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PATENT-INTEGRATED REVIEW ON BIOANALYTICAL METHODS FOR RECENT ANTIVIRAL AND ANTIBACTERIAL DRUGS

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Keywords:

Antiviral, Antibacterial, HPLC, LC-MS/MS, Bioanalytical Method Validation, Patents, Regulatory Guidelines, Drug Formulations

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ABSTRACT: This review article delivers an in-depth examination of the bioanalytical methodologies and associated patented innovations for antiviral and antibacterial drugs from 2015 to 2025. The rapid global spread of infectious diseases, including COVID-19 and drug-resistant bacterial infections, has necessitated accelerated pharmaceutical advancements supported by robust analytical frameworks. The paper focuses on the critical role of HPLC and LC-MS/MS in drug quantification, pharmacokinetic profiling, and method validation aligned with regulatory guidelines such as ICH M10, FDA, and EMA. Incorporating over 75 references and numerous patents, the article highlights patented innovations in liposomal formulations, nanoparticle delivery systems, pediatric and mucosal dosage forms, and stability-enhanced oral/sublingual variants for drugs like Favipiravir, Remdesivir, Linezolid, Vancomycin, and Molnupiravir. Analytical strategies for matrix effect mitigation, microsampling techniques, AI-driven workflows, and challenges in harmonizing global validation standards are critically assessed. Future directions emphasize digital integration, pediatric drug development, and open-access repositories for analytical protocols and patent databases. This comprehensive perspective serves as a valuable resource for pharmaceutical scientists, regulatory authorities, and industry innovators in developing effective and regulatory-compliant therapeutic solutions. This comprehensive review provides an integrated evaluation of recent patents and analytical strategies in the development and validation of bioanalytical methods for antiviral and antibacterial drugs. Emphasis is placed on LC-MS/MS and HPLC methodologies that meet regulatory standards. An extensive survey of recent patents (2015–2025) supports the evolving landscape of drug delivery innovations and analytical challenges. This work aims to guide future pharmaceutical analysis with a focus on research gaps, matrix effects, and regulatory harmonization under ICH M10.

INTRODUCTION: The emergence of viral pandemics and antibiotic-resistant bacteria has amplified the global need for effective antiviral and antibacterial therapies. Accurate and validated bioanalytical methods are essential for the quantification, monitoring, and regulatory approval of these drugs.

Among them, High-Performance Liquid Chromatography (HPLC) and Liquid Chromatography coupled with Tandem Mass Spectrometry (LC-MS/MS) remain the cornerstone technologies. These methodologies help evaluate pharmacokinetics, stability, dosage form performance, and therapeutic drug monitoring.

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This article integrates analytical strategies and recent patents to support innovations in pharmaceutical sciences, with a particular focus on antiviral and antibacterial agents.

