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A REVIEW ON METHOD DEVELOPMENT AND VALIDATION OF ANTICANCER DRUG ENSARTINIB BY USING DIFFERENT ANALYTICAL TECHNIQUES

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ABSTRACT

Ensartinib is a potent, orally active, next-generation anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitor used in the treatment of ALK-positive non-small-cell lung cancer (NSCLC). Development of a simple, rapid, accurate, precise, and robust analytical method is important for the quantitative estimation of ensartinib in pharmaceutical formulations and biological samples. The present study focuses on the development and validation of an analytical method for the estimation of ensartinib using a suitable chromatographic technique. Method development involves optimization of chromatographic parameters such as stationary phase, mobile phase composition, flow rate, injection volume, detection wavelength, and run time to obtain satisfactory separation and peak characteristics. The developed method is subsequently validated according to ICH guidelines with respect to system suitability, specificity, linearity, accuracy, precision, limit of detection (LOD), limit of quantification (LOQ), robustness, and solution stability. The method is expected to provide good linearity over the selected concentration range with acceptable accuracy and precision. The optimized chromatographic conditions should produce a sharp and symmetrical ensartinib peak with an appropriate retention time and adequate resolution. The validated method can be applied for the routine quality control analysis of ensartinib in bulk drug and pharmaceutical dosage forms. Thus, the developed method provides a reliable, reproducible, and economical approach for the estimation of ensartinib and may be useful for pharmaceutical quality-control studies.

KEYWORDS: Pharmaceutical analysis, ensartinib, ICH, LOD, analytical method development.

INTRODUCTION

PHARMACEUTICAL ANALYSIS

Pharmaceutical Analysis: Pharmaceutical analysis is a branch of pharmaceutical science concerned with the identification, determination, separation, purification, and quantification of drugs and pharmaceutical substances. It is used to determine the identity, purity, strength, safety, and quality of active pharmaceutical ingredients (APIs), excipients, and finished pharmaceutical products. Pharmaceutical analysis involves both qualitative analysis, which identifies the substances present, and quantitative analysis, which determines their amounts.

Pharmaceutical analysis plays an important role in drug development, quality control, quality assurance, and stability studies. Various analytical techniques such as titrimetric methods, UV–Visible spectroscopy, IR spectroscopy, HPLC, HPTLC, GC, mass spectrometry, and electroanalytical methods are used for pharmaceutical testing. These techniques help ensure that medicines meet the required identity, purity, potency,

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efficacy, and safety standards before they are released for patient use.

DIFFERENT ANALYTICAL TECHNIQUES

1. Classical Analytical Techniques

- **Volumetric analysis (Titrimetry)**

Acid–base titration
Redox titration
Precipitation titration
Complexometric titration

- **Gravimetric analysis:** Determination of analyte based on measurement of mass.

2. Spectroscopic Techniques

UV–Visible spectroscopy – based on absorption of UV/visible radiation.
Infrared (IR) spectroscopy – identifies functional groups.
Fluorescence spectroscopy – measures fluorescence emitted by substances.
NMR spectroscopy – provides information about molecular structure.
Atomic absorption spectroscopy (AAS) – determination of metal elements.
Atomic emission spectroscopy (AES) – elemental analysis.

3. Chromatographic Techniques

Paper chromatography (PC)
Thin-layer chromatography (TLC)
High-performance liquid chromatography (HPLC)
Gas chromatography (GC)
Ion-exchange chromatography
Size-exclusion chromatography
HPTLC

4. Electro-analytical Techniques

Potentiometry – measures potential difference.
Conductometry – measures electrical conductance.
Voltammetry – measures current as a function of applied potential.
Polarography – a type of voltametric analysis.
Amperometry – measures current at a fixed potential.

5. Thermal Analytical Techniques

Thermogravimetric analysis (TGA) – measures change in mass with temperature.
Differential thermal analysis (DTA) – measures temperature difference.
Differential scanning calorimetry (DSC) – measures heat flow associated with thermal transitions.

6. Mass Spectrometric Techniques

Mass spectrometry (MS) – determines molecular mass and structural information.
LC–MS/MS – combines liquid chromatography with tandem mass spectrometry.
GC–MS – combines gas chromatography with mass spectrometry.

