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A REVIEW ON METHOD DEVELOPMENT AND VALIDATION OF SELECTED ANTI CANCER DRUGS ZANUBRUTINIB, ERDAFITINIB BY DIFFERENT ANALYTICAL TECHNIQUES

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ABSTRACT

Pharmaceutical analysis plays a very prominent role in quality assurance as well as quality control of bulk drugs and pharmaceutical formulation. Rapid increase in pharmaceutical industries and production of drug in various parts of the world has brought a rise in demand for new analytical techniques in the pharmaceutical industries. As a consequence, analytical method development has become the basic activity of analysis. Zanubrutinib is a kinase inhibitor used to treat mantle cell lymphoma, a type of B-cell non-Hodgkin lymphoma, in adults who previously received therapy. It effectively relieve symptoms like diarrhoea, constipation, nausea, muscle spasms. Erdafitinib is a fibroblast growth factor receptor tyrosine kinase inhibitor used to treat locally advanced or metastatic urothelial carcinoma. It effectively relives symptoms like nausea, diarrhoea, vomiting, abdominal pain, constipation.

KEYWORDS: Pharmaceutical analysis, Zanubrutinib, Erdafitinib, analytical method development.

Analytical method development

Analytical chemistry deals with methods for identification, separation, and quantification of the chemical components of natural and artificial materials. The choice of analytical methodology is based on many considerations, such as: chemical properties of the analyte and its concentration sample matrix, the speed and cost of the analysis, type of measurements i.e., quantitative or qualitative and the number of samples. A qualitative method yields information of the chemical identity of the species in the sample. A quantitative method provides numerical information regarding the relative amounts of one or more of the analytes in the sample.

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 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.

Steps for analytical method development

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

1. 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.

2. Highlighting of steps

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

3. 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.

4. 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.

5. 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.

6. 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.

7. 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.

8. 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.

9. 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.

10. Development method evaluation

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

11. 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 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 a number of 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 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 different 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 analyzer 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.

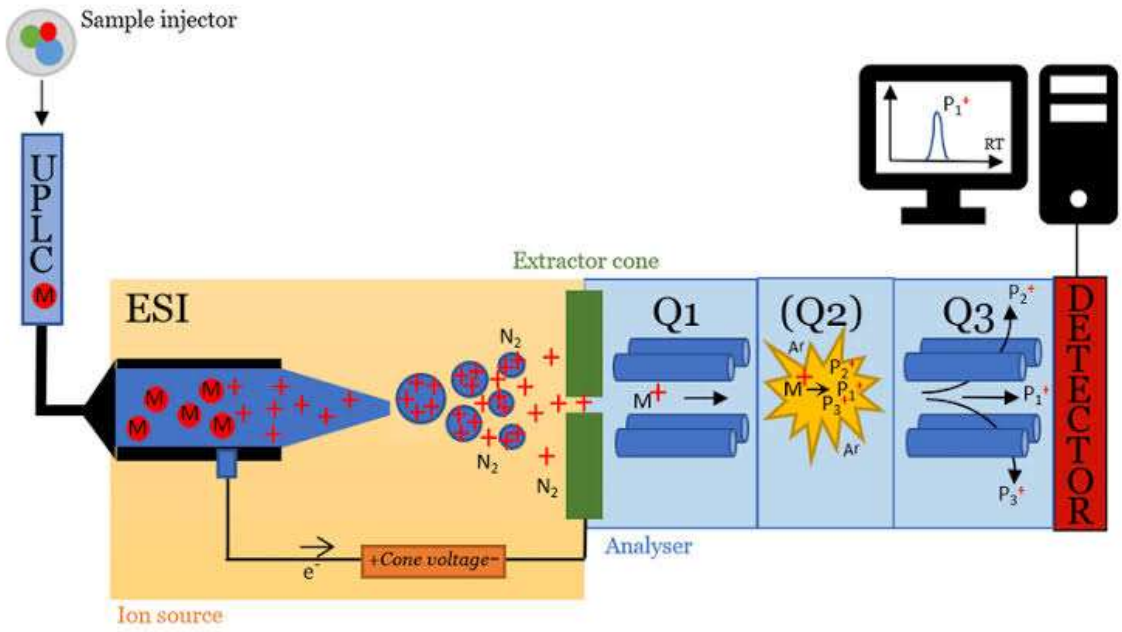


Fig- : LC-MS Instrumentation.