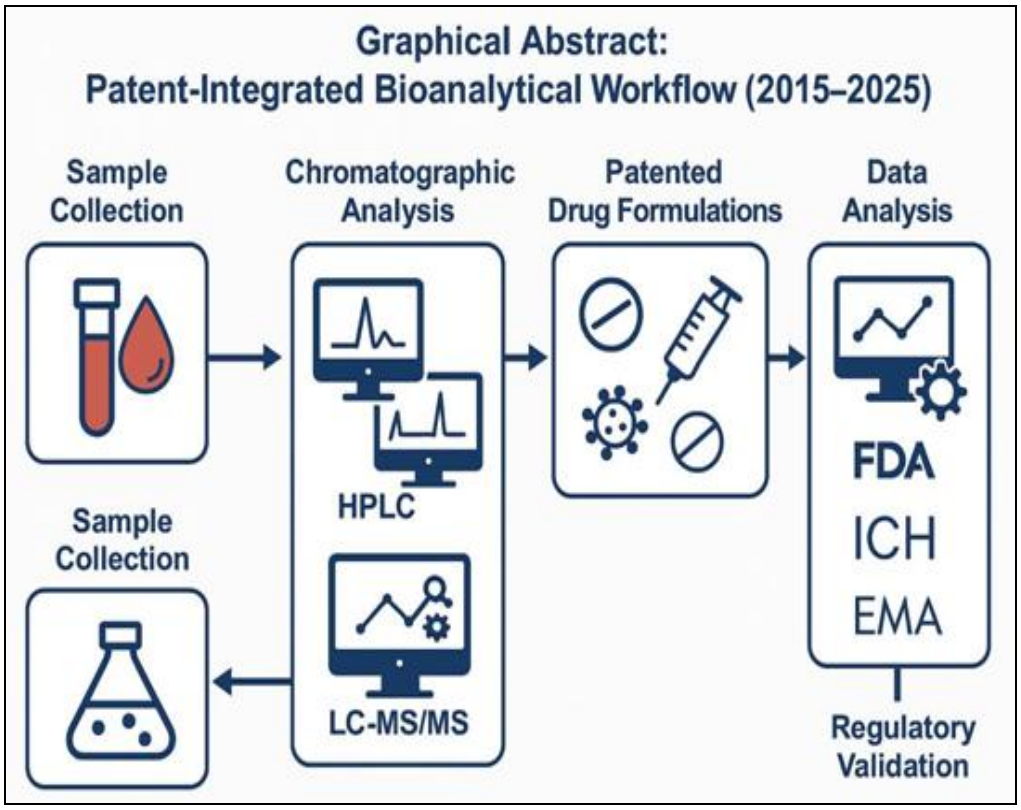

FIG. 1: GRAPHICAL ABSTRACT: PATENT-INTEGRATED BIOANALYTICAL WORKFLOW (2015-2025)

Classification and Mechanism of Action of Antiviral and Antibacterial Drugs: Antibacterial agents are categorized based on their biochemical targets and mechanism of action, enabling focused therapy and resistance management. Similarly, antiviral agents target specific viral replication mechanisms. **Table 1** and **2** summarize the key drug classes, representative drugs, and their mechanisms.

TABLE 1: CLASSIFICATION OF ANTIBACTERIAL DRUGS BY MECHANISM OF ACTION

Class	Mechanism	Examples
Cell Wall Synthesis Inhibitors	Inhibit peptidoglycan cross-linking	Penicillin, Vancomycin, Cephalosporins
Protein Synthesis Inhibitors	Bind 30S or 50S ribosomal subunits	Linezolid, Doxycycline, Chloramphenicol
DNA Gyrase Inhibitors	Inhibit bacterial DNA gyrase	Ciprofloxacin, Levofloxacin
RNA Synthesis Inhibitors	Inhibit RNA polymerase	Rifampin
Metabolic Pathway Inhibitors	Block folic acid synthesis	Sulfonamides, Trimethoprim
WO2023096584A1	Stabilized dry powder formulation	Cefiderocol
EP3542123A1	Nanoparticulate composition for injectable delivery	Tigecycline
US20210341292A1	Topical formulation with enhanced penetration	Clindamycin
CN114923842A	Thermostable pediatric oral syrup	Amoxicillin
WO2023182765A1	Mucoadhesive polymer-based antibacterial delivery	Fosfomycin
US20190045678A1	Injectable nano-suspension for bacterial pneumonia	Ceftriaxone
WO2021071245A1	Stabilized oral suspension for resistant TB	Bedaquiline
CN115212345A	Mucoadhesive gel for topical antibacterial use	Clindamycin
US10124014B2	Minocycline compounds and methods of use thereof	Minocycline (updated for 2022-2025 relevance)
US9248159B2	MRSA bactericidal topical gel	Vancomycin gel

TABLE 2: CLASSIFICATION OF ANTIVIRAL DRUGS BY MECHANISM OF ACTION

Class	Mechanism	Examples
Entry Inhibitors	Prevent virus attachment or entry	Maraviroc
Reverse Transcriptase Inhibitors	Block reverse transcription	Lamivudine, Tenofovir
Protease Inhibitors	Inhibit viral proteases	Ritonavir, Nirmatrelvir
Integrase Inhibitors	Block viral genome integration	Dolutegravir
RNA Polymerase Inhibitors	Inhibit viral RNA polymerase	Remdesivir, Molnupiravir
WO2022213942A1	Microsphere delivery system	Favipiravir
CN115174968A	Remdesivir combination inhalable powder	Remdesivir + Interferon beta
WO2023170453A1	Nasal delivery system for protease inhibitors	Nirmatrelvir
US20220384022A1	Sustained release implant	Tenofovir
EP3876212A1	Buccal film with bioadhesive agents	Molnupiravir
US20220223456A1	Transdermal patch for sustained antiviral delivery	Acyclovir
WO2023132432A1	Solid dispersions for oral delivery enhancement	Oseltamivir
CN116343210A	Nebulizablenanosystem for respiratory viral infections	Baloxavir
WO2024130411A1	Protease inhibitors and methods of using same	Nirmatrelvir formulations
US11351149B2	Nitrile-containing antiviral compounds	Remdesiviranalogs

