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A Review on Method Development and Validation of Anticancer Drugs Pralsetanib and Azacitidine by Different Analytical Techniques

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Abstract

Pharmaceutical analysis is a broader term which can be defined in many ways. It is the series of processes that are used for identification, determination, separation, purification, and structure elucidation of the given compound used in the formulation of pharmaceutical products. Recent development in analytical methods has been resulted from the advancement of analytical instruments. The improvement of the analytical method development and analytical instruments like UV, HPLC, LC-MS, GC are required for reduced the time of analysis, increased precision and accuracy and reduced costs of analysis. Pralsetinib is a RET receptor tyrosine kinase inhibitor for the treatment of metastatic RET-driven non-small cell lung cancer. Azacitidine is in a class of medications called demethylation agents. Azacitidine (5-azacytidine) is a chemical analogue of the cytosine nucleoside present in DNA and RNA. It induces antineoplastic activity by inhibiting DNA methyl transferase at low doses and inducing cytotoxicity by incorporating itself into RNA and DNA at high doses.

Keywords: Analytical method development, validation, Pralsetinib, Azacitidine, UV, HPLC, LC-MS, GC

INTRODUCTION

Analytical method:

Analytical methods development plays important role in drug discovery, generic product development and manufacture of pharmaceuticals. Method development is the process of identifying set of parameters which provides desired analytical performance. Below are the important parameters which needs to be considered during method development.

Solubility profile:

Solubility of interested compound/API in different solvents such as water, acetonitrile, methanol, isopropyl alcohol etc. is useful while selecting diluents for standard solutions and extraction solvents for test solutions. The pH solubility data of API also helps in selecting diluent during sample and standard preparation. BCS and saturation solubility data is used for selecting media for dissolution method.

Analytical profile:

The spectral profile is useful in understanding the absorption characteristics, which helps in selection of detector and the wavelength for analysis. Understanding the degradation profile will help in developing the method for separation and estimation of all possible impurities and degradants. Information regarding possible process related impurities and degradants shall be obtained.

Selection and optimization of mobile phase:

The primary objective in selection and optimization of mobile phase is to achieve optimum separation of all the individual impurities and degradants from analytic (API) peak. The selection of mobile phase is always done in combination with selection of column (stationary phase). Following are the parameters which shall be taken into consideration while selecting and optimizing the mobile phase.

(a) Buffer, if any and its strength and pKa.

(b) pH of the buffer or pH of the mobile phase.

(c) Mobile phase composition.

Selection of column:

Following are the parameters of a chromatographic column which are to be considered while choosing a column for separation of interested compounds such as impurities and degradants.

(i) Length and diameter of column.

(ii) Packaging material

(iii) Shape of the particles

(iv) Size of the particles

METHOD DEVELOPMENT

Method development consists of three main stages: feasibility where you determine if the method will work with your sample; development where you optimize the method; and validation where the optimized method is validated to the relevant regulatory requirements," explains Vincent Thibon, technical development lead, RSSL. "Developing a robust method will ensure that routine testing occurs smoothly and limits the amount of testing required."

Step one feasibility:

The method to be suitable for drug substance (DS) initially, but maybe potentially further down the line for drug product (DP) it is crucial to collect as much background information as possible on the API to understand its characteristics or what development challenges it poses," "In order to develop an accurate, reproducible, and reliable method, there must be an understanding of the final purpose of the method. This purpose should be the driving principle behind the research and development stages," the phase of the development of the product, which impacts the amount of work required, should be assessed. Defining the phase of development early on is important, Analyses might also be unknowns belonging to broader categories of chemicals, which require a different approach compared to a targeted method for a known compound."