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).

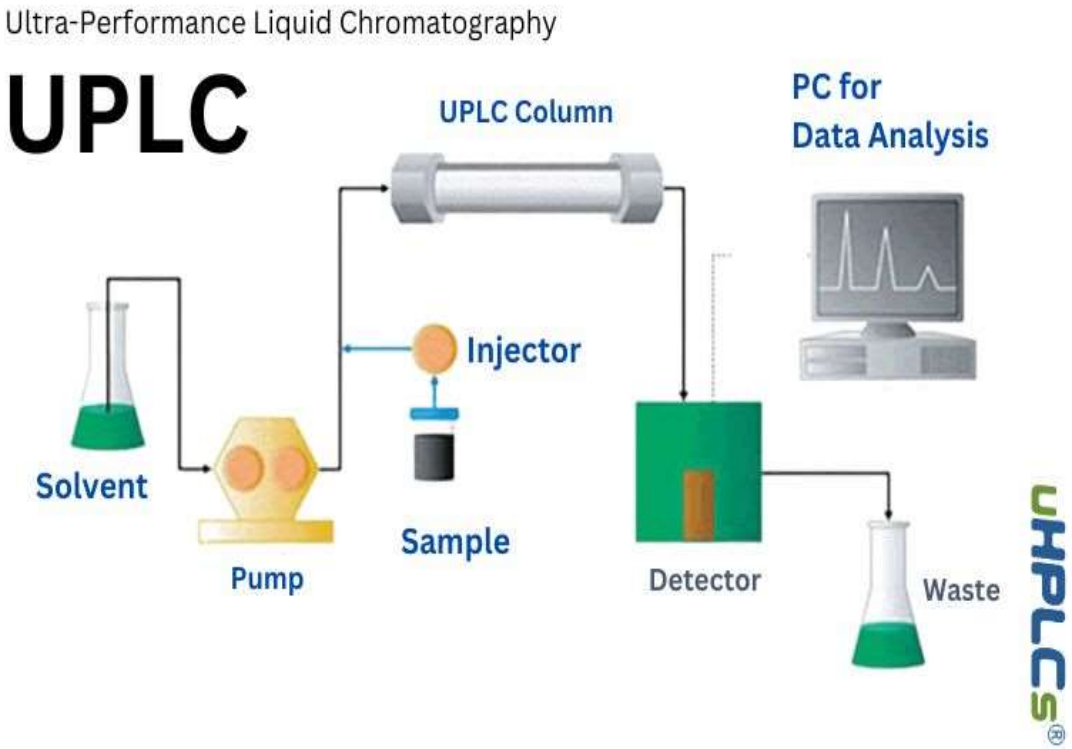


Fig- : UPLC Instrumentation.

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 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.