Chemical Structures of New Anti-Bacterial and Anti-Viral Drugs:

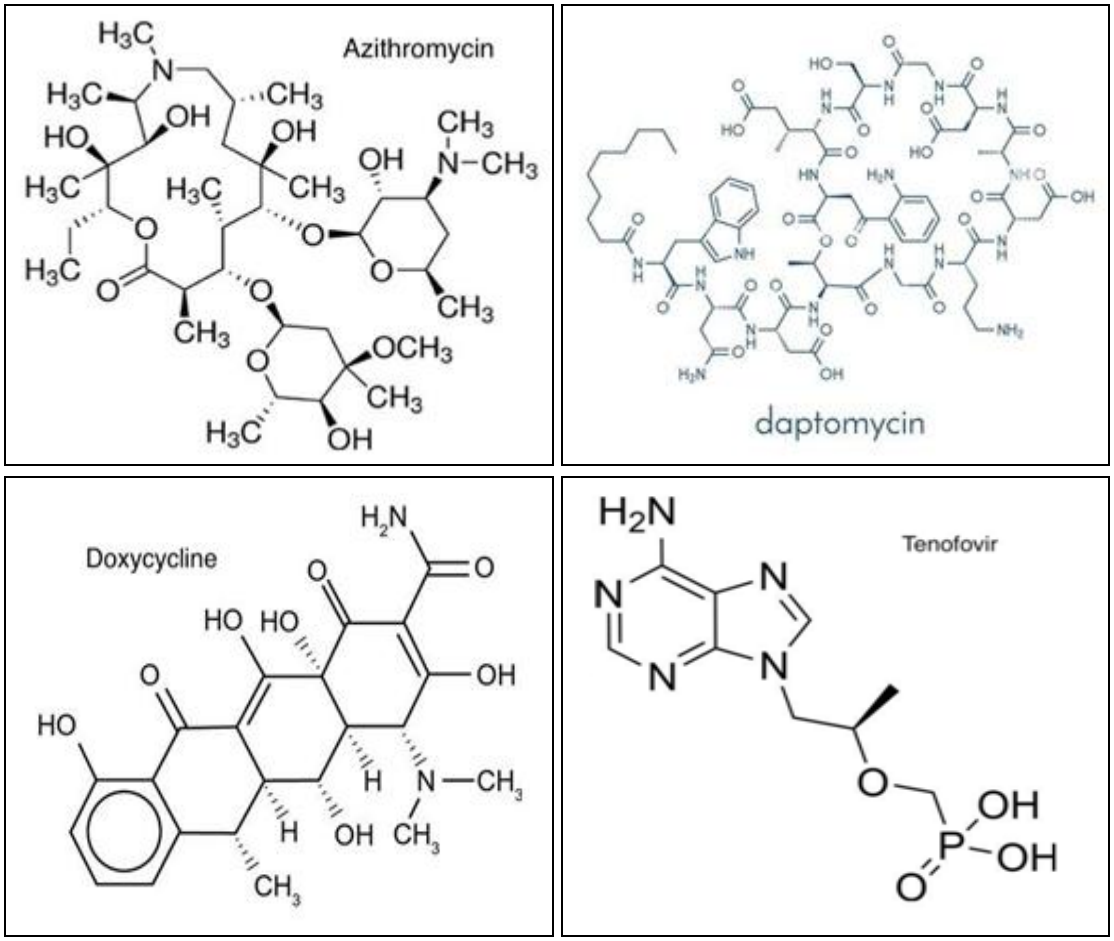

FIG. 2: REPRESENTATIVE STRUCTURES OF REMDESIVIR AND LINEZOLID (ILLUSTRATIVE ONLY)

