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UV METHOD DEVELOPMENT FOR SIMULTANEOUS ESTIMATION OF LAMIVUDINE AND TENOFOVIR IN FIXED DOSE TABLET COMBINATION"

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INTRODUCTION

Lamivudine (LAM) and tenofovir disoproxil fumarate (TDF) are mixed together in one pill to treat HIV because they work together to block the virus's DNA-making enzyme. But both of them absorb UV light in similar areas—around 260–270 nm—so their UV signals overlap a lot.

This makes it tricky to measure each drug separately using UV spectroscopy.

A **Quality by Design (QbD)** approach utilizing factorial designmodelling, optimized at λmax of 272 nm for LAM and 259 nm for TDF, with broader linearity (2–100 µg/mL) and high recoveries (LAM: 98.9–100.8 %; TDF: 101.6–102.4 %).

Derivative UV spectrophotometry: employing third-order derivative (D_3), resolving overlapping spectra effectively, establishing linearity ranges of 2–10 µg/mL (LAM) and 8–24 µg/mL (TDF), with strong accuracy, precision (RSD < 2 %), and LOQ values at 1.40 µg/mL (LAM) and 7.90 µg/mL (TDF).

OBJECTIVES

- **Select optimal wavelengths**: Identify appropriate λ□ $_{ax}$for LAM and TDF (e.g., ~276 nm and ~260 nm) to enable accurate measurement using the simultaneous-equation method.
- **Establish linearity range**: Confirm Beer's Law across a specified concentration range (commonly 5–25 µg/mL or up to 100 µg/mL depending on method design).
- **Validate method per ICH guidelines**: Evaluate accuracy (recovery ~98–102%), precision (RSD <2%), LOD, LOQ, and robustness to ensure reliability.
- **Apply to commercial dosage forms**: Quantify LAM and TDF directly in fixed-dose combination tablets without prior separation.

AIM

To develop and validate a simple, rapid, accurate, precise, and economical UV spectrophotometric method for the simultaneous estimation of lamivudine (LAM) and tenofovir disoproxil fumarate (TDF) in a fixed-dose combination tablet, following ICH Q2(R1) validation guidelines.

Rationale

FDCs of lamivudine (LAM) and tenofovir disoproxil fumarate (TDF) are pivotal in HIV therapy, yet their UV absorption spectra overlap significantly within the 250–280 nm range, making simultaneous estimation challenging. UV–visible spectrophotometry offers a cost-effective, accessible alternative to HPLC—especially in resource- limited settings—provided the spectral overlap can be resolved.

Techniques like the simultaneous equation method, validated under ICH guidelines, enable accurate, precise, and direct quantification of both drugs in a single analysis without prior separation.

Literature Review

UV Spectrophotometric Methods for Simultaneous Estimation of LAM and TDF

Study	Methodology	Key Findings
Bhadauria & Gupta (2020)	Simultaneous Equation Method	Developed a UV method using 276 nm for LAM and 260 nm for TDF in water. Linearity observed in the range of 5–25 µg/mL for both drugs. Recovery rates ranged from 98.31% to 98.94%, with RSD < 2%, indicating suitability for routine analysis.

Study	Methodology	Key Findings
Vidyadhara et al. (2016)	Simultaneous Equation Method	Applied simultaneous equations at 260 nm (TDF), 347 nm (Efavirenz), and 272 nm (LAM). Beer's law obeyed in the concentration ranges of 10– 40 µg/mL for TDF, and 5– 20 µg/mL for LAM and Efavirenz. Recovery studies showed RSD < 2%.
Vaikosen et al. (2024)	Derivative Spectrophotometry	Utilized third-order derivative spectra to resolve overlapping peaks of LAM and TDF. Calibration curves showed linearity with $R^2 \geq 0.998$. Recovery studies confirmed accuracy and precision.
Asnani et al. (2021)	Quality by Design Approach	Employed a 3-level factorial design to optimize UV method conditions. Linearity observed from 2–100 µg/mL for both drugs. Recovery rates were 98.90–100.77% for LAM and 101.63–102.43% for TDF.
Padmavathi et al. (2020)	Multi-Component Mode	Developed a method using phosphate buffer (pH 5) and methanol (50:50 v/v) as solvent. Linearity observed in the range of 0.4–24 µg/mL for Efavirenz, 0.2–12 µg/mL for TDF, and 0.2– 12 µg/mL for LAM. Limit of

Study	Methodology	Key Findings
		quantitation values were 0.192 µg/mL for Efavirenz, 0.198 µg/mL for TDF, and 0.385 µg/mL for LAM.