Step two development:

The next stage is about minimizing the complexity of the methods to ensure they are user-friendly for routine use, Curzon continues. "[A method] will be used by different analysts and may be transferred between different labs, analysts and may be transferred between different labs," "Developers need to select an appropriate solvent system for dissolving the sample and they should also choose a suitable separation mode, such as reversed phase chromatography or hydrophilic interaction chromatography (HILIC)," states . "A detection principle should also be chosen for example, for [ultraviolet] UV or visible light, an appropriate detection wavelength should be selected. UV detection is preferred if the analyses contain a UV chromophore due to the widespread availability of UV detectors

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Step three optimization:

Finally, the specificity and sensitivity of the method should be considered, "The analytic may be a primary component of the matrix, or it might be an impurity present at trace levels. Instrumentation and sample preparation approaches may change if trace level sensitivity is required," she reveals. "Regulatory guidelines and a knowledge of toxicology are especially important for impurity methods, as these often dictate the permissible limits. Given the trend for increasingly tight regulatory limits, such as for nitrosamines, then it might be prudent to develop a method with sensitivity beyond the

minimum requirements in case regulatory authorities decide to lower limits in the future and to fully understand the risk to the consumer."

"With optimization, you want to make sure your initial method is compatible with the sample matrix," confirms Curson. "To meet the industry standard, we subject the product to harsh, acidic or basic conditions, oxidation, temperature, and heat so that we are forcing degradation products to be produced, the method must be capable of showing the degradation products and that they do not interfere with the active product potency."

ANALYTICAL METHOD VALIDATION

Method validation can be defined as per ICH "Establishing documented evidence which provides a high degree of assurance that a specific activity will consistently produce a desired result or product meeting its predetermined specifications and quality characteristics".

ICH Method validation parameters

For chromatographic methods used in analytical applications there is more consistency in validation. Related substances are commonly present in the pharmaceutical products but those are always within the limits as specified in ICH (Q2B).

- Specificity
- Linearity
- Accuracy
- Precision
- Limit of Detection
- Limit of Quantitation
- Robustness
- System suitability

Specificity/Selectivity:

Specificity is ability to assess unequivocally the analyze 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 analytic 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. If the response is distinguished from all other responses, the method is said to be selective. Since there are very few methods that respond to only one analytic, the term selectivity is usually more appropriate.

Accuracy:

The Accuracy of analytical procedure expresses the closeness of agreement between the value that is accepted either as a conventional true value or as an accepted reference value and value found.

Accuracy may be inferred once precision, linearity and specificity have been established. Accuracy for the area percent method should be established from 50% of the ICH reporting limit to the nominal concentration of drug substance in the sample solution.

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. ICH has defined precision to contain three components: repeatability, intermediate precision and reproducibility. Ruggedness as defined in USP XXII <1225>, 1990 incorporates the concepts described under the terms *"intermediate precision", "reproducibility*" and *"repeatability*" of this guide.

Linearity:

Linearity of an analytical procedure as its ability (within a given range) to obtain test results that are directly proportional to the concentration (amount) of analytic in the sample.

Limit of detection:

Limit of detection (LOD) is the lowest concentration of analytic in a sample that can be detected, but not necessarily quantitated, under the stated experimental conditions. With UV detectors, it is difficult to assure the detection precision of low level compounds due to potential gradual loss of sensitivity of detector lamps with age or noise level variation by detector manufacturer. At low levels, assurance is needed that the LOD and LOQ limits are achievable with the test method each time. With no reference standard for a given impurity or means to assure detectability, extraneous peak(s) could "disappear / appear." A crude method to evaluate the feasibility of the extraneous peak detection is to use the percentage claimed for LOD from the area counts of the analytic.

The LOD may be expressed as:

$$\mathbf{LOD = 3.3\ \sigma / S}$$

Where,

σ = Standard deviation of Intercepts of calibration curves

S = Mean of slopes of the calibration curves

The slope S may be estimated from the calibration curve of the analytic.

Limit of quantification:

Limit of quantitation (LOQ) is the lowest concentration of analytic in a sample that can be determined with acceptable precision and accuracy under the stated experimental conditions.

The LOQ may be expressed as

Where,

$$\mathbf{LOQ = 10\ \sigma / S}$$

σ = Standard deviation of Intercepts of calibration curves

S = Mean of slopes of the calibration curves

The slope S may be estimated from the calibration curve of the analytic.

Robustness:

The robustness of an analytical procedure is defined as a measure of its capacity to obtain comparable and acceptable results when perturbed by small but deliberate variations in specified experimental conditions.