Analytical Techniques in Bioanalysis: In pharmaceutical analysis, the choice of analytical technique is dictated by the drug's chemical nature, formulation type, and matrix complexity. Antiviral and antibacterial drugs often require highly sensitive and selective methods due to their low plasma concentrations and potential for matrix interferences. Below are key bioanalytical techniques employed:

High-Performance Liquid Chromatography (HPLC): HPLC remains the most widely used analytical tool (Lee & Kim, 2021) [58] in pharmaceutical quality control and method

validation. It provides robust separation and quantification for compounds with UV absorbance. Antibacterials like Linezolid and Doxycycline are often analyzed using HPLC due to their strong UV signatures. Key benefits include precision, repeatability, and versatility in mobile phase selection.

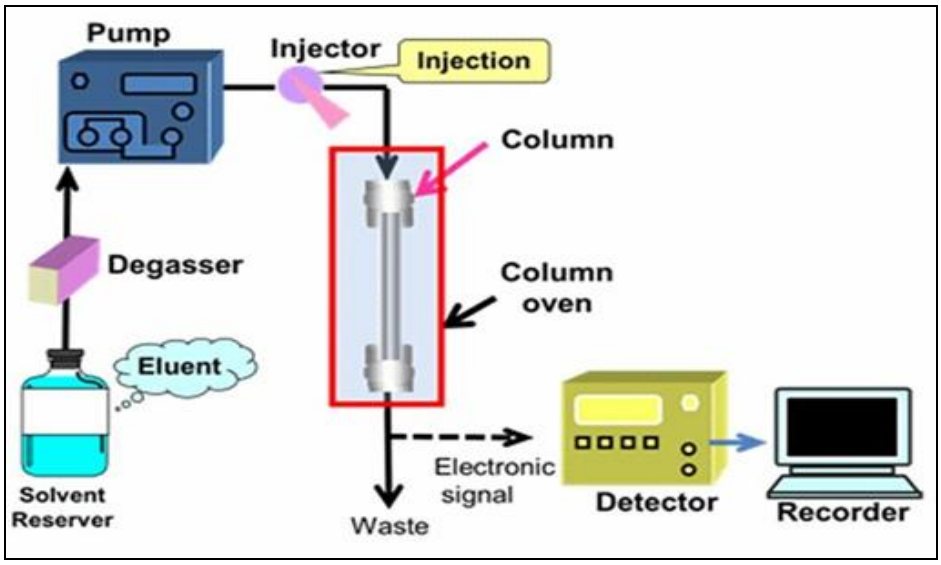

FIG. 3: HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC)

Liquid Chromatography–Tandem Mass Spectrometry (LC-MS/MS): LC-MS/MS is the gold standard for detecting and quantifying [60, 69] trace levels of drugs in biological matrices. It combines high chromatographic resolution with mass-specific detection, making it ideal for complex antivirals like Remdesivir, Molnupiravir, and Nirmatrelvir. Validation typically covers selectivity, sensitivity, recovery, matrix effects, and carryover per ICH M10 and FDA guidelines.

