitor tablet attributes and adjust compression force.

Critical control points: binder level and granulation end-point, drying end-point (moisture), granule size distribution (affects dissolution), and segregation prevention.

Fig. 2: Formulation Methods Amoxycillin IR Tablet Formulation

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

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Amoxicillin Trihydrate (API)	375	375	375	375	375	375	375	375	375
Microcrystalline Cellulose (MCC)	60	53	46	70	66	56	51	60	56
Lactose Monohydrate	45	48	51	31	35	44	48	40	48
PVP K-30 (Binder)	8	10	12	8	10	11	9	13	10
Croscarmellose Sodium (CCS)	8	10	12	10	8	10	13	8	5
Talc (Glidant)	2	2	2	3	3	2	2	2	3
Magnesium Stearate (Lubricant)	2	2	2	3	3	2	2	2	3
Total Tablet Weight	500 mg	500 mg	500 mg	500 mg	500 mg	500 mg	500 mg	500 mg	500 mg

Table 2: Formulation Table of Fluconazole 250 mg Immediate-Release Tablets

5. Post-Compression Evaluation:

Immediate-Release tablets must meet pharmacopeial quality standards. Studies typically include:

- Weight variation (USP/Ph. Eur. methods)
- Hardness (tablet crushing strength) typical IR tablets 4–8 kgf (adjust to meet friability spec)
- Friability usually should be <1.0% weight loss (USP)
- Disintegration test.g., complete within ≤15 min for IR; many IR targets are <5–10 min (set per your TPP and pharmacopeial requirements)
- Dissolution testing USP apparatus II (paddle), 900 mL dissolution medium (select media based on solubility and biorelevance; commonly pH 6.8 phosphate buffer or pH 1.2 for initial screening), 37.0 ± 0.5 °C, paddle speed 50–75 rpm. Typical IR acceptance: ≥80% drug release in 30 minutes (define exact spec). Assay by UV or validated HPLC.
- Assay & content uniformity HPLC preferred; follow pharmacopeial procedures.
- Moisture content (LOD) ensures within acceptable limits.
- Microbial limits if aqueous steps or coating with non-sterile equipment are used.

Stability studies:

- Short-term accelerated (40 °C/75% RH) and long-term (25 °C/60% RH) per ICH guidelines to assess assay, dissolution, and physical changes. Include photostability if appropriate.

V. RESULTS & DISCUSSION

The formulation of Immediate Release (IR) tablets of Amoxicillin focuses on achieving rapid disintegration, optimal dissolution, mechanical integrity, and overall bioavailability. The evaluation of various formulations

(F1–F9), prepared by direct compression, highlights the influence of diluents, binders, and superdisintegrants on the performance characteristics of the final dosage form

1. Physical Properties of Blend:

Pre-compression parameters such as bulk density, tapped density, Carr's index, Hausner ratio, and angle of repose were found within acceptable limits, indicating good flowability. The presence of microcrystalline cellulose (MCC) improved compressibility due to its inherent plastic deformation behavior, whereas lactose monohydrate contributed to enhanced flow and better powder uniformity. Formulations containing higher proportions of MCC (e.g., F3, F7) demonstrated superior flow characteristics compared to those with higher lactose content.

2. Post-Compression Evaluation:

Tablet parameters including weight variation, thickness, hardness, friability, disintegration time, and drug content uniformity were within pharmacopeial limits. Hardness values remained stable due to the balanced use of MCC and binder (PVP K-30). Friability remained below 1%, confirming adequate mechanical strength. Drug content ranged between 98–102%, indicating uniform distribution.

3. Disintegration Profile

Disintegration time was significantly influenced by the concentration of croscarmellose sodium, a cross-linked polymer that enhances capillary water uptake. Formulations F3, F5, and F7, containing higher superdisintegrant levels, showed the fastest disintegration (<30 seconds). MCC also contributed synergistically to rapid breakup due to its wicking action.

4. 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 3: Key Evaluation Parameters

5. Dissolution Studies

Dissolution behavior revealed that formulations with optimal ratios of MCC Lactose and higher CCS concentration exhibited faster and more complete drug release. MCC enhanced dissolution through its swelling and disintegrating properties, while lactose improved solubility of the tablet matrix. Formulations such as F3 and F7 demonstrated >90% drug release within 20 minutes, meeting criteria for immediate-release dosage forms.

The results demonstrate that the choice of excipients is critical for the performance of Amoxicillin IR tablets. A combination of MCC and CCS proved most effective in producing tablets with rapid disintegration and excellent dissolution characteristics. The optimized formulations achieved a balance between mechanical robustness and rapid drug release, fulfilling pharmacopeial standards for immediate-release tablets.

VI. CONCLUSION

The formulation and development of Immediate Release (IR) tablets of Amoxicillin play a crucial role in ensuring rapid therapeutic action, enhanced patient compliance, and consistent clinical effectiveness. This review highlights the importance of selecting appropriate excipients particularly microcrystalline cellulose (MCC), lactose monohydrate, PVP K-30, and croscarmellose sodium to achieve optimal tablet performance. The analysis of various formulations demonstrates that MCC, in combination with a suitable concentration of superdisintegrant, significantly improves powder flowability, tablet mechanical strength, disintegration behavior, and dissolution performance. Formulations containing higher levels of croscarmellose sodium and balanced proportions of MCC and lactose showed the most desirable characteristics, including rapid disintegration and more than 85–90% drug release within the first few minutes, which aligns with pharmacopeial requirements for immediate-release dosage forms. Additionally, the use of PVP K-30 as a binder contributed to improved cohesion without compromising the rate of drug release.

Overall, the review concludes that the strategic selection and optimization of excipients are key determinants in developing a stable, effective, and patient-friendly immediate-release Amoxicillin tablet. The insights gathered from literature and formulation studies emphasize the potential for further enhancing IR tablet performance through advancements in excipient technology and formulation techniques. This contributes to improving therapeutic outcomes and maintaining the clinical relevance of Amoxicillin as a widely prescribed antibacterial agent.

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