System Suitability:

According to the USP, system suitability tests are an integral part of chromatographic methods. These tests are used to verify that the resolution and reproducibility of the system are adequate for the analysis to be performed. The purpose of the system suitability test is to ensure that the complete testing system is suitable for the intended application.

High Performance Liquid Chromatography (HPLC):

HPLC is a technique in analytical chemistry used to separate, identify, and quantify specific components in mixtures. The mixtures can originate from food, chemicals, pharmaceuticals, biological, environmental and agriculture, etc, which have been dissolved into liquid solutions.

It relies on high pressure pumps, which deliver mixtures of various solvents, called the mobile phase, which flows through the system, collecting the sample mixture on the way, delivering it into a cylinder, called the column, filled with solid particles, made of adsorbent_material, called the stationary phase.

Shows a basic overview of the HPLC

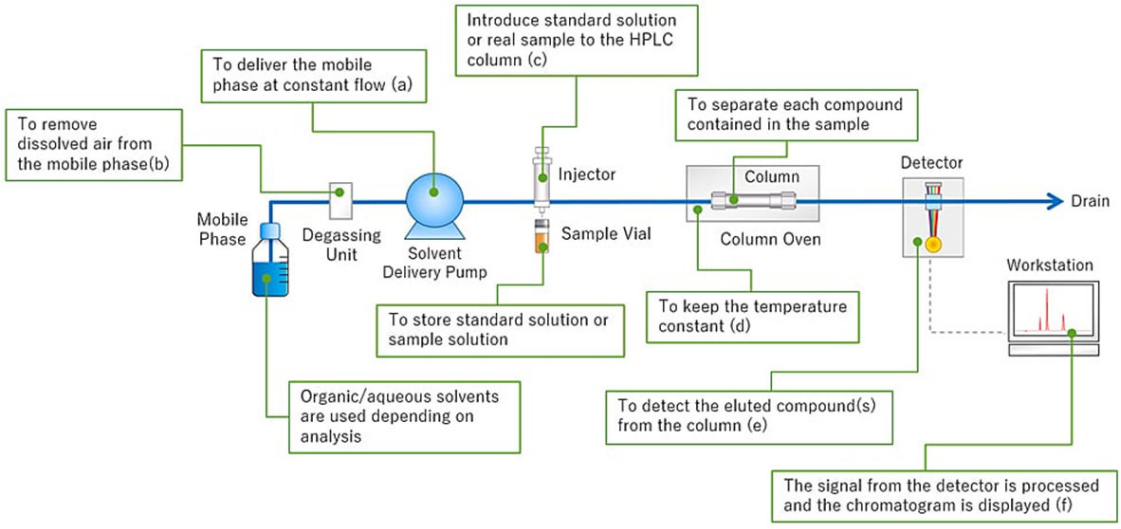


Fig.1: HPLC Flow Diagram

Liquid chromatography–Mass spectrometry (LC–MS)

Liquid chromatography–mass spectrometry (LC–MS) is an analytical chemistry technique that combines the physical separation capabilities of liquid chromatography (or HPLC) with the mass analysis capabilities of mass spectrometry (MS). Coupled chromatography – MS systems are popular in chemical analysis because the individual capabilities of each technique are enhanced synergistically. While liquid chromatography separates mixtures with multiple components, mass spectrometry provides spectral information that may help to identify (or confirm the suspected identity of) each separated component. MS is not only sensitive, but provides selective detection, relieving the need for complete chromatographic separation. LC–MS is also appropriate for metabolomics because of its good coverage of a wide range of chemicals. This tandem technique can be used to analyze biochemical, organic, and inorganic compounds commonly found in complex samples of environmental and biological origin. Therefore, LC–MS may be applied in a wide range of sectors including biotechnology, environment monitoring, food processing, and pharmaceutical, agrochemical, and cosmetic industries. Since the early 2000s, LC–MS (or more specifically LC–MS–MS) has also begun to be used in clinical applications.