7. X-ray Techniques

X-ray diffraction (XRD) – studies crystalline structure.
X-ray fluorescence (XRF) – elemental analysis.

8. Microscopic Techniques

Optical microscopy
Electron microscopy
Scanning electron microscopy (SEM)
Transmission electron microscopy (TEM)

GAS CHROMATOGRAPHY MASS SPECTROSCOPY

GC–MS (Gas Chromatography–Mass Spectrometry)
GC–MS is a powerful hyphenated analytical technique that combines Gas Chromatography (GC) and Mass Spectrometry (MS). GC separates the components of a complex mixture, while MS identifies the separated compounds based on their molecular mass and fragmentation pattern. Because it provides both separation and structural information, GC–MS is widely used in pharmaceutical, environmental, forensic, clinical, and food **analysis.**

Principle

The sample is first vaporized and introduced into the gas chromatograph. The components are separated according to their volatility and interaction with the stationary phase of the GC column. Each separated component then enters the mass spectrometer, where it is ionized and fragmented. The resulting ions are separated according to their mass-to-charge ratio (m/z) and detected to produce a mass spectrum. The spectrum is compared with reference spectra or libraries for identification.

Main Components of GC–MS

1. Gas chromatograph
2. Mass spectrometer

Ion source
Mass analyzer
Detector
Vacuum system
Data-processing system
Working Injector
Carrier gas system
GC column
Oven
Temperature-control system

Sample → Injection → Vaporization → GC separation → Ionization → Fragmentation → Mass analysis → Detection → Mass spectrum → Identification

Common Ionization Method

Electron ionization (EI) – commonly used in GC–MS.
Chemical ionization (CI) – provides softer ionization and can give useful molecular-ion information.

Applications in Pharmaceutical Analysis

Identification of drugs and pharmaceutical compounds
Impurity profiling

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Identification of degradation products
Analysis of volatile and semi-volatile compounds Drug and metabolite analysis
Residual solvent analysis
Stability studies
Forensic drug analysis
Quality control of pharmaceutical products
Detection of contaminants.

Advantages
High sensitivity
High selectivity
Excellent separation capability
Provides molecular and structural information
Can analyze complex mixtures
Mass spectral libraries facilitate compound identification
Suitable for both qualitative and quantitative analysis

Limitations
Mainly suitable for volatile and thermally stable compounds
Non-volatile or thermally unstable drugs may require derivatization
Instrumentation is relatively expensive
Requires trained personnel
Sample preparation can sometimes be complicated

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 pharmacopeias. 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 pharmacopeias. 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.

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.

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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 analyzing 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 50150% 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 (LCMS)
Liquid chromatography-mass spectrometry (LCMS) 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.

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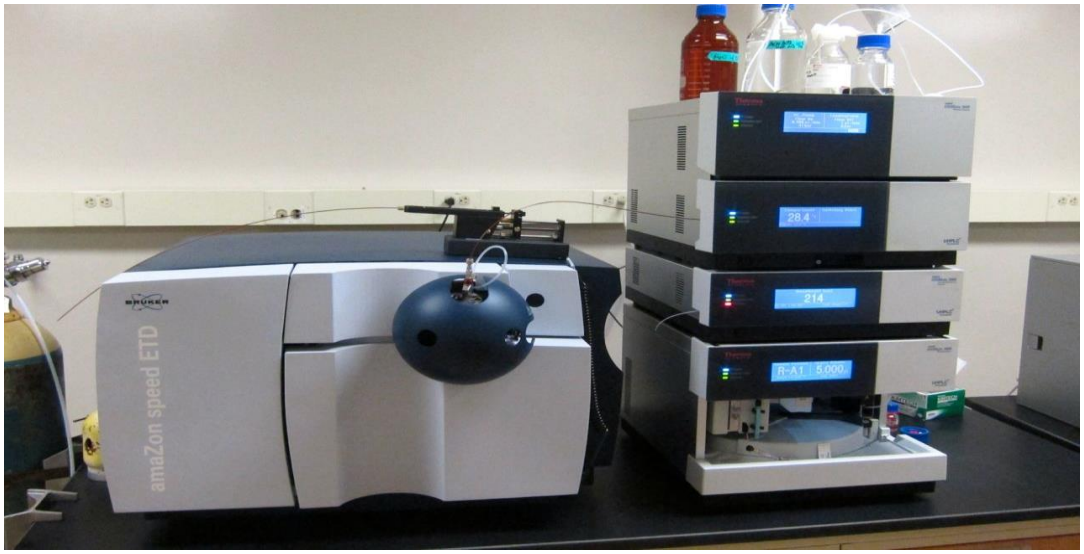