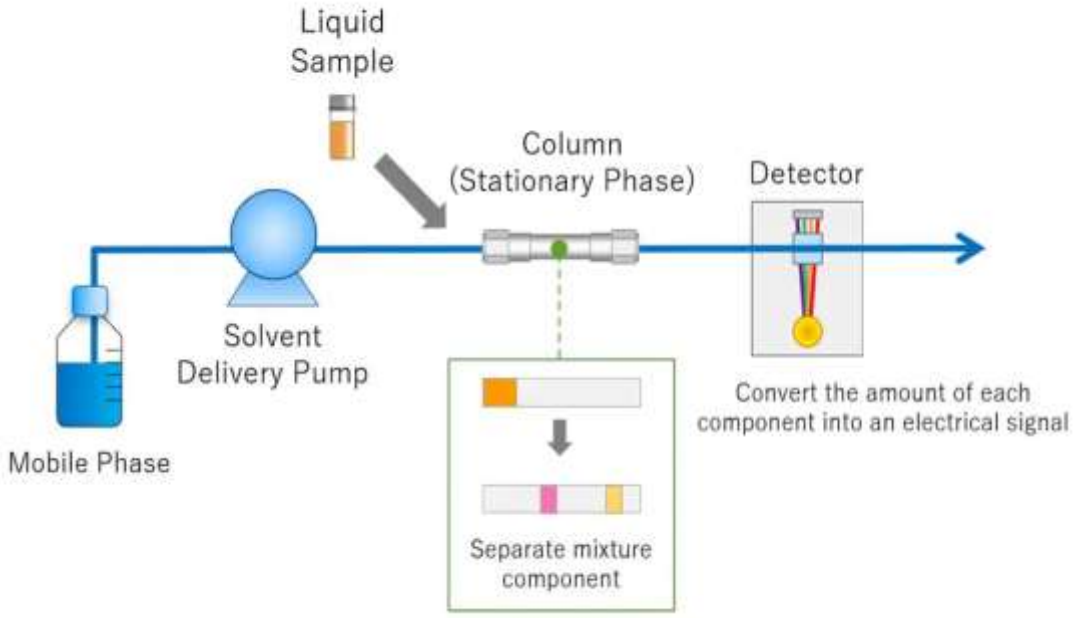


Fig- : HPLC Instrumentation.

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 analyzed 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.

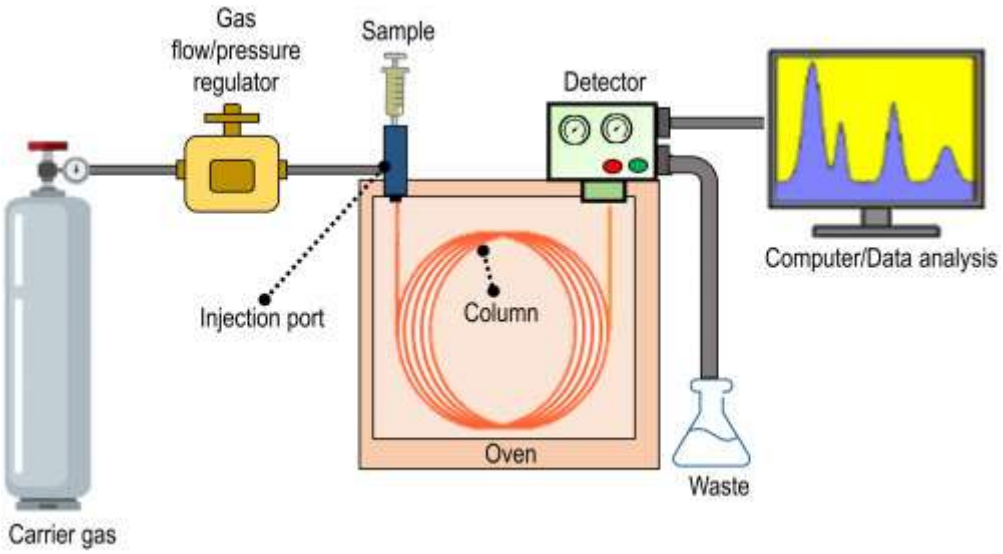


Fig- : Gas Chromatography Instrumentation.

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:

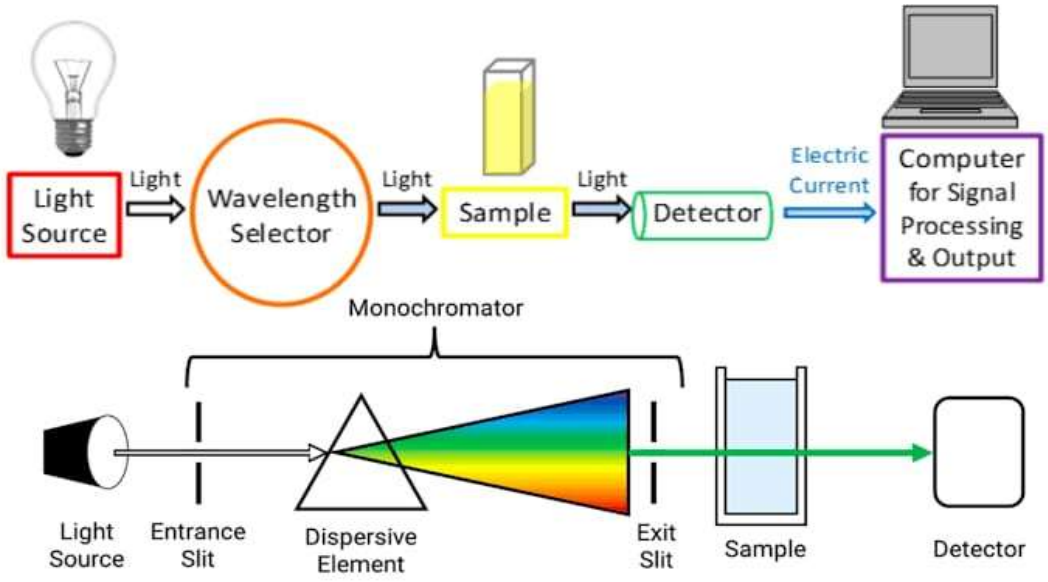


Fig- : UV Spectrophotometer Instrumentation.

Drug profile

Name: Zanubrutinib

IUPAC Name

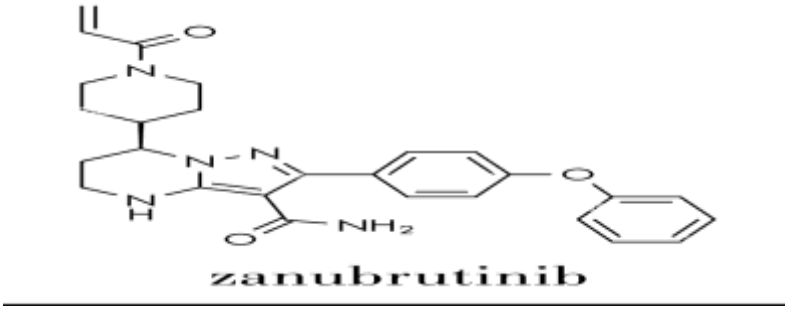
(S)-7-(1-acryloylpiperidin-4-yl)-2-(4-phenoxyphenyl)-4,5,6,7-tetrahydropyrazolo[1,5-a]pyrimidine-3-carboxamide.

Chemical formula

C27H29N5O3

Molecular mass 471.55–471.561 g/mol

Structure

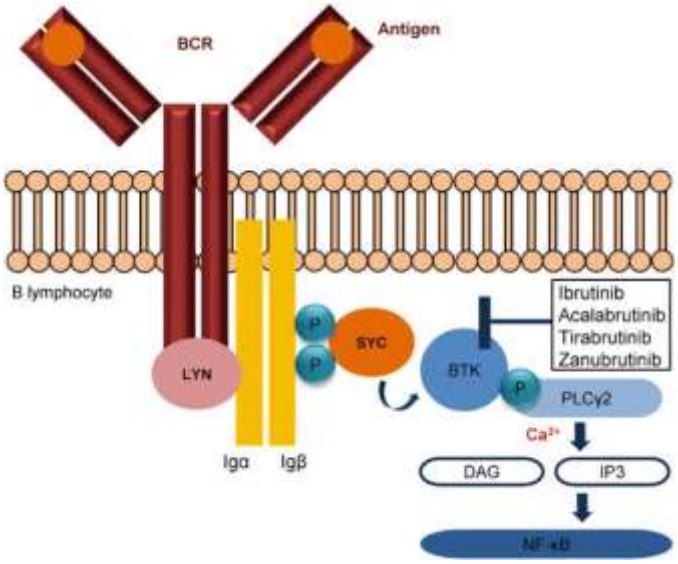


Pharmacodynamics

Zanubrutinib is an immunomodulating agent that decreases the survival of malignant B cells. It inhibits BTK by binding to its active site. It works to inhibit the proliferation and survival of malignant B cells to reduce the tumour size in mantle cell lymphoma.