Gas Chromatography

Gas chromatography (GC) is an analytical technique used to separate and detect the chemical components of a sample mixture to determine their presence or absence and/or quantities. These chemical components are usually organic molecules or gases. For GC to be successful in their analysis, these components need to be volatile, usually with a molecular weight below 1250 Da, and thermally stable so they don't degrade in the GC system. GC is a widely used technique across most industries, including for:

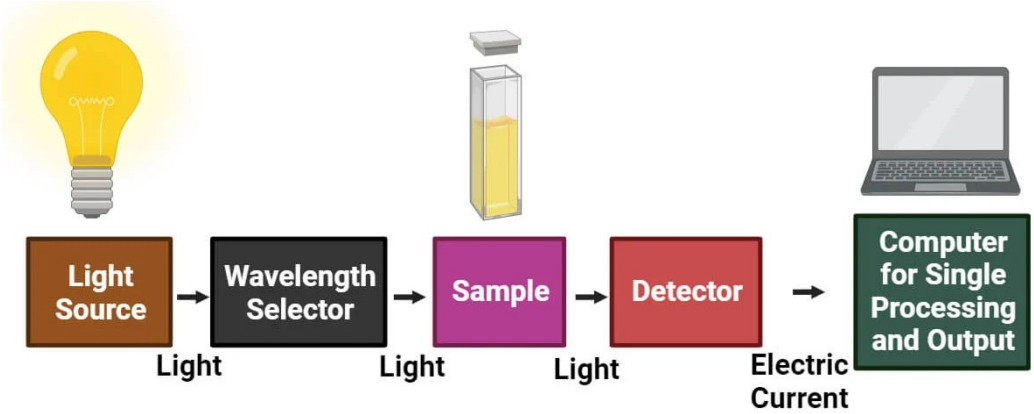
- Quality control in the manufacture of many products from cars, to chemicals and petrochemicals, to pharmaceuticals
- Research purposes from the analysis of meteorites to natural products
- Safety and monitoring from environmental samples, micro plastics and food and wine, to forensics.

Gas chromatographs are frequently hyphenated to mass spectrometers (GC-MS) to enable the identification of the chemical components.

Uv Spectroscopy

UV- spectroscopy is an analytical technique that measures the amount of discrete wavelengths of UV or visible light that are absorbed by or transmitted through a sample in comparison to a reference or blank sample. This property is influenced by the sample composition, potentially providing information on what is in the sample and at what concentration. Since this spectroscopy technique relies on the use of light, let's first consider the properties of light.

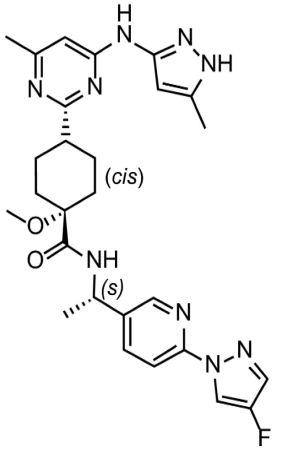
Light has a certain amount of energy which is inversely proportional to its wavelength. Thus, shorter wavelengths of light carry more energy and longer wavelengths carry less energy. A specific amount of energy is needed to promote electrons in a substance to a higher energy state which we can detect as absorption. Electrons in different bonding environments in a substance require a different specific amount of energy to promote the electrons to a higher energy state. This is why the absorption of light occurs for different wavelengths in different substances. Humans are able to see a spectrum of visible light, from approximately 380 nm, which we see as violet, to 780 nm, which we see as red. UV light has wavelengths shorter than that of visible light to approximately 100 nm. Therefore, light can be described by its wavelength, which can be useful in UV-Vis spectroscopy to analyze or identify different substances by locating the specific wavelengths corresponding to maximum absorbance



DRUG PROFILE

NAME: PRALSETINIB

DESCRIPTION: Pralsetinib is a RET receptor tyrosine kinase inhibitor for the treatment of metastatic RET-driven non-small cell lung cancer.