Fig.1: LC-MS Instrumentation/

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).

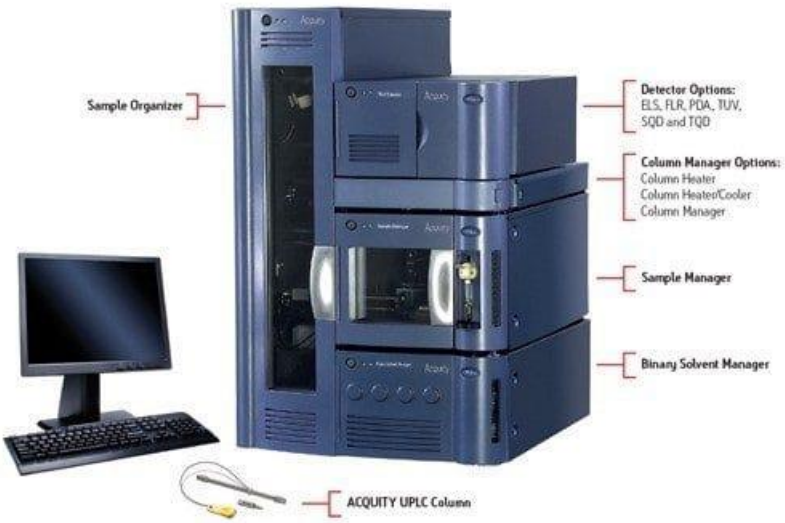

Fig. 2: UPLC Instrumentation.

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 analysed 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

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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.

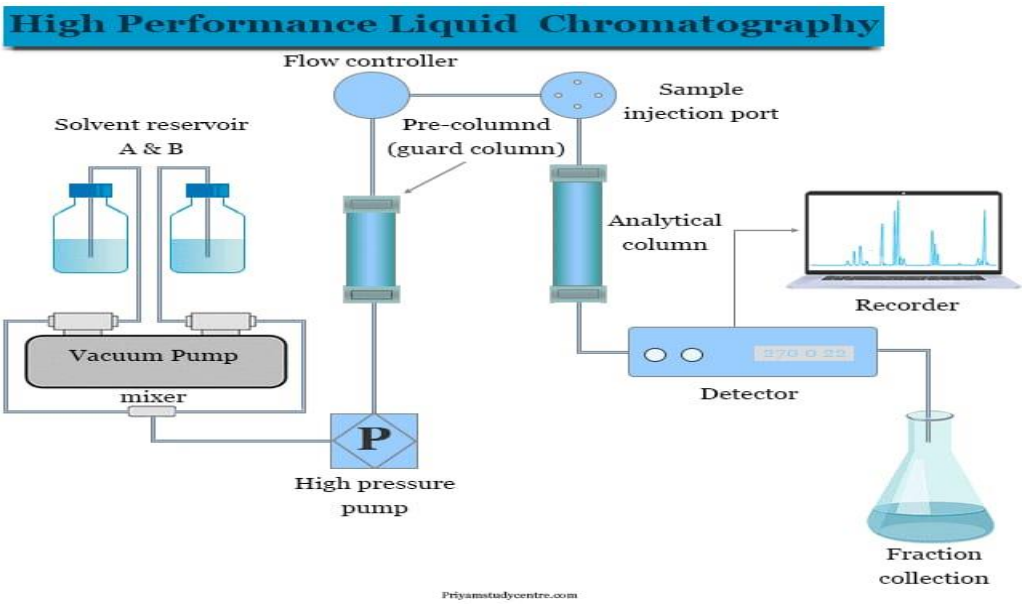

Fig. 3: HPLC Instrumentation.

