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A REVIEW ON METHOD DEVELOPMENT AND VALIDATION OF SELECTED ANTI VIRAL DRUG LENACAPAVIR BY USING DIFFERENT ANALYTICAL TECHNIQUES

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ABSTRACT

Lenacapavir is a long-acting, first-in-class HIV-1 capsid inhibitor used for the prevention and treatment of HIV-1 infection. It acts by binding to the HIV-1 capsid protein and interfering with multiple stages of the viral replication cycle. Lenacapavir disrupts capsid assembly and disassembly, thereby affecting the proper formation and maturation of viral particles. Analytical method development is essential for the accurate identification, estimation, purity determination, and quality control of lenacapavir in pharmaceutical formulations. Various analytical techniques, including UV-visible spectroscopy, HPLC, RP-HPLC, HPTLC, and LC-MS, can be employed for the estimation of lenacapavir. Method validation ensures that the developed analytical procedures provide reliable, accurate, precise, and reproducible results. Important validation parameters include accuracy, precision, specificity, linearity, range, robustness, limit of detection, and limit of quantification. This review focuses on different analytical methods reported for the determination of lenacapavir and evaluates their analytical performance. It also highlights the applicability of different techniques for routine pharmaceutical analysis and quality control of lenacapavir**.**

KEYWORDS: Lenacapavir, HIV-1, Capsid inhibitor, Capsid protein, Analytical method development, Method validation, RP-HPLC, LC-MS.

INTRODUCTION

Analytical method development

Analytical method development is the process of establishing a suitable analytical procedure for the identification, quantification, purity determination, and characterization of a drug substance or pharmaceutical formulation. It involves the systematic selection and optimization of analytical conditions such as the analytical technique, solvent, mobile phase, stationary phase, wavelength, flow rate, temperature, and sample preparation conditions. The developed method should be capable of providing accurate, precise, specific, sensitive, and reproducible results. In pharmaceutical analysis, analytical method development is an important step in ensuring the quality, safety, efficacy, and consistency of drug substances and drug products.

Criteria for the development of new analytical method

Drug analysis is the basis for the determination of the product. Very often, there is a time lag from the date of introduction of a drug into the market to the date of its

inclusion in pharmacopeia's. This happens because of the possible uncertainties in the continuous and wider usage of these drugs, report of new toxicities and development of patient resistance and introduction of better drugs by the competitors.

The new drug or drug combination may not be official in any pharmacopeia's. A proper analytical procedure for the drug may not be available in the literature due to patent regulations. Analytical methods may not be available for the drug in the form of formulation excipients. Analytical methods for a drug in combination with other drugs may not be available. Analytical methods for the quantitation of the drug in biological fluids may not be available. The existing analytical procedures may require expensive reagents and solvents. It may also involve cumbersome extraction and separation procedure and these may not be reliable.

Steps for analytical method development

The procedure for analytical method development follows a set of steps as below:

Purpose of Analytical Method

Development In the pharmaceutical industry, analytical method development gives important information on the potency of a drug, the drugs' bioavailability, the drugs' stability and also its effects. In the very first step, the purpose of conducting any Analytical Method Development is established.

Highlighting of Steps

In the second step of Analytical Method Development, the steps involved in the development are recorded in a laboratory book.

Characterization of the Analyte

In this step, both the biological and chemical properties in addition to the physical properties of the analyte are collected. After that, the analyte is obtained and stored according to its specific requirements. The methods for analysis are then recorded with an example being the chromatography technique which employs different methods such as the High-Performance Liquid Chromatography.

Definition of Requirements

Requirements for the method development of the analysis are done and recorded. All the materials, reagents and instruments are procured those are required for the analysis of the sample.

Review of Literature and Previous Methods

All literature information related to the specific analyte e.g. a specific drug is assessed for any biological, chemical and chemical properties regarding the analyte. Reference is then made from journals, books and any other publications.

Choosing an Analytical Method

From the information obtained from the literature during the literature review, a specific methodology is modified to cater for accurate output and also because methods change with the requirements of the analyte. If there are no previous methods in the literature being reviewed regarding the analyte, the procedure goes on uninterrupted.

Setting up of Instruments

Appropriate instruments for the analytical method development are set up in the laboratory by each of the instruments standard operating procedures. Standard Operating Procedures usually abbreviated as SOP's are a set of instructions or steps to aid in performing a specific procedure in a laboratory set up. They are usually universal and standardized for ease of use in any laboratory set up.

Optimization of the Method

In carrying out the optimization of the analytical method, parameters are changed individually depending on the arising interests. Optimization of an analytical method is done in reference to a systematic and procedural plan while making sure to critically follow all the documented steps.