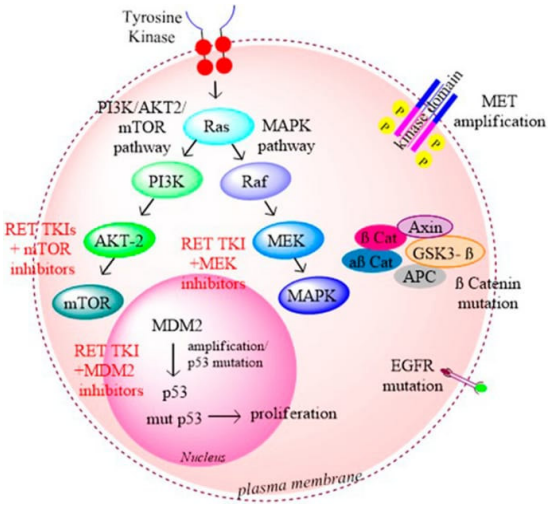
IUPAC NAME: N-[(1S)-1-[6-(4-fluoropyrazol-1-yl) pyridin-3-yl] ethyl]-1-methoxy-4-[4-methyl-6-[(5-methyl-1H-pyrazol-3-yl) amino] pyrimidin-2-yl] cyclohexane-1-carboxamide.

CHEMICAL FORMULA: $C_8H_{12}N_4O_4$

MOLECULAR MASS: 533.61 g/mol

CATEGORY: Pralsetinib is a kinase inhibitor, an antineoplastic agent, and a Rearranged during Transfection (RET) inhibitor.

MECHANISM OF ACTION: Rearranged during transfection (RET) is a transmembrane receptor tyrosine kinase containing extracellular, transmembrane, and intracellular domains whose activity is required for normal kidney and nervous system development. Constitutive RET activation is achieved through chromosomal rearrangements producing 5' fusions of dimerizable domains to the 3' RET tyrosine kinase domain leading to constitutive dimerization and subsequent auto phosphorylation; the most common fusions are KIF5B-RET and CCDC6-RET, although more than 35 genes have been reported to fuse with RET Constitutive activation leads to increased downstream signalling and is associated with tumour invasion, migration, and proliferation.

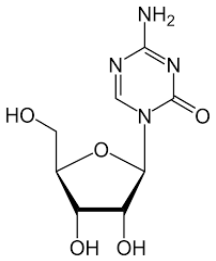


METABOLISM: Pralsetinib is metabolized in vitro primarily by CYP3A4 and to a lesser extent by CYP2D6 and CYP1A2. Pralsetinib given as a single oral dose of 310 mg in healthy volunteers led to the detection of metabolites from both oxidation (M453, M531, and M549b) and glucuronidation (M709), although these constituted less than 5% of the detected material.

AZACITIDINE

NAME: Azacitidine

STRUCTURE:



DESCRIPTION: Azacitidine (4-amino-1-ß-D-ribofuranosyl-1, 3, 5-triazin-2(1H)-one) is sold under the trade name Vidaza, it is a chemical analogue of cytidine, a nucleoside present in DNA and RNA. Azacitidine and its deoxy derivative, decitabine (also known as 5-aza-2′deoxycytidine), are used in the treatment of myelodysplastic syndrome.

IUPAC NAME: 4-amino-1- [3,4-dihydroxy-5-(hydroxymethyl)oxolan-2-yl]-1,3,5-triazin-2-one.

CHEMICAL FORMULA: $C_8H_{12}N_4O_5$.

CATEGORY: Azacitidine is in a class of medications called demethylation agents.

MECHANISM OF ACTION:

Azacitidine (5-azacytidine) is a chemical analogue of the cytosine nucleoside present in DNA and RNA. It induces antineoplastic activity by inhibiting DNA methyltransferase at low doses and inducing cytotoxicity by incorporating itself into RNA and DNA at high doses.

METABOLISM:

Azacitidine is metabolized through spontaneous hydrolysis and deamination mediated by cytidine deaminase.