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.

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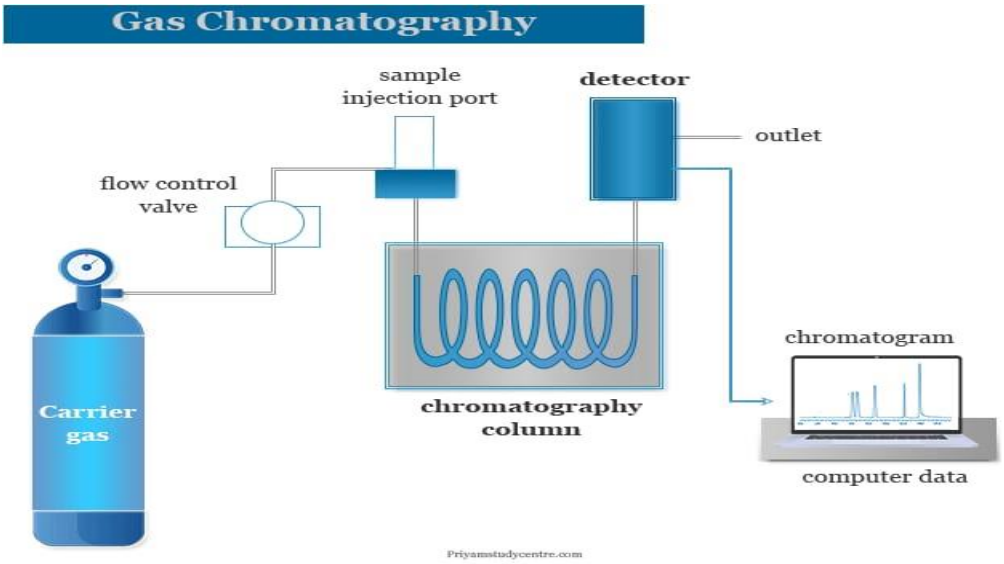

Fig. 4: Gas Chromatography Instrumentation.

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.

Fig. 5: UV Spectroscopy Instrumentation.

DRUG PROFILE

Name: Ensartinib

IUPAC Name: N-(5-chloro-2-methoxyphenyl)-6-(4-(4-methylpiperazin-1-yl) piperidin-1-yl) pyrido [3,4-d] pyrimidin-4-amine.

CHEMICAL FORMULA: C26H30ClN7O

MOLECULAR MASS: 472.589 g/mol

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STRUCTURE

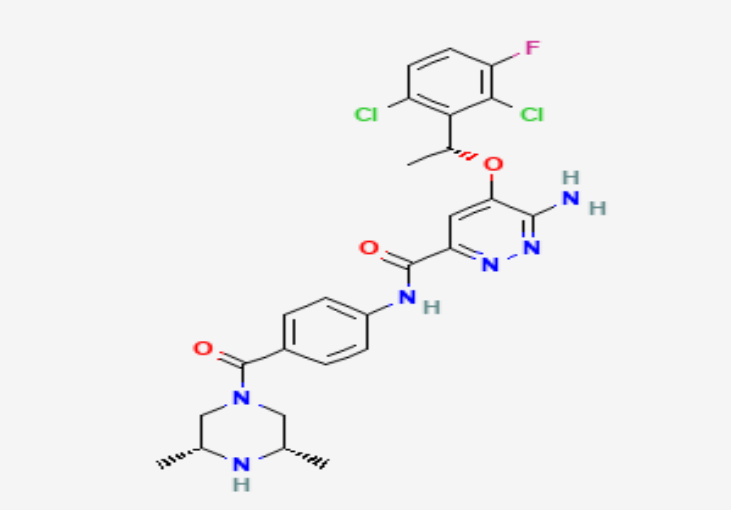

Fig.6: Structure of Ensartinib.

PHARMACODYNAMICS

Ensartinib is a second-generation, oral small-molecule tyrosine kinase inhibitor (TKI) that primarily targets and suppresses anaplastic lymphoma kinase (ALK) to treat ALK-positive non-small cell lung cancer (NSCLC).