Analytical Figures of Merit Documentation:

Documentation of the analytical figures of merit decided upon is done. These analytical figures of merit include quantification limits, detection limits, analysis time frame, operational costs and sample preparation.

Development Method Evaluation

The resultant product of analysis should give a desirable result as expected in the identification of the analyte.

Sample Estimation, Quantitative Demonstration and Analysis of Samples

Estimation of an analyte with an example being a drug in a matrix sample containing the analyte is done here.

Analytical method validation

It establishes documented evidence that the procedure adapted for a test is fit for the intended purpose in terms of quality, reliability, and consistency of results.

Parameters to be checked for method validation

Selectivity/specificity

Specificity is the ability to assess unequivocally the analyte in the presence of components that may be expected to be present. The terms selectivity and specificity are often used interchangeably. According to ICH the term specific generally refers to a method that produces a response for a single analyte only while the term selectivity refers to a method that provides responses for a number of chemical entities that may or may not be distinguished from each other.

Precision
ICH defines the precision of an analytical procedure as the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions. Precision is the measure of how close the data values are to each other for several measurements under the same analytical conditions.

Accuracy
The accuracy of an analytical method is the degree of agreement of test results generated by the method to the true value.

Accuracy is measured by spiking the sample matrix of interest with a known concentration of analyte standard and analysing the sample using the "method being validated." The procedure and calculation for Accuracy (as% recovery) will be varied from matrix to matrix and it will be given in respective study plan or amendment to the study plan.

Linearity
The linearity of an analytical method is its capability to elicit check consequences which might be at once, or with the aid of well described mathematical adjustments, proportional to the concentration of analytes in within a given range.

Linearity is determined by injecting a series of standards of stock solution/diluted stock solution using the solvent/mobile phase, at a minimum of five different concentrations in the range of 50–150% of the expected working range. The linearity graph will be plotted manually/using Microsoft Excel or software of the computer (Concentration vs. Peak Area Response) and which will be attached to respective study files.

Range
The range of an analytical method is the interval between the upper and lower levels that have been demonstrated to be determined with precision, accuracy and linearity using the set method. This range will be the concentration range in which the Linearity test is done.

Limit of detection and limit of quantitation
The limits of detection (LOD) and quantification (LOQ) are defined as the lowest concentration of the analyte that can be reliably detected and quantified, respectively. Usually, the LOD and LOQ refer to the limits associated with 95% probability of obtaining a correct result Limit of detection

Different Analytical techniques
Liquid chromatography-mass spectrometry (LC–MS)
Liquid chromatography-mass spectrometry (LC–MS) is a powerful analytical technique used for separation, identification, and quantification of both unknown and known compounds as well as to elucidate the structure and chemical properties of different molecules.

Mass spectrometry (MS) is an analytical technique that measures the mass-to-charge ratio (m/z) of charged particles (ions). Although there are many kinds of mass spectrometers, all of them make use of electric or magnetic fields to manipulate the motion of ions produced from an analyte of interest and determine their m/z. The basic components of a mass spectrometer are the ion source, the mass analyser, the detector, and the data and vacuum systems. The ion source is where the components of a sample introduced in a MS system are ionized by means of electron beams, photon beams (UV lights), laser beams or corona discharge. In the case of electrospray ionization, the ion source moves ions that exist in liquid solution into the gas phase. The ion source converts and fragments the neutral sample molecules into gas-phase ions that are sent to the mass analyser. While the mass analyser applies the electric and magnetic fields to sort the ions by their masses, the detector measures and amplifies the ion current to calculate the abundances of each mass-resolved ion. In order to generate a mass spectrum that a human eye can easily recognize, the data system records, processes, stores, and displays data in a computer.

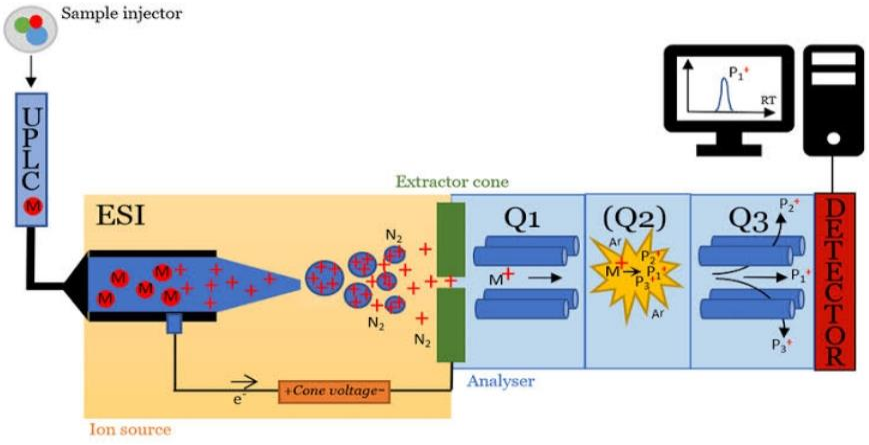

Fig. 1: LC-MS Instrumentation.