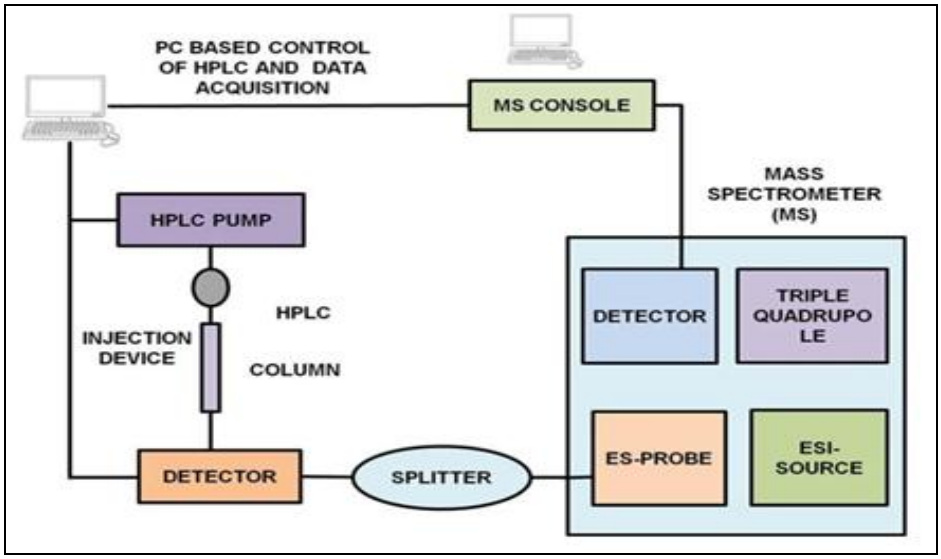

FIG. 4: LIQUID CHROMATOGRAPHY–TANDEM MASS SPECTROMETRY (LC-MS/MS)

Ultra-Performance Liquid Chromatography (UPLC): UPLC offers higher resolution and faster run times compared to conventional HPLC. It is well-suited for high-throughput labs involved in pharmacokinetic studies. This technique is increasingly applied to combination drug analysis and stability indicating methods.

UV-Visible Spectrophotometry: Although not as selective as chromatographic techniques, UV-Vis spectrophotometry is used for in-process control, especially during manufacturing. It is applicable to antibiotics like Doxycycline and some antivirals in bulk or simple formulations.

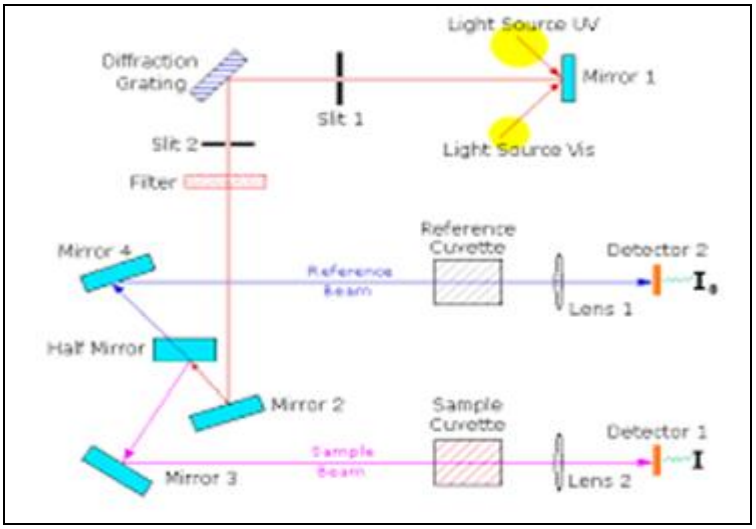

FIG. 5: UV-VISIBLE SPECTROPHOTOMETRY

Review of Patents for Antiviral and Antibacterial Drugs (2015–2025): Recent years have seen a surge in patents focused on novel drug formulations [72, 79], stability enhancement, and targeted delivery systems. These innovations often integrate with bioanalytical method development to ensure quantification and quality control. Below is a categorized review of recent patents related to antibacterial and antiviral drugs.

TABLE 3: NOTABLE PATENTS FOR ANTIBACTERIAL DRUGS (2015–2025)

Patent Number	Innovation	Drug/Formulation
CN104941283A	Daptomycin liposomal injection	Daptomycin
CN107595782A	Linezolid dry suspension	Linezolid
WO2017158269A1	Stabilized vancomycin solution	Vancomycin
CN105267977A	Dissolvable pediatric doxycycline powder	Doxycycline
CN113520994A	Mupirocin stable cream formulation	Mupirocin
CN112315904A	Thermostable injectable formulation	Vancomycin
WO2023096584A1	Nanoparticle formulation for pulmonary delivery	Azithromycin
US10124014B2	Minocycline compounds and methods of use thereof	Doxycycline analogs
US9248159B2	MRSA bactericidal topical gel	Vancomycin

TABLE 4: NOTABLE PATENTS FOR ANTIVIRAL DRUGS (2015–2025)