MECHANISM OF ACTION

Ensartinib is a second-generation tyrosine kinase inhibitor (TKI) that competitively binds to the ATP-binding pocket of anaplastic lymphoma kinase (ALK), blocking downstream cancer cell signaling and triggering apoptosis (cell death).

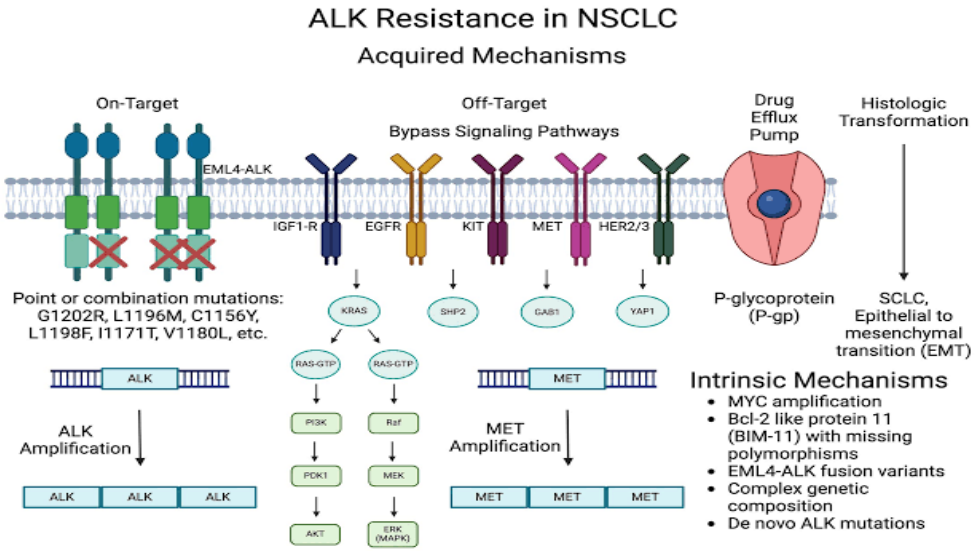

Fig. 7: Ensartinib mechanism of action.

VOLUME OF DISTRIBUTION: The mean apparent volume of distribution of ensartinib at steady-state is1,720 L.

PROTEIN BINDING

Ensartinib is 91.6% bound to human plasma proteins.

METABOLISM

Ensartinib is predominantly metabolized in the liver primarily by the cytochrome P450 enzyme CYP3A.

ROUTE OF ELIMINATION

Ensartinib is primarily excreted through the feces, accounting for roughly 91% of the administered dose, while renal excretion via urine plays a minor role at about 10%.

HALF-LIFE: The mean steady-state half-life of ensartinib is approximately 30 hours (with a standard deviation of about 20 hours), meaning it takes about 30 hours for your body to eliminate half of the drug at a steady concentration.

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Table No. 1: Different analytical techniques of Ensartinib.

S.no	Drug name	Analytical technique	Description of technique	Author & year
1	Ensartinib	UPLC-MS/MS	System / Model UPLCMS/MS; rat plasma Column: Waters Acquity BEH C18 Mobile phase:0.1% formic acid in water + acetonitrile Flow rate: NR Run time: NR Linearity: Ensartinib: 0.1100 ng/mL; M465: 0.0510 ng/mL LOQ / LLOQ Ensartinib: 0.1 ng/mL; M465: 0.05 ng/mL	Shiqi Jiang et al. (2026)
2	Ensartinib	UV visible spectrophotometer	System / Model: Spectrofluorometer UV Visible spectrophotometer Linearity:100-1000 ng/mL,1.0-10.0 µg/mL LOQ:64.1 ng/mL,400 ng/mL LOD:21.2 ng/mL,132 ng/mL Wavelength: Not reported in the provided abstract,550 nm Ph:3.3,Not reported	Hesham Salem et al. (2026)
3	Ensartinib	UPLC-MS/MS	System / Model: UPLC-MS/MS; human liver microsomes (HLMs) Column : Eclipse Plus C18 Mobile phase: Isocratic mobile phase; exact composition not stated in the abstract Linearity: 1-3000 ng/mL Half-life (t½): 19.29 min	Mohamed W. Attwa et al. (2025)
4	Ensartinib	RP-LCMS/MS	System / Model: RP-LCMS/MS; human plasma Column: Acquity BEH C18 Mobile phase: 0.1% formic acid in water + acetonitrile: methanol (50:50, v/v) Flow rate: 0.5 mL/min Linearity: 50-50,000 ng/mL	Marinda Meertens et al. (2025) Ensartinib
5	Ensartinib	HPLC-MS/MS	System / Model HPLC-MS/MS; human plasma Column: Phenomenex Luna Phenyl-Hexyl, [50 × 2.0 mm, 5 µm] Linearity: 0.5-500 ng/mL LOQ: 0.5 ng/mL Sample extraction: liquid extraction Precision: Intra- and inter-run RSD <15% Accuracy: Relative error within ±15%	Hua Li et al. (2023)