Table 1:- Different analytical techniques of anti-cancer drugs

S.No	Drug Name	Analytical Technique	Description of Technique	Author & Year
1	Pralsetinib	RP-HPLC	Column: BDS hypersil c18 (250mmx4.6mm. 5µ particle size) Mobile phase: OPA buffer pH3.0 methanol (45:55) Flow rate: 1ml/min Wave length: 270nm Linearity: 80-100µg/ml LOD: 2.34µg/ml LOQ: 7.07µg/ml Run time: 12min	Rushita sardhara et al**...** 2023
2	Pralsetinib	HPLC	Column: Water x Bridge C18 column (4.6mm x 250mm. 5µm particle size) Mobile phase: potassium dihydrogen phosphate: acetonitrile (19:1) Flow rate: 1.0ml/min Wavelength: 260nm System: An agilent 1200 HPLC LOD: 0.4µg/ml LOQ: 0.025µg/ml Run time: 40 min	Liang liang cai et al
3	Pralsetinib	HPLC-MS/MS	System: Agilent, USA, a 2695 series HPLC Column: x Bridge RP-C18 Column (250mm x 4.6mm,5µm) Mobile phase: ethanol: 50mm formic acid Wavelength: 254nm	Rajesh Varma, Bhupatiraju et al… 2024

			Flow rate: 0.7ml/min Run time: 15min LOQ: 0.025µg/ml Injection volume: 5µl	
4	Pralsetinib	UPLC-MS/MS	Column: Acquit UPLC HSS T3 column (2.1x100mm,1.8µm) Mobile phase: 0.17 formic acid and acetonitrile Flow rate: 0.4 ml/min Runtime :7mins	ZICHEN ZHAO et al… 2024
5	Pralsetinib & selpercatinib	LC-MS/MS	Column: van guard pre-column (5x24mm) Mobile phase: Ammonium hydroxide (in water) And methanol (45:55 Run time:2mins Flow rate:600µl/min Injection volume:10ml	RAHIME SENTURK et al… 2022
6	Aacitidine	RP-HPLC	Column: Zorbax buns RP (250MM x 4.6mm, 5µ column). Mobile phase: ammonium acetate buffer: acetonitrile (75:25). Flow rate: 1.0ml/min. Injection volume: 10 µl. Wavelength: 242nm. LOD: 0.0239 µg/ml. LOQ: 0.0723 µg/ml. Linearity: 15-225 µg/ml. Run time: 30mins.	Kuturu Deepthi et.al 2022
7	Azacitidine	RP-HPLC	Column: YMCODS AQ-5, (250 x 4.6mm), 5µm column. Mobile phase: mixture of buffer, methanol & acetonitrile (500: 300: 200). Flow rate: 1.0ml/min Wavelength: 242nm Linearity: 400 µg.ml-1 Run time: 60mins.	Brahmaiah Marineni et.al 2014
8	Azacitidine	UPLC	Column: ACQUITY UPLC BEH C18 (100mm x 3.0mm, 1.7µm, water crop, Milford, MA, USA) Mobile phase: CO2/Methanol Run time: 3.5min LLOQ: 20ng/ml	Dongpoli et.al 2013
9	Azacitidine	HPLC	Column: Chiral Pak IA (250 x 45mm, 5µm) Mobile phase: n-Hexane-ethanol (50: 50, v/v) LOD: 0.18 µg/ml. LOQ: 0.60 µg/ml.	

			Linearity: 6.0 µg/ml.	T. Satyanarayana Raju et.al 2012

Different Brands of Pralsetinib & Azacitidine

S.no	Brand Name	API	Manufacturing Company
1	Xpreza	Azacitidine	Natco
2	Azacytin	Azacitidine	Dr. Reddy's
3	Azacite	Azacitidine	Getwell
4	Gavreto	Pralsetinib	Genentech
5	Lucipra	Pralsetinib	Lucius
6	Pranib	Pralsetinib	Pharma Lord

CONCLUSION

A survey of literature reveals that smart analytical strategies don't seem to be offered for the drug Pralsetinib & Azacitidine. 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; hence its planned to enhance the present strategies and to develop new strategies for the assay of Pralsetinib & Azacitidine in pharmaceutical dose forms adapting totally different offered analytical techniques like Uv spectrophotometry, HPLC, GC 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.

