IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
HUMAN

Human Journals
Review Article
January 2024 Vol.:30, Issue:1

A Review on Analytical Method Development and Validation of Recently USFDA-Approved Anti-Cancer Drugs

IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
HUMAN

Barla Karuna Devi*[1], Soujanya Chaganti [1], Veluvolu Tejaswini[2]

[1]*Department of Pharmaceutical Chemistry, Gokaraju Rangaraju College of Pharmacy, Hyderabad-500 090, Telangana, India.*

[2]*Department of Pharmaceutical Analysis, Gokaraju Rangaraju College of Pharmacy, Hyderabad-500 090, Telangana, India.*

Submitted: 25 December 2023
Accepted: 31 December 2023
Published: 30 January 2024

Keywords: HPLC, anticancer agents, dosage forms, analytical techniques.

ABSTRACT

High Performance Liquid Chromatography is one of the most important analytical technique used for the separation of the mixture. Capmatinib, Lorlatinib, Erdafitinib, Selepercatinib, Zanubrutinib, Rucaparib, Talozoparib, and Dacomitinib are the recently USFDA-approved anticancer agents. The present review highlights the various HPLC methods that were developed for estimation of the above-mentioned drugs.

HUMAN JOURNALS
ijppr.humanjournals.com

1. INTRODUCTION

HPLC is a chromatographic technique used to separate a mixture of compounds in analytical chemistry and biochemistry to identify, quantify, or purifying the individual components of the mixture (1). In High Performance Liquid chromatography (HPLC) the principle is based on adsorption as well as partition chromatography is depending on the nature of the stationary phase, if the stationary phase is solid principle is based on adsorption chromatography and if stationary phase is liquid principle is based on partition chromatography (2). There are different types of HPLC methods such as normal phase, reversed phase, adsorption, ion chromatography, size exclusion chromatography (3,4). When compared to other analytical techniques HPLC offers the following advantages such as rapid and precise quantitative analysis, automated operation, high-sensitive detection, high efficiency, high accuracy, high resolution, quantitative sample recovery and amenable to diverse samples (2). Though it is having many advantages there are certain limitations like there is no universal detector, less separation efficiency than capillary gas chromatography, gas chromatography is better option for separation of unstable substances and difficult to be handled by beginners (5). HPLC techniques are widely used in forensic, clinical, and food industries in addition to the pharmaceutical industry (6). HPLC is used not only to determine drug substances but also to perform stability studies, plant extracts, proteins, and environmental pollutants. It can also be used to separate isomers (7). The present review highlights the HPLC techniques by which recently USFDA-approved anticancer agents are analyzed (Table 1).

2. APPLICATIONS

By using HPLC technique various anticancer agents such as Capmatinib, Lorlatinib, Erdafitinib, Selepercatinib, Zanubrutinib, Rucaparib, Talozoparib, and Dacomitinib were analysed. All the above-mentioned drugs were approved by US-FDA in the past decade. Cancer is a large group of diseases that occur when abnormal cells divide rapidly and can spread to other parts of the body. These rapidly growing cells may cause tumors. They may also disrupt the body's regular function. Benign tumor, Malignant tumour and Premalignant tumor are the three types of tumours that have been classified based on the ability to undergo metastasis (8). Cancer can occur to different organs (9) such as lungs, colon, anal, mouth, bone, adrenal glands, appendix, anus, liver etc. Chemotherapy, radiotherapy, surgery and immunotherapy (10) are various treatment methods available. All these drugs Capmatinib,

Lorlatinib, Erdafitinib, Selepercatinib, Zanubrutinib, Rucaparib, Talozoparib, and Dacomitinib are especially used in chemotherapy to treat lung cancer.

Table 1 Analytical method validation of various anticancer drugs by HPLC method.