Table 2: Brand Names.

S. NO	BRAND NAME	API	MANUFACTURING COMPANY
1.	Ensacove	Ensartinib hydrochloride	Xcovery Holdings, lnc.

CONCLUSION

The literature review indicates that ensartinib is a potent second-generation anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitor used in the treatment of ALK-positive non-small-cell lung cancer (NSCLC). Various analytical methods have been reported for the estimation and quantification of ensartinib, including UV-Visible spectrophotometry, spectro fluorometry, HPLC-MS/MS, and UPLC-MS/MS. the reported chromatographic methods provide good sensitivity, selectivity, accuracy, precision, and linearity, making them suitable for pharmaceutical and bioanalytical applications. Spectroscopic methods offer simpler and more economical approaches for routine analysis. However,

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differences in analytical conditions and applications indicate a need for further development of simple, rapid, accurate, precise, and robust HPLC methods for the estimation of ensartinib in pharmaceutical formulations.

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CONSENT AND ETHICAL APPROVAL
It is not applicable.

COMPETING INTERESTS
Authors have declared that no competing interests exist.

REFERENCES

1. Li H, Wang Y, Chen X, Chen C, Cui J, Han Y, Ding L. Development of HPLC-MS/MS assay for quantitation of ensartinib in human plasma and its application to a pharmacokinetics study in Chinese patients.
2. Attwa MW, Abdelhameed AS, Ali AM, AlRabiah H, Kadi AA. Development and validation of a quick and sensitive UPLC-MS/MS method for measuring ensartinib in HLMs.
3. Meertens M, de Jong LD, de Vries N, Rosing H, Beijnen JH, Huitema ADR. LC-MS/MS method development and validation for novel targeted anticancer therapies adagrasib, capmatinib, ensartinib, entrectinib, larotrectinib, lorlatinib, pralsetinib, selpercatinib and sotorasib. J Pharm Biomed Anal., 2025.
4. Yang C, et al. Development and validation of a UPLC-MS/MS method for simultaneous quantification of ensartinib and its major metabolite M465 in rat plasma and application to pharmacokinetic studies. Drug Design, Development and Therapy., 2026.
5. Salem H, et al. Spectrofluorometric and spectrophotometric assay of anticancer drug ensartinib using ion-pair complex formation reaction with eosin Y., 2026.
6. Chennupati V. Suresh, Santhosh Illendula; a review on method development and validation of fexofenadine By different analytical techniques, IJMPR, 2024; 8(3): 44-50.
7. 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
8. 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
9. U.S. Food and Drug Administration. Drug Trials Snapshot: ENSACOVE (ensartinib). Silver Spring (MD): FDA; 2024. Approval date: December 18, 2024.
10. U.S. Food and Drug Administration.
11. U.S. Food and Drug Administration. ENSACOVE (ensartinib) capsules: prescribing information. Silver Spring (MD): FDA; 2024. FDA Access Data. DailyMed. ENSACOVE ensartinib capsule. Xcovery Holdings, Inc.; updated February 17, 2026.
12. Agrawal T. Efficacy and safety of ensartinib in the treatment of non-small cell lung cancer: a systematic review of clinical trials.
13. https://en.wikipedia.org/wiki/Ensartinib
14. https://go.drugbank.com/drugs/DB14860

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