BIBILOGRAPHY

1. International Conference on Harmonization, "Q2A: Text on Validation of Analytical Procedures," Federal Register 60(40), 11260–11262 (1995).
2. International Conference on Harmonization, "Q2B: Validation of Analytical Procedures: Methodology; Availability," Federal Register 62(96), 27463–27467 (1997).
3. FDA, "Analytical Procedures and Methods Validation: Chemistry, Manufacturing and Controls Documentation; Availability," Federal Register (Notices) 65(169), 52776–52777 (2000).
4. Validation of analytical procedures, Methodology, ICH harmonized tripartite guideline, 108, 1996.
5. Yonghong Zhu, Jisu Qin, Wenyi Wu and Liang Cai, Development and validation of a novel high-performance liquid chromatography (HPLC) method for the detection of related substances of pralsetinib, a new anti-lung cancer drug, Frontiers in chemistry, Volume 12 - 2024 .
6. Rajesh Varma Bhupatiraju, Pavani Peddi, Venkata Swamy Tangeti, and Battula Sreenivasa Rao, Establishing and validating an HPLC protocol for pralsetinib impurities analysis, coupled with HPLC-MS/MS identification of stress degradation products, analytical science & technology, Vol. 37 No. 5, 280-294, 2024.
7. Santhosh Illendula, Shailesh sharma; UPLC method development and validation of acalabrutinib in bulk and pharmaceutical dosage form , International journal of chemical and biochemical sciences IJCBS, 25(14) 2024 , 397-411.
8. Rahime Senturk, Yaogeng Wang, Alfred Schinkel, Jos H. Beijnen, Quantitative bioanalytical assay for the selective RET inhibitors selpercatinib and pralsetinib in mouse plasma and tissue homogenates using liquid chromatography-tandem mass spectrometry, Journal of Chromatography, 2020, 1147:12213
9. Santhosh illendula, Suthakaran raj, Srujana; a review on method development and validation of selected anticancer drugs zanubrutinib, erdafitinib by different analytical techniques, World Journal of Pharmaceutical Research WJPR (2024) Volume 14, Issue 01, 263-281. DOI: 10.20959/wjpr202401-35043
10. Kuturu Deepthi, Abdullah khan. A review on Analytical Method Development and Validation for Determination of Azacitidine by High Performance Liquid Chromatography. Journal of Survey in Fisheries Sciences. 2022 8(3) 586-590.

11. CH. V. Suresh, Santhosh illendula, J. Rajeshwari; Method Development and Validation for the Quantitative Determination of Vericiguat in Bulk Form and Marketed Pharmaceutical Dosage Forms by using RP-HPLC, International Journal of Pharmacy and Biological Sciences-IJPBS (2024) 14 (2): 89-98. DOI: https://doi.org/10.5281/zenodo.12790508
12. Brahmaiah Marineni, T Reddy. A review on Development and validation stability-indicating RP-HPLC assay method for azacitidine and its bulk drug. Int. J. Pharmacy and Pharmaceutical Sci. 2014 6(8) 0975-1491.
13. Dongpo Li, Tian hong Zhang, Longfa Kou, Youxi Zhang, Jin Sun, Zhonggui He. A review on Development of a Supercritical Fluid Chromatography-Tandem Mass Spectrometry Method for the Determination of Azacitidine in Rat Plasma and Its Application to a Bioavailability Study. 2013 19(1) 342-351.
14. Santhosh Illendula, A. Navyasree, CH. Ganesh, K. Sneha & KNV Rao; Method development and validation of Axitinib in bulk and pharmaceutical dosage form by UV spectroscopic method, Indo American journal of pharmaceutical sciences IAJPS;2019 06(03) :6221-6227.
15. T Satyanarayana Raju, L Kalyanaraman, KSV Raghava chary, P Yadagiri Swamy. A review on A Novel Normal Phase HPLC Method for the Quantification of N-Formyl Impurity in Azacitidine Active Pharmaceutical Ingredients and Pharmaceutical Dosage Forms. Journal of liquid chromatography & related technologies. PUB MED. 2012 35(8) 1070-1080.
16. https://en.wikipedia.org/wiki/Pralsetinib.
17. https://en.wikipedia.org/wiki/Azacitidine
18. https://go.drugbank.com/drugs/ DB00928
19. https://go.drugbank.com/drugs/ DB15822