KEYWORDS AND REFRENCE SEARCH STRATEGY

- **Keywords**
  - Lamivudine
  - Tenofovir disoproxil fumarate
  - Fixed-dose combination tablets
  - UV spectrophotometry
  - Simultaneous estimation
  - Analytical method development

Reference Search Strategy

1. Database Selection

Utilize reputable academic databases to gather peer-reviewed literature:

- **PubMed**: For biomedical and pharmaceutical research articles.
- **ScienceDirect**: For comprehensive scientific and technical research.
- **Google Scholar**: For a broad range of scholarly articles.
- **SpringerLink**: For access to journals and books in various disciplines.
- **Scopus**: For abstracts and citations of peer-reviewed literature.

2. Search Execution

- **Basic Search**: Start with simple keyword combinations like "Lamivudine Tenofovir UV spectrophotometry".
- **Advanced Search**: Use Boolean operators (AND, OR, NOT) to refine searches. For example:
  - "Lamivudine AND Tenofovir AND UV spectrophotometry"
  - "Simultaneous estimation AND Lamivudine AND Tenofovir"
- **Filters**: Apply filters to narrow results by publication date, article type, and language.

3. Review of Abstracts and Titles

- Skim through abstracts and titles to identify relevant studies.
- Prioritize studies that focus on UV spectrophotometric methods for simultaneous estimation of LAM and TDF.

RESULTS AND DISCUSSION

A few UV-based methods have been developed to measure both **lamivudine (LAM)** and **tenofovir disoproxil fumarate (TDF)** from the same tablet, without needing expensive equipment or separation steps.

In the **simultaneous equation method**, absorbance measurements at **276 nm (LAM)** and **260 nm (TDF)**

show strong linearity between **525 µg/mL**. It's accurate (recoveries 98.398.9%) and precise (RSD < 2%), making it reliable for routine testing.

CONCLUSION

UV–visible spectrophotometry offers a practical and validated alternative to HPLC for simultaneous estimation of LAM and TDF in fixed-dose combinations—particularly valuable in resource-limited or high-throughput settings where simplicity, affordability, and speed are essential.

METHODS

SIMULTANEOUS EQUATION METHOD

- ✓ Choose wavelengths
- ✓ Prepare standard stock & working solutions
- ✓ Determine absorptivities for each drug at both wavelengths
- ✓ Measure mixture absorbances
- ✓ Simultaneous equations

PLAN OF WORK SINCE P-1

1) Project overview & objective
2) Literature & pre-work
3) Materials & instrumentation
4) Method development plan
5) Validation experiments

❖ **Completed**

- ✓ Collected & reviewed recent literature on Lamivudine and tenofovir by UV spectrometer.
- ✓ Literature review

❖ **In- progress**

- ✓ Review Article
- ✓ Collecting more data from research papers & studies

INSTRUMENTS

- UV Spectrometer
- Analytical Balance
- Sonicator (Ultrasonic Bath)
- Volumetric Glassware
- pH Meter

KNOWLEDGE AND SKILL DEVELOPED

1. Theoretical Knowledge Gained

- ✓ Understanding of UV–Visible Spectrophotometry
- ✓ Drug Profile Understanding

2. Practical Skills Developed

- ✓ Instrumental Handling
- ✓ Solution Preparation and Dilution Techniques
- ✓ Preparation of Calibration Curve

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REFERENCES

1. Bhadauria & Gupta (2020) Developed and validated a simultaneous equation UV method using 276 nm for LAM and 260 nm for TDF, with linearity in the range of 5–25 µg/mL, recovery of 98.31–98.94%, and RSD < 2%, allowing direct analysis without separation. Drug Delivery Journal
2. Quality-by-Design (QbD) Optimized UV Method Applied a factorial design approach to optimize conditions— distilled water as solvent, 272 nm (LAM) and 259 nm (TDF) wavelengths. Achieved broad linearity (2–100 µg/mL) and recovery of 98.90–100.77% (LAM) and 101.63–102.43% (TDF). IJPSR
3. Simultaneous Spectrophotometric Estimation in Multi-Drug Formulation Developed methods using simultaneous equations at 260, 347, and 272 nm for TDF, efavirenz, and LAM respectively. Linearity: 10–40 µg/mL (TDF), 5–20 µg/mL (others); validated with RSD < 2%. iScholar
4. Direct Assay of Lamivudine via UV Spectrophotometry Established a simple method to quantify lamivudine alone in API and tablets at 270 nm (methanol), with linearity from 5– 15 µg/mL, R^2 > 0.999, RSD ~0.5%, and recovery of 98–102%. PMCPubMed
5. Multi-Method Spectrophotometric Analysis Including TDF and LAM in a Triple-component Tablet Employed three UV methods: simultaneous equation, multicomponent analysis, and derivative spectroscopy. Absorption maxima: 247 nm (efavirenz), 259 nm (TDF), 272 nm (LAM); linear ranges: efavirenz 10–60 µg/mL, TDF 5–30 µg/mL, LAM 5–30 µg/mL. PMC