Ultra Performance Liquid Chromatography

UPLC stands for Ultra Performance Liquid Chromatography, a technique used in liquid chromatography analysis. It's an improvement on HPLC (high-performance liquid chromatography) and offers better resolution and sensitivity, shorter run times, and the ability to analyse more samples in less time. Ultra-performance liquid chromatography (UPLC), developed in 2004 by Waters, is a modern liquid chromatographic system, which is simply the modification of HPLC.

The smaller particle size of sorbent (diameter less than 2 µm) in UPLC offers better resolution, speed, and sensitivity compared with HPLC. The basic principle of UPLC for the separation of components in a matrix is same as HPLC, the main difference is in the particle size of sorbent of the column, which is less than 2 µm. The small particles in UPLC require a high pressure (6000 psi) to work with. A significant decrease in the particle size of stationary phase below 2.5 µm provides a remarkable increase in the effectiveness of the column, which does not reduce on increasing the linear speed or rate of flow. The use of speed, particles with a small radius, and maximum number of resolvable peaks (peak capacity) comprehends the efficiency together with resolution. UPLC cuts the mobile phase volume consumption by at least 80% compared to HPLC with a very short runtime (even less than 1 min).

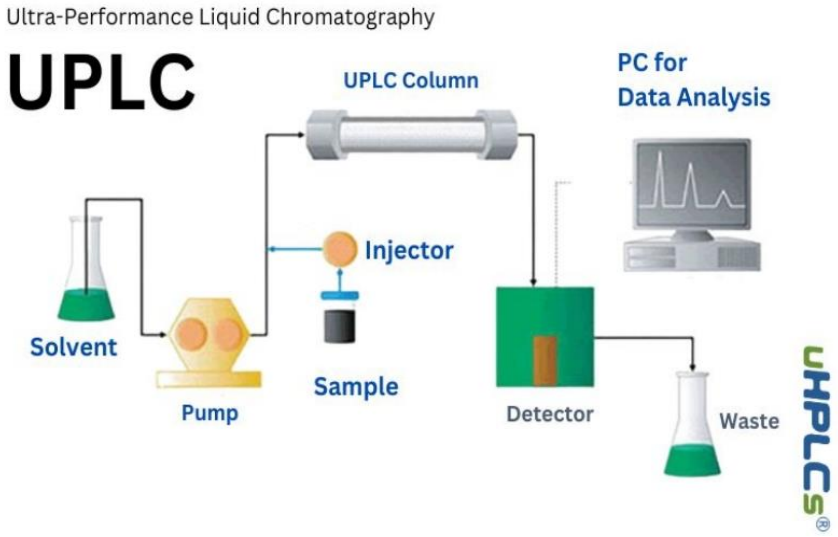

Fig. 2: UPLC Instrumentation.

High-Performance Liquid Chromatography

HPLC is an abbreviation for High-Performance Liquid Chromatography. "Chromatography" is a technique for separation, "chromatogram" is the result of chromatography, and "chromatograph" is the instrument used to conduct chromatography.

Only compounds dissolved in solvents can be analyzed with HPLC. HPLC separates compounds dissolved in a liquid sample and allows qualitative and quantitative analysis of what components and how much of each component are contained in the sample.

It shows a basic overview of the HPLC process. The solvent used to separate components in a liquid sample for HPLC analysis is called the mobile phase. The mobile phase is delivered to a separation column, otherwise known as the stationary phase, and then to the detector at a stable flow rate controlled by the solvent delivery pump. A certain amount of sample is injected into the column and the compounds contained in the sample are separated. The compounds separated in the column are detected by a detector downstream of the column and each compound is identified and quantified.

There are two phases for HPLC: the mobile phase and the stationary phase. The mobile phase is the liquid that dissolves the target compound. The stationary phase is the part of a column that interacts with the target compound.

In the column, the stronger the affinity (e.g.; van der Waals force) between the component and the mobile phase, the faster the component moves through the column along with the mobile phase. On the other hand, the stronger the affinity with the stationary phase, the slower it moves through the column. Fig. 3 shows an example in which the yellow component has a strong affinity with the mobile phase and moves quickly through the column, while the pink component has a strong affinity with the stationary phase and moves through slowly. The elution speed in the column depends on the affinity between the compound and the stationary phase.