Mechanism of action

Zanubrutinib (Brukinsa) is a drug that works by inhibiting Bruton's tyrosine kinase (BTK), a signalling molecule that plays a role in the proliferation and survival of B cells.



Volume of distribution: 182 L

Protein binding: The plasma protein binding of Zanubrutinib is approximately 94%.7

Metabolism: Zanubrutinib is predominantly metabolized by CYP3A4.7 Its metabolites have not been characterized.

Route of elimination: 87% of the dose was excreted in the feces and about 8% of the dose was recovered in the urine.

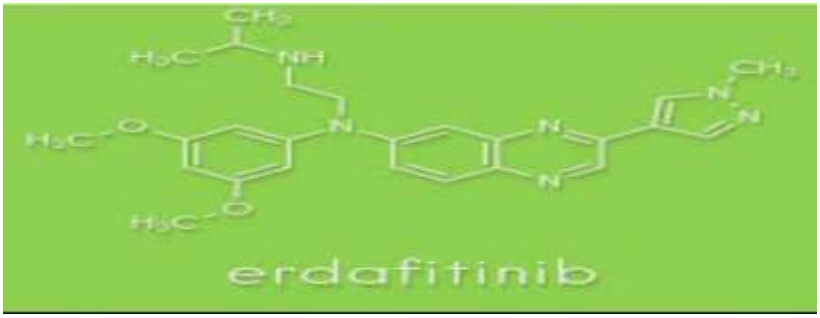
Half-life: 2 to 4 hours

Name: Erdafitinib

Description: A medication used to treat some cancers of the urinary tract.

Chemical formula: C25H30N6O2

Structure



IUPAC name

Erdafitinib is N'-(3,5-dimethoxyphenyl)-N'-[3-(1-methylpyrazol-4-yl)quinoxalin-6-yl]-N-propan-2-ylethane-1,2-diamine.

Molecular mass: 446.555 g/mol

Category: Erdafitinib is a potent inhibitor of all of the fibroblast growth factor kinases and is classified as a pan-FGFR inhibitor

Mechanism of action

Fibroblast growth factor receptor (FGFR) is a transmembrane protein that is expressed ubiquitously in normal tissues and is involved in various endogenous bio-physiological processes including the homeostasis of phosphate and vitamin D, cell proliferation, cell anti-apoptotic signaling, and cell migration in a variety of cell types.1 Concurrently, genetic mutations such as gene amplification, point mutations, and chromosomal translocations of all four FGFR genes (FGFR1, FGFR2, FGFR3, and FGFR4) or deregulation of FGFR pathways have been implicated in the pathogenesis of various cancers, including urothelial cancer, as they promote cell proliferation, migration, angiogenesis, and anti-apoptosis.

Pharmacodynamics

Upon administration, it was observed that erdafitinib increased serum phosphate levels as a consequence of FGFR inhibition. Erdafitinib should be increased to the maximum recommended dose to achieve target serum phosphate levels of 5.5– 7.0 mg/dL in early cycles with continuous daily dosing.[1,3,6]

Subsequently, in erdafitinib clinical trials, the use of drugs that could increase serum phosphate levels, such as potassium phosphate supplements, vitamin D supplements, antacids, phosphate-containing enemas or laxatives, and medications known to have

phosphate as an excipient were prohibited unless no alternatives existed.[1,3,6] To manage phosphate elevation, phosphate binders were utilized. Additionally, the concomitant use of agents that can alter serum phosphate levels before the initial erdafitinib dose increase period based on serum phosphate levels was also avoided.[1,3,6]

Furthermore, based on the evaluation of QTc interval in an open-label, dose escalation, and dose expansion study in 187 patients with cancer, erdafitinib had no large effect (i.e., > 20 ms) on the QTc interval.