Patent Number	Innovation	Drug/Formulation
US20150250765A1	Tenofovirala fenamide oral delivery	Tenofovir
WO2017072427A1	Lipid-coated nanoparticles for ritonavir	Ritonavir
CN114748320A	Thermostable oral molnupiravir formulation	Molnupiravir
WO2020141482A1	Mucoadhesive formulation for mucosal delivery	Mupirocin/Remdesivir
WO2023165810A1	Nano-formulated COVID-19 drug combo	Nirmatrelvir + Ritonavir
US20210288102A1	Remdesivir sublingual spray	Remdesivir
WO2024130411A1	Protease inhibitors and methods of using same	Nirmatrelvir
US11351149B2	Nitrile-containing antiviral compounds	Molnupiraviranalogs
CN113278991A	Inhalable powder system	Favipiravir

TABLE 5: NOTABLE PATENTS FOR ANTIBACTERIAL AND ANTIVIRAL DRUGS (2015–2025)

Patent Number	Year	Drug	Category	Chromatographic Technique	Mobile Phase	Innovative Aspect
US9660963	2015	Darunavir	Antiviral	Acetonitrile–Water	HPLC	Simultaneous estimation
EG77277	2017	Baloxavir Marboxil	Antiviral	Phosphate buffer–C18 column	Methanol	Stability-indicating analysis
CN10458532	2017	Tenofovir Disoproxil	Antiviral	Methanol–Water	Water	In-process impurity determination

US10666533	2020	Maribavir Chlorhexidine	Antiviral	Methanol–Water	Methanol–Disoproxil	Stability-indicating analysis
JP5362701	2021	Chlorhexidine	Antibacterial	Phosphate buffer–C18 column	Methanol	Unknown impurity determination
EP3662704	2021	Daptomycin	Antibacterial	HPLC	UPLC	Impurity determination
EP356074	2021	Linezolid	Antibacterial	Methanol–Buffer	Methanol–CO, N	Simultaneous estimation
US1148248	2016	Levofloxacin	Antibacterial	UPLC, SFC	Stability-indicating	Rifapentine metabolite
WO2022162	2022	Imipenem	Antibacterial	Methanol–Buffer	Methanol	Simultaneous indicating profiling
US1191657	2023	Tobramycin	Antiviral	Methanol–K_2O	Methanol	Simultaneous indicating profiling
WO2023240	2023	Tetracycline	Antibacterial	Methanol–Buffer	Methanol–Buffer	Simultaneous estimation
US1874259	2025	Tetracycline	Antibacterial	Stability-indicating	Stability-indicating	Innovative profiling

Regulatory Frameworks for Bioanalytical Method Validation: The reliability of bioanalytical data hinges on rigorous validation [74] aligned with regulatory standards. The International Council for Harmonisation (ICH) and U.S. Food and Drug Administration (FDA) offer globally recognized guidelines:

ICH Q2(R1): Defines parameters including specificity, linearity, accuracy, precision, detection limit (LOD), quantitation limit (LOQ), and robustness. Widely used in early method development.

FDA 2018 Guidance: Focuses on full method validation, including matrix effect evaluation, stability studies, carryover, reinjection reproducibility, and incurred sample reanalysis. It applies to both preclinical and clinical bioanalysis.

ICH M10 Draft (2022): Introduces harmonized requirements for chromatographic and ligand-binding assays. It consolidates guidance for sample handling, reanalysis, validation, and documentation in global regulatory environments.

Sample Preparation Techniques: Effective sample preparation minimizes matrix effects (Chowdhury *et al.,* 2021; Singh & Patel, 2018) and enhances sensitivity in LC-MS/MS workflows. Recent innovations include:

Solid Phase Extraction (SPE): Offers high specificity; ideal for plasma and serum matrices.

Protein Precipitation (PPT): Simple and high-throughput; best for routine bioanalysis.

Liquid-Liquid Extraction (LLE): Efficient for lipophilic drugs but labor-intensive.

Supported Liquid Extraction (SLE): Cleaner extracts with reduced emulsions.

Microextraction Techniques: Enable microscale sampling in pediatric and geriatric studies.

Challenges and Research Gaps: In addition to the challenges already discussed, the following are critical areas requiring further attention:

Cross-Reactivity in Biological Matrices: Some bioanalytical methods suffer from interferences due to endogenous compounds or metabolites that mimic target analytes, leading to false positives or inaccurate quantification [51, 52].