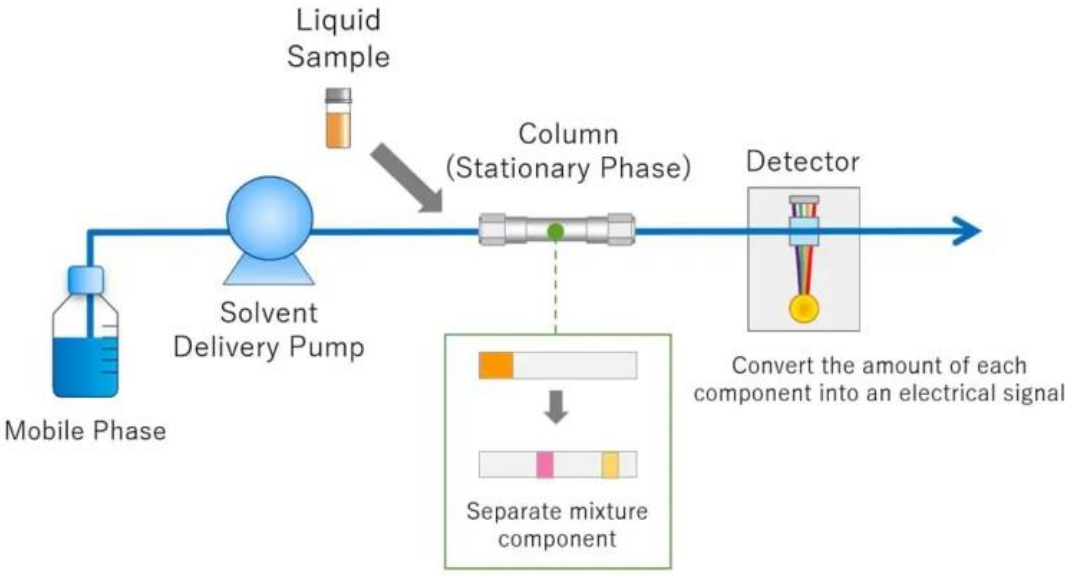

Fig. 3: HPLC Instrumentation.

Gas chromatography

Gas Chromatography (GC or GLC) is a commonly used analytic technique in many research and industrial laboratories for quality control as well as identification and quantitation of compounds in a mixture. GC is also a frequently used technique in many environmental and forensic laboratories because it allows for the detection of very small quantities. A broad variety of samples can be analysed as long as the compounds are sufficiently thermally stable and reasonably volatile.

In gas-solid chromatography, a solid adsorbent is utilised as the stationery and separational phase. In gas liquid chromatography with a stationary phase adsorption process Solid consists of a thin covering of immobile liquid with help and detachment. Through the process of breaking up. Gas liquid chromatography is the most generally used organization. The break up sample is first vaporized and also combined with the gas Mobile stage. In the stationary phase, quickly patches run mostly densely & in the stationary phase, the bottom answerable factors run quickly. The sample result stored in the gadget, which is together for distribution, enters the gas stream that passes through the division pipe called "column". (Helium or nitrogen is known as carrier gas.) different factors are break up under the column. The detector calculates the number of factors leaving the column. To calculate a sample with an unknown concentration, a standard sample with a known concentration is fitted into the instrument. The peak retention time (external form) and area of the standard sample are contrast with the test sample to calculate the concentration.

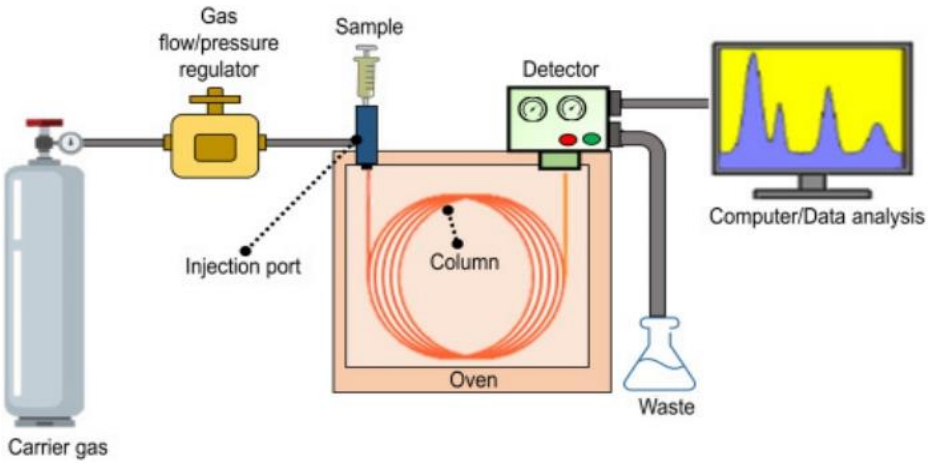

Fig. 4: Gas Chromatography Instrumentation.