Volume of distribution: 26 to 29 L

Protein binding: The protein binding recorded for erdafitinib is approximately 99.8%, and it was determined to be primarily bound to alpha-1-acid glycoprotein.

Metabolism

Erdafitinib is primarily metabolized by the cytochrome CYP2C9 and CYP3A4 isoenzymes in humans to form the O-demethylated major metabolite.[6,7] The contribution of CYP2C9 and CYP3A4 in the total clearance of erdafitinib is estimated to be 39% and 20% respectively.6 Unchanged erdafitinib was ultimately the predominant drug-related moiety found in the plasma - no circulating metabolites were observed.

Route of elimination

After administering a single oral dose of radiolabelled erdafitinib, about 69% of the dose was recovered in faces (19% as unchanged) and 19% in urine (13% as unchanged).

Half-life: 50 to 60 hours.

Different analytical techniques of anti-cancer drugs

S. no.	Drug name	Analytical technique	Description of technique	Author & Year
1	Zanubrutinib	UHPLC-MS/MS	System: Shimadzu 8040 UHPLC-MS/MS. Column: Shim-pack Velox C18 column (2.1 x 50mm, 2.7 µm). Mobile phase: Methanol& 0.1%formic acid, water. (Gradient model) 1:9 v/v. Flow rate: 0.4ml/min. Run time: 03min. Linearity :1-1000ng/ml.	Hong-lei Ge, Chuan-feng shao, et.al 2023

			LLOQ: 1ng/ml.	
2	Zanubrutinib	UPLC-MS/MS	System: Acquity BEHC18 column [2.1mm x 50mm, 1.7µm]. Injection volume: 2µl. LOQ: 1ng/ml. Mobile phase: 0.1% formic acid B: acetonitrile. Linearity: 1.0-1,000ng/ml.	Yong-liang Zhu. et.al 2023
3	Zanubrutinib	RP-UPLC	Column: 150 x 4.6mm x-bridge C18 Column. Flow rate: 1.0 ml/min. Wavelength: 216nm. Detector: PDA. Relation coefficient: 0.999. Mobile phase: Trifluoracetic acid [0.1%] in h2o & acetonitrile.	Subrahmanyam talari. et.al 2023
4	Zanubrutinib	RP-HPLC	Column: Phenyl column x-bridge [150 x 4.6mm, 3.5µ]. Run time: 60min. Flow rate: 1ml/min. Mobile phase: Acetonitrile & hexane, sulfonic acid.	Madhavi, Nannapaneni. et.al 2023
5	Zanubrutinib	LC-MS	Column: Luna C18 Column [250 x 4.6mm, 5µm]. Mobile phase: Acetonitrile: 0.1% triethyl amine [65:35v/v]. Wavelength: 219nm. Linearity: 4-60µg/ml. Injection volume: 10µl. Flow rate: 1ml/min. Runtime: 10 mins.	Gowri gollu. et.al 2022
6	Zanubrutinib	HPLC	Mobile phase: Acetonitrile: 0.1% orthophosphoric acid [50:50v/v]. Flow rate: 1ml/min. Runtime: 6min. Wavelength: 220nm. Linearity: 2-30µg/ml. LOD: 0.02µg/ml. LOQ: 0.2µg/ml. Injection volume: 10µl. Column: Luna C18 [250 x 4.6mm,5µ].	Vijaya Kumari et.al 2020
1	Erdafitinib	(LC-ESI/MS/MS)	Column: **(**50 x 4.6mm; 5µm)C18 analytical column. Injection volume**:** 250µl. Flow rate: 0.80ml/min.	Yarra Raviteja, G .Suresh 2022