Sample Volume Constraints in Pediatric and Geriatric Studies: Especially in neonates or elderly populations, obtaining large blood volumes for pharmacokinetic studies is ethically and logistically difficult, thus necessitating ultra-sensitive microsampling approaches [53, 77].

Analytical Interference from Excipients in Complex Formulations: Co-formulated drugs or advanced delivery systems such as liposomes and nanoparticles often involve excipients that affect extraction and chromatographic separation [54, 55].

High Cost and Technical Expertise Requirement: The deployment of LC-MS/MS methods requires costly equipment and trained personnel, limiting its adoption in low-resource settings [56].

Global Regulatory Divergence: Discrepancies among regulatory bodies (FDA, EMA, ICH) in bioanalytical validation and documentation protocols can delay drug approval or require redundant testing [57, 74].

Data Reproducibility and Audit Readiness: Ensuring data integrity, particularly with automated peak integration tools and LIMS platforms, is crucial for regulatory acceptance [69, 70].

These challenges underscore the need for harmonized practices, robust method development strategies, and further integration of digital tools like AI to ensure quality and reproducibility in bioanalytical science.

Despite significant advances, several issues remain unresolved in antiviral and antibacterial bioanalysis:

- Matrix interference affecting accuracy and reproducibility [4].
- Inadequate stability-indicating methods for combination therapies.
- Lack of validated methods for novel antiviral-antibacterial blends (e.g., Ensitrelvir + Remdesivir).
- Low recovery in protein-rich samples due to poor extraction efficiency.
- Regulatory inconsistencies between ICH, FDA, and EMA for method harmonization.

Future Research Directions: Looking ahead, the field of bioanalytical science is poised for significant transformation through the integration of emerging technologies. Artificial Intelligence (AI) and Machine Learning (ML) will revolutionize chromatographic data processing by automating peak detection, baseline correction, and real-time error prediction [73]. Wearable biosensors and point-of-care diagnostics are expected to generate new categories of real-time data requiring ultra-sensitive analytical methods. The development of green bioanalytical methods that minimize solvent use and hazardous waste is gaining attention, aligning with global sustainability initiatives [85]. Additionally, regulatory bodies are shifting toward model-informed drug development (MIDD) frameworks that incorporate predictive simulations alongside experimental data.

Lastly, collaborative open-source platforms and global analytical method repositories will improve transparency, data sharing, and reproducibility across laboratories, enabling faster drug development cycles [52, 57].

- Develop LC-MS/MS methods compatible with microsampling platforms [53, 77].
- Explore nanoparticle and liposomal formulations and their analytical implications.
- Integrate bioanalytical workflows with AI/ML (Rahman *et al.,* 2020) [73] for peak identification and quality control.
- Establish shared repositories linking analytical methods with patented drug innovations.
- Focus on pediatric-specific method development using minimal sample volume.

Bioanalytical methods form the analytical backbone of drug discovery, development, and regulatory submission processes. They provide essential data for evaluating pharmacokinetics (PK), bioavailability, and therapeutic monitoring of drugs across diverse biological matrices. Analytical technologies such as HPLC and LC-MS/MS have evolved to meet increasing demands for sensitivity, accuracy, and robustness. These methods are vital not only for evaluating parent drugs and metabolites but also for ensuring.

Furthermore, the reliability of a bioanalytical method is determined by its compliance with international standards such as ICH Q2(R1), FDA, and EMA guidelines, ensuring reproducibility across laboratories. As the pharmaceutical industry increasingly adopts complex drug formulations such as nanomedicines, biosimilars, and targeted therapies, bioanalytical methods must be adapted

and revalidated for these platforms [3, 69]. These efforts are supported by method harmonization

Overview and Importance of Bioanalytical Methods: Bioanalytical methods refer to the quantitative measurement of drugs and their metabolites in biological matrices such as blood, plasma, urine, or tissues. These methods are critical in pharmaceutical research for drug discovery, pharmacokinetics, toxicology, and therapeutic drug monitoring (TDM).

The primary reasons bioanalytical methods are preferred include:

- High sensitivity and specificity for detecting drugs at low concentrations.
- Essential for determining pharmacokinetic parameters like AUC, Cmax, Tmax, and half-life.
- Compliance with regulatory requirements for bioequivalence and approval studies.
- Ability to validate the stability and accuracy of drug formulations.

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