UV Spectroscopy

Spectroscopy is the measurement and interpretation of electromagnetic radiation absorbed or emitted when the molecules or atoms or ions of a sample move from one energy state to another energy state. UV spectroscopy is a type of absorption spectroscopy in which light of the

ultra-violet region (200-400 nm) is absorbed by the molecule which results in the excitation of the electrons from the ground state to a higher energy state.

UV Vis spectroscopy is a scientific technique used to measure the amount of light that is absorbed or transmitted by a sample at different wavelengths of ultraviolet (UV) and visible (Vis) light.

The process involves shining a beam of UV Vis light through the sample and measuring the amount of light that passes through it. By analysing the pattern of absorption and transmission of light, scientists can identify and quantify the components of the sample.

A unique relationship exists between the substance and its UV Vis spectrum when a substance absorbs the maximum light at a specific wavelength. This relationship can be used for:

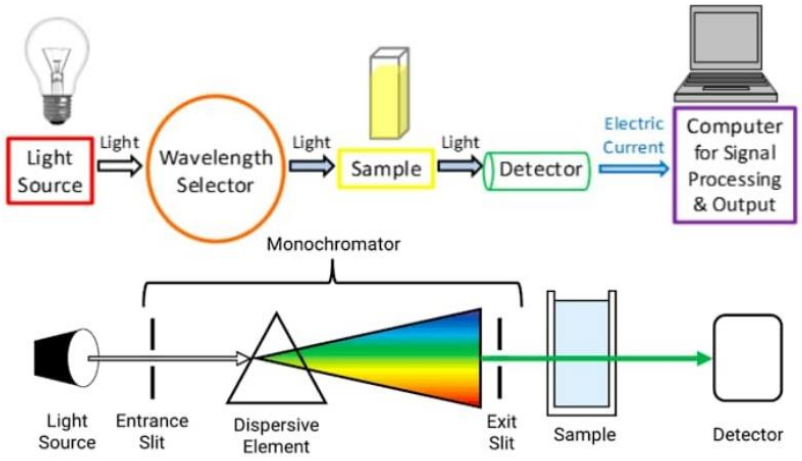

Fig. 5: UV Spectrophotometer Instrumentation.

DRUG PROFILE

LENACAPAVIR

IUPAC Name: N-[(1S)-1-{3-[4-chloro-3-(methanesulfonamido)-1-(2,2,2-trifluoroethyl)-1H-indazol-7-yl]-6-[3-(methanesulfonyl)-3-methylbut-1-yn-1-yl]pyridin-2-yl}-2-(3,5-difluorophenyl)ethyl]-2-[(3bS,4aR)-5,5-difluoro-3-(trifluoromethyl)-3b,4,4a,5-tetrahydro-1H-cyclopropa[3,4]cyclopenta[1,2-c]pyrazol-1-yl]acetamide

CHEMICAL FORMULA: $C_{39}H_{32}ClF_{10}N_7O_5S_2$

MOLECULAR MASS: 968.28 g/mol

STRUCTURE

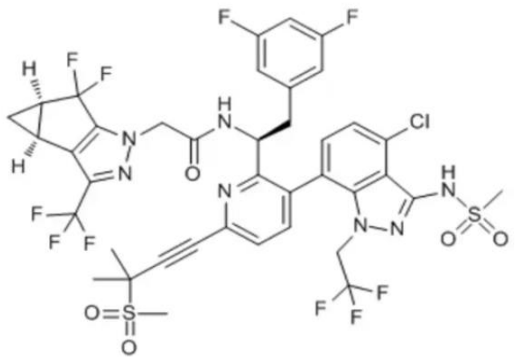

Fig. 6: Structure of lenacapavir.

PHARMACODYNAMICS

Lenacapavir is administered orally or via subcutaneous injection. Oral tablets can be taken with or without food, while the subcutaneous formulation provides a slow-release depot that allows dosing once every six months. It should not be co-administered with strong CYP3A inducers such as rifampin or carbamazepine, as these significantly reduce drug exposure.

MECHANISM OF ACTION

Lenacapavir is a first-in-class HIV-1 capsid inhibitor. It binds to a hydrophobic pocket in the capsid protein (p24), interfering with multiple stages of the viral life cycle. During early infection, it prevents capsid disassembly and nuclear import of the viral genome. In later stages, it disrupts capsid assembly and maturation, resulting in non-infectious viral particles.