2	Erdafitinib	UPLC-MS/MS	Run time: 3.5min. LLOQ**:** 69.95ng/ml. Linearity**:** 69.95-2798.00ng/ml. Column: BEH C18 (2.1mm x 100mm, 1.7µm). Linearity**:** 0.5-1000ng/ml. LOQ**:** 0.5ng/ml. Mobile phase**:** 0.1% formic acid in acetonitrile & water (0.1% formic acid)(65:35). Run time**:** 2.0 min. Injection volume: 100µg/ml. LLOQ**:** 1000.0ng/ml. Flow rate:0.25ml/min.	Essam A. Ali, Gamal A. Mostafa etal… 2022 Tarek elwady etal…. 2021
3	Erdafitinib	HPLC-UV	Column: Eclipse plus C18 column (4.6 x 100mm, 3.5 µm) Mobile phase**:** Acetonitrile 0.01M ammonium acetate aqueous solution with acetic acid(26:74, v/v). Flow rate**:** 1.2ml/min Run time: 11min Wavelength: 292nm Linearity**:** 0.05-2.00µg/ml LLOQ**:** 0.05µg/ml	Xiang-jun Qiu etal… 2021
4	Erdafitinib	UPLC-MS/MS	Column**:** UPLC BEH C18 (2.1 X 50mm, 1.7µm). Linearity: 1-500ng/ml. LLOQ: 1.0 ng/ml. Mobile phase**:** Acetonitrile & 0.1% Formic acid in water. Flow rate**:** 0.40ml/min. LOQ:1ng/ml. Injection volume:5.0µl.	Fathalla Belal ,Nahed EI-Enany, etal… .2020
5	Erdafitinib	LC-MS/MS	Column**:** Eclipse plus C18 Column (3.0 x 150mm, 5um) Mobile phase**:**0.01M ammonium formate aqueous solution, 0.1% formic acid (35:65, v/v). Flow rate**:** 0.6ml/min. LLOQ**:** 3.0ng/nl. Run time:3.5 min.	M.Maithani, D.Dwivedi, etal…. 2020
6	Erdafitinib	RP-HPLC	Column**:** Hypersil ODS C18 column (150mm x 4.6mm) Mobile phase**:** 20mM sodium acetate buffer**,** methanol & acetonitrile (60:10:30 v/v/v).	

			Wave length: 310nm. Flowrate: 1.0ml/min. Run time: 10min. Linearity: 5-35µg/ml. Injection volume**:**10µl.	

Brand names

S. no	Brand name	Api	Manufacturing company
1	Brukinsa	Zanubrutinib	BeiGene
2	Balversa	Erdafitinib	Jansson
3	LuciErda	Erdafitinib	Lucius
4	Eradafixen	Erdafitinib	Everest
5	Eradanib	Erdafitinib	Drug international LTD

CONCLUSION

A survey of literature reveals that smart analytical strategies don't seem to be offered for the anti-cancer drugs Zanubrutinib, Erdafitinib. Despite the fact that only a few strategies of estimation of on top of medicine square measure offered, several of them suffer from one disadvantage or the opposite, like low sensitivity, lack of property and ease etc. the present chemical science strategies square measure inadequate to fulfil the requirements; thence its planned to enhance the present strategies and to develop new strategies for the assay & stability studies of Zanubrutinib, Erdafitinib in pharmaceutical dose forms adapting totally different offered analytical techniques like ultraviolet illumination spectrophotometry, HPLC, UPLC and LC-MS.

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Consent and Ethical approval

It is not applicable

Competing interests

Authors have declared that no competing interests exist.

REFERENCE

1. Peng-Fei Tang, Su-su Bao, Zhong-Xiang Xiao, Wei-Fei Xie, Xue-meng Wu, Hong-lei Ge and Chuan-feng Shao; A novel UHPLC–MS/MS method for quantitative analysis of

Zanubrutinib in rat plasma: application to an in vivo interaction study between Zanubrutinib and triazole antifungal, BMC Chemistry, 2023; 17, 107: 1-9.