In addition, lenacapavir's mechanism is unique because it targets a structural protein rather than an enzyme, unlike most existing antiretrovirals. By stabilizing or destabilizing the capsid at critical points, it blocks interactions with host factors such as CPSF6 and Nup153, which are essential for viral integration. This dual action—affecting both early and late replication steps—provides a robust barrier against viral escape and contributes to its effectiveness in multidrug-resistantHIV.

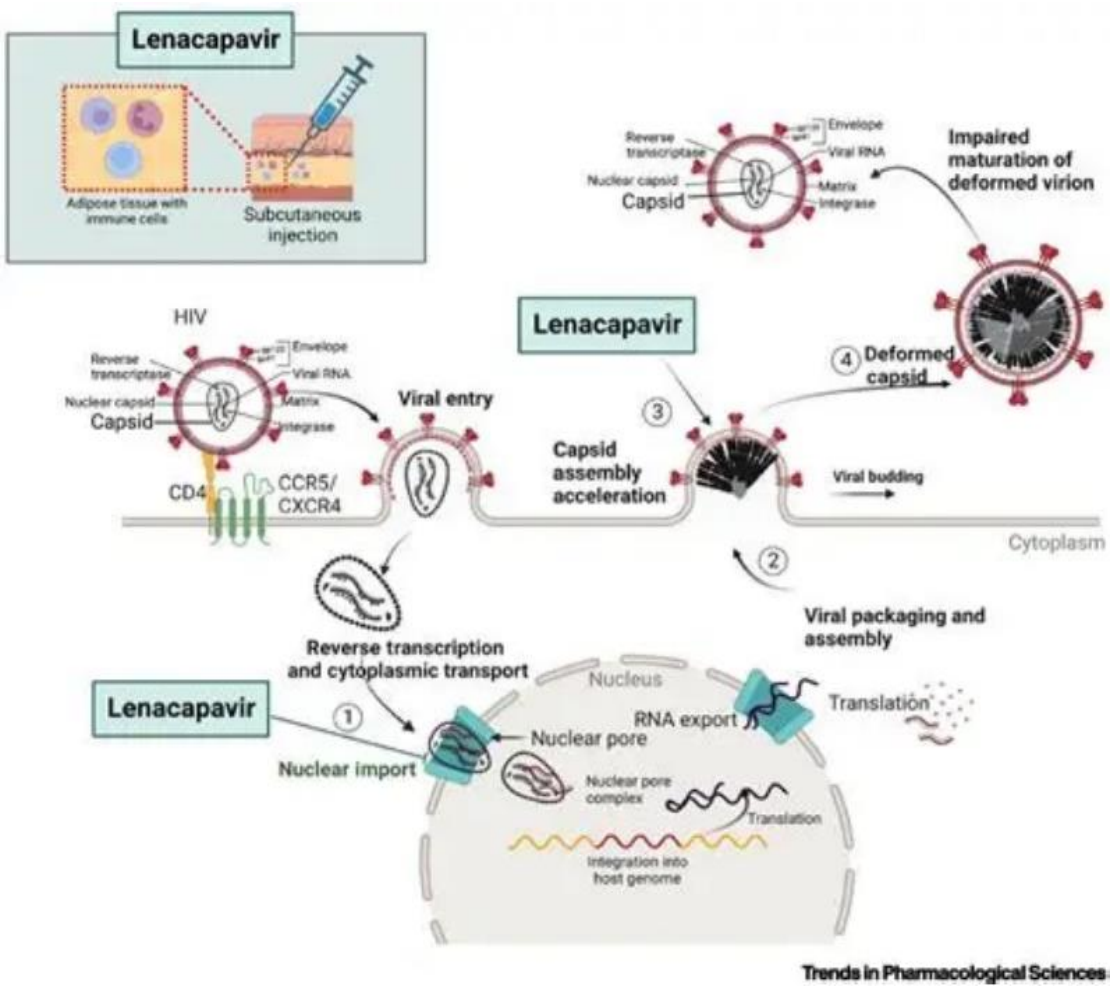

Fig. 7: Lenacapavir mechanism of action.

VOLUME OF DISTRIBUTION: The apparent volume of distribution of lenacapavir is approximately 200–250 L, indicating extensive tissue penetration.

PROTEIN BINDING

Lenacapavir is highly protein-bound in plasma, with >98.5% bound, primarily to albumin. This contributes to its long duration of action.

METABOLISM

Lenacapavir is metabolized primarily by the enzyme CYP3A4, with a minor contribution from UGT1A1. It is also a substrate of P-glycoprotein (P-gp), which influences its absorption and distribution. The parent drug remains the major active circulating component in plasma, while its metabolites are considered inactive. This metabolic profile means that co-administration with strong CYP3A inducers can significantly reduce lenacapavir exposure, while inhibitors of CYP3A4 may increase drug levels.

ROUTE OF ELIMINATION

Lenacapavir is eliminated mainly through the faeces, with approximately 76% of the administered dose recovered in this route. Urinary excretion is minimal, accounting for less than 1% of the dose, and unchanged parent drug is negligible in both urine and feces. This elimination pathway highlights the importance of hepatic metabolism in its clearance, while renal excretion plays only a minor role.

HALF-LIFE

Lenacapavir has an exceptionally long half-life:

- **Oral tablets:** ~8–12 days
- **Subcutaneous injection:** ~15–122 days

This supports biannual dosing for HIV

Table No. 1: Different analytical techniques of Lenacapavir.

S.NO	DRUG NAME	ANALYTICAL TECHNIQUE	DESCRIPTION OF TECHNIQUE	AUTHOR & YEAR
1	lenacapavir	RP-HPLC	Technique: RP-HPLC Type: Review Drug: Lenacapavir and its combinations Column technologies: Reviewed Mobile phase strategies: Reviewed Detection options: Reviewed Sample preparation: Reviewed Automation: Reviewed Validation: Regulatory-aligned practices Special focus: Multi-analyte methods, hyphenated techniques, green analytical chemistry and sensitivity/matrix-complexity challenges	Dr. M. Sumithra et al. (2026)
2	lenacapavir	RP-HPLC	Technique: Stability-indicating RP-HPLC Column: Phenomenex Luna® (4.6 × 250 mm, 5 µm) Mobile phase: 0.1% OPA buffer & acetonitrile (60:40 v/v) Flow rate: 1.0 mL/min Wavelength: 254 nm Retention time: 2.816 min Linearity: 5–50 µg/mL R^2: >0.999 Precision: %RSD <2% Recovery: 99–100% LOD: 0.5 µg/mL LOQ: 1.5 µg/mL Validation: ICH Q2(R1)	Mr. Prasanth V G et al. (2025)
3	lenacapavir	RP-HPLC	Technique: RP-HPLC Column: Zorbax SB C18 (250 × 4.6 mm, 5 µm) Mobile phase: Acetonitrile & ammonium formate buffer (pH 3.0) (30:70 v/v) Flow rate: 1.0 mL/min Wavelength: 269 nm Detector: Photodiode array Retention time: 4.142 min Linearity: 12.5–75 µg/mL R^2: 0.99967 Precision: RSD <0.5% Recovery: 99.2–101.5% LOD: 0.15 µg/mL LOQ: 0.5 µg/mL	Raviteja Bandla et al. (2025)
4	lenacapavir	LC-MS	Technique: LC-MS Internal standard: D6-LCV Column: Waters Symmetry C18 (150 × 4.6 mm, 3.5 µm) Mobile phase: Acetonitrile & 0.1% formic acid buffer Linearity: 5–100 ng/mL R^2: 0.9999 Extraction: Liquid-liquid extraction Recovery: 98.97%, 99.51%, 99.49% Stability: Stable under various storage conditions	Edward Raju Gope et al. (2025)

5	lenacapavir	RP-HPLC	Technique: RP-HPLC Column: Hypersil ODS C18 (4.6 × 250 mm, 5 µm) Mobile phase: 0.1% OPA buffer & acetonitrile Mode: Gradient Flow rate: 1.0 mL/min Wavelength: 220 nm Injection volume: 20 µL Retention time (LENA): 2.17 min Retention time (BIC): 11.46 min Linearity (LENA): 72–216 µg/mL Linearity (BIC): 24–72 µg/mL Recovery: 98–102% Validation: Specificity, linearity, accuracy, precision, robustness, LOD and LOQ	Arram Madhavi et al. (2024)
6	lenacapavir	UHPLC-MS/MS	Technique: UHPLC-MS/MS Sample: Human plasma Sample preparation: Protein precipitation with acetonitrile followed by dilution Internal standard: Stable isotope-labeled lenacapavir Separation: Multi-step UPLC gradient Retention time: 1.90 min Linearity: 0.1–500 ng/mL R^2: ≥0.9960 Trueness: 89.7–104.1% Precision: CV <15% Validation: FDA bioanalytical method validation guidelines	Raymond E. West III et al. (2023)
7	lenacapavir	RP-HPLC	Technique: RP-HPLC Column: BDS C18 (150 × 4.6 mm, 5 µm) Mobile phase: Acetonitrile & 0.01 N KH_2PO_4 buffer (60:40 v/v) Flow rate: 1.0 mL/min Temperature: 30°C Wavelength: 257 nm Retention time (Lenacapavir): 3.052 min Precision (%RSD): 0.4% for both drugs 99.15% for Lenacapavir LOD (Lenacapavir): 0.05 µg/mL LOQ (Lenacapavir): 0.15 µg/mL	Julia Paik et al. (2022)

Table No. 2: Brand Names.