2. Gowri Gollu 1, *, Sowjanya Gummadi2, Venkata Deepthi Vemuri1, Swathi Nalla1, Nalini Mathala1, and Sasikala Allam1; Forced Degradation Study of Zanubrutinib: An LC–PDA and LC–MS Approach, Journal of Chromatographic Science, 2022; 60, 9: 807–816.
3. M. Vijaya kumari1,2*, Ch. Bala Sekhar reddy3; stability indicating validated Hplc method for the determination of Zanubrutinib in bulk and pharmaceutical dosage form, asian journal and pharmaceutical and clinical research, 2020; 13(10): 159-162.
4. Subrahmanyam Talari, Anuradha Vejendla, K. Deepthi, G. R. Satyanarayana & K. Chandra Mohan; Development and Validation of a New Reverse Phase Ultra Performance Liquid Chromatography Method for the Estimation of Related Substances of the Anticancer Drug Zanubrutinib and Characterization of its Degradants Using Liquid Chromatography Mass Spectrometry, Pharmaceutical chemistry journal, 2023; 57(7): 1118–1129.
5. Ibrahim Baje Syed, Madhavi Nannapaneni*; Related Substances Method Development and Validation of Axitinib, Zanubrutinib and Upadacitinib Using RP-HPLC and its Degradation Products were Characterized by Using LC-MS/MS, International Journal of Pharmaceutical Investigation, 13(1): 113-121.
6. Yong-liang Zhu, Hao-Zhe Ding, Kai-feng Gou, Bo Sun, Ye Chen, He-Wei Zhang; A rapid and sensitive UPLC–MS/MS method for the determination of Zanubrutinib in beagle plasma and its application in pharmacokinetics, Biomedical Chromatography, 2023; 37(1): e5504.
7. Lan-hong Ruan, Ling-ling Fan, Kun Wang, Wan-qi Zhang, Xiao-jun Wang, Xiang-jun Qiu;The Effect of Posaconazole and Isavuconazole on the Pharmacokinetics of Erdafitinib in Beagle Dogs by UPLC-MS/MS; Frontiers in Pharmacology, 2021; 12.
8. Essam A. Ali 1,*, Muzaffar Iqbal 1, Gamal A. Mostafa 1, Mohamed R. Alhazani 1 and Yousif A. Asiri 2.Ecofriendly, Simple, Fast and Sensitive UPLC-MS/MS Method for Determination of Erdafitinib, a Novel Tyrosine Kinase Inhibitor, in Plasma and Its Application to Metabolic Stability. Journal of applied sciences. Appl. Sci, 2022; 12: 8625.
9. Santhosh Illendula, D. Priyanka & Rajeswar Dutt; A new simple method development & validation of Ibrutinib in bulk & pharmaceutical dosage form by RP-HPLC, IJPBS, 2019; 09(01): 36-46.

10. Tarek Elawady, Alaa Khedr, Nahed El-Enany, Fathalla Belal. HPLC-UV determination of erdafitinib in mouse plasma and its application to pharmacokinetic studies. journal of Science Direct, 2021; 1171, 1: 122629.
11. Santhosh Illendula, Naveen Kumar Singhal; A Review: Novel analytical method development & validation for the determination of selected anti cancer & anti viral drugs, WJPPS, 2022; 11(07): 533-566.
12. Yarra Raviteja1, G. Suresh2. A Novel Liquid Chromatography-Electrospray Ionization-Mass Spectrometry (LC–ESI/MS/ MS) Method Development and Validation for the Quantification of Erdafitinib in Human Plasma. International Journal of Current Research and Review, 2022; 14: 04.
13. Qinghua Weng, Wei Tan b, Ren-yue Yu, Yu Chen c, Ren-ai Xu. A novel bioanalytical method for the quantification of pemigatinib in rat plasma by UPLC-MS/MS. Journal of pharmaceutical and Bio medical Analysis, 2021; 5: 114137.
14. Tarek Elawady, Alaa Khedr Nahed El-Enany, Fathalla Belal. LC-MS/MS determination of erdafitinib in human plasma after SPE: Investigation of the method greenness. Micro chemical journal, 2020; 154: 104555.
15. https://go.drugbank.com/drugs/DB15035
16. https://en.wikipedia.org/wiki/Zanubrutinib