S.NO	BRAND NAME	API	MANUFACTURING COMPANY
1	Sunlenca	Lenacapavir	Gilead Sciences
2	Yeztugo	Lenacapavir	Gilead Sciences

CONCLUSION

A comprehensive review of reported analytical methods for the estimation of Lenacapavir by different analytical techniques is expected. The review is expected to identify commonly used techniques, analytical conditions, sample-preparation procedures, and validation parameters. The reported methods are expected to demonstrate suitable characteristics such as linearity, accuracy, precision, sensitivity, and robustness within their intended applications. A comparison of UV-Visible spectrophotometry, RP-HPLC, UHPLC-MS/MS, and LC-MS/MS is expected to highlight the advantages and limitations of each technique. The review is expected to establish the scope for the development and validation of a simple, rapid, accurate, precise, and reproducible analytical method for Lenacapavir. The work is expected to provide a useful reference for the selection and validation of analytical methods for Lenacapavir in pharmaceutical analysis.

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CONSENT AND ETHICAL APPROVAL
It is not applicable.

COMPETING INTERESTS
Authors have declared that no competing interests exist.

REFERENCES

1. ICH, *Validation of Analytical Procedures: Text and Methodology Q2(R1)*, International Conference on Harmonisation, 2005.
2. Gilead Sciences, Sunlenca (lenacapavir) – Prescribing Information, U.S. Food and Drug Administration.
3. Noah C. Neverette, Julie B. Dumond, Deborah K. McMahon, Aaron S. Devanathan, "Lenacapavir: Playing the Long Game in the New Era of Antiretrovirals," *Clinical Pharmacology & Therapeutics*, 2024; 117(2): 353–367.
4. Raymond E. West III, Patrick J. Oberly, Sharon A. Riddler, Thomas D. Nolin, "Development and validation of an ultra-high performance liquid chromatography-tandem mass spectrometry method for quantifying lenacapavir plasma concentrations: Application to therapeutic monitoring," *Journal of Chromatography B*, 2023; 1230: 123905. DOI: 10.1016/j.jchromb.2023.123905.
5. Chennupati V. Suresh, Santhosh Illendula; a review on method development and validation of fexofenadine By different analytical techniques, IJMPR, 2024; 8(3): 44-50.
6. Santhosh Illendula., et al; A Review on Method Development and Validation of Anticancer Drugs Pralsetanib and Azacitidine by Different Analytical Techniques. International Journal of Pharmacy and Analytical Research, 2026; 15(1): [23-32]. DOI: https://doi.org/10.61096/ijpar.v15.iss1.2026.23-32
7. Santhosh Illendula et al; a review on method development and validation of selected anticancer drugs zanubrutinib, erdafitinib by different analytical techniques. World Journal of Pharmaceutical Research, 2024, 14(01), 263-281. DOI: 10.20959/wjpr202401-35043
8. Arram Madhavi, Medidi Srinivas, Niraj Gupta, "Application of Reversed-Phase HPLC Method for the Simultaneous Determination of Lenacapavir and Bictegravir in Tablets Dosage Form," *Journal of Young Pharmacists*, 2024; 16(4): 745–752. DOI: 10.5530/jyp.2024.16.94.
9. Kethavath Avinash, Raviteja Bandla, "Stability-Indicating High Performance Liquid Chromatographic Method for the Assay of Lenacapavir in Bulk and Formulated Dosage Forms," *International Journal of Advanced Research in Engineering and Applied Sciences*, 2025; 13(1).
10. Edward Raju Gope, Srikanth Pottendla, Suneetha Yaparthi, "Establishment and validation of LC-MS/MS technique for Lenacapavir quantification in rat plasma, with application to pharmacokinetic assessment," *Journal of Applied Pharmaceutical Science*, 2025; 15(5): 112–120. DOI: 10.7324/JAPS.2025.229006.
11. Prasanth V. G., Ankit Singh, "Development and Validation of a Reverse-Phase HPLC Method for Estimation of Lenacapavir in Pure and Pharmaceutical Formulations," *Entire Research International Multi-Disciplinary Research Journal*, 2025; 17(2).
12. Revathi B., Gowthami B., Harini D., Sravya G. V., Varsha M., "Method Development and Method Validation for Simultaneous Estimation of Lenacapavir–Bictegravir Using RP-HPLC Method," *Malla Reddy Institute of Pharmaceutical Sciences Journal*, 2025.
13. https://go.drugbank.com/drugs/DB15673
14. https://en.wikipedia.org/wiki/Lenacapavir