S. No:	Drug Name	Approved Year	Analytical method	Dosage form	System suitability parameters
1	Capmatinib (11)	06-05-2020	HPLC	Tablets	Mobile Phase: Phosphate buffer: methanol (50:50 v/v) Column: Zorbax Eclipse XDB-C18 (4.6 mm *150 mm, 5 µm) Flowrate: 1 mL/min. Linearity: 5-45 µg/mL. Wavelength: 255 nm. Retention time: 6.5 min. LOD: 1 µg/mL LOQ: 3 µg/mL
2	Capmatinib (12)	06-05-2020	HPLC	Tablets	Mobile Phase: d buffer (PH 6.5): MeoH (60:40) v/v. Column: C18 (250 x 4.6mm, 5µ) Flowrate: 1 mL/min. Wavelength: 231 nm. Retention time: 4.327 min.
3	Capmatinib (13)	06-05-2020	HPLC	Tablets	Mobile Phase: Methanol: Phosphate buffer pH 3 (65:35 % v/v) Column: C18 Column (150 mm x 4.6 mm i.d., 5µ) Flowrate: 0.6 ml/min. Linearity: 10-50µg mL. Wavelength: 218 nm. Retention time: 4.3 min. LOD: 0.027 µg/ml LOQ: 0.09 µg/m
4	Lorlatinib (14)	03-03-2021	RP-HPLC	Tablets	Mobile phase: Potassium dihydrogen orthophosphate, Acetonitrile, and methanol (50:30:20 v/v). Column: Eclipse plus C18 (250 mm×4.6 mm,3 µm). Flowrate: 1 ml/min. Linearity: 50-150 µg/mL. Wavelength: 310 nm Retention time:7.87 min LOD: 0.03 µg/mL LOQ: 0.05 µg/mL
5	Erdafitinib	12-04-2019	HPLC	Tablets	Mobile phase: 20mM sodium

	(15)				acetate buffer (pH 4. ±0.02), methanol and acetonitrile (60:10:30 v/v/v) Column persil™ ODS C18 Column (150 mm × 4.6 mm, 5 µ). Linearity: 5-35 µg/mL. Wavelength: 310 nm Flowrate: 1 mL/min Retention time: 3.38 min LOD: 0.2 µg/mL LOQ: 5 µg/mL
6	Selpercatinib (16)	08-09-2020	RP-HPLC	Capsules	Mobile phase: 0.1% orthophosphoric acid and acetonitrile (60:40 v/v) Column: Zorbax C18 column (150×.6 mm, 5µ). Flowrate: 1 mL/min Wavelength: 220 nm Linearity: 2-30 µg/ml Retention time: 2.653 min LOD: 0.02µg/mL. LOQ: 0.05µg/mL.
7	Zanubrutinib (17)	14-11-2019	HPLC	Capsules	Mobile phase: 0.1% ortho phosphoric acid and acetonitrile 50:50 v/v. Column: Luna C18 (250x 4.6 mm, 5 µ) Wavelength: 220 nm Flowrate:1 mL/min Linearity range: 2-30 µg/mL Retention time: 4.358 min LOD: 0.02 µg/mL LOQ: 0.2 µg/mL
8	Rucaparib (18)	19-12-2016	RP-HPLC	Tablets	Mobile phase: phosphate (0.02 M) methanol (65:35 % v/v). Column: C-18 ODS (25 cm, 0.46 cm diameter, 5 µm). Wavelength: 286 nm Flowrate:1 mL/min. Retention time: 5.484 min. Linearity: 6-14 µg/mL. LOD: 0.49 µg/mL. LOQ: 1.486 µg/mL.
9	Talozoparib (19)	16-10-2018	RP-HPLC	Tablet	Mobile phase: Methanol: Acetate Buffer (pH-4.2) (40:60% v/v)). Column: Inertsil ODS C18

					(4.6mm x 250mm, 5µm). Wavelength: 225 nm Flowrate:1 mL/min. Retention time: 3.388 min. Linearity: 60-140 ng/mL. LOD: 1.5 ng/mL. LOQ: 4.5 ng/mL.
10	Talozoparib Tosylate (20)	16-10-2018	HPLC	Tablet	Mobile phase: of Methanol: acetonitrile: 0.1 % sodium perchlorate in the ratio of 25:75:05 (v/v) Column: Spherisorb ODS2 C18 column (250mm × 4.5 mm; 5µm). Wavelength: 269 nm Flowrate:1 mL/min. Retention time: 2.74 min. Linearity: 15–90 µg/mL. LOD: 0.03µg/mL. LOQ: 0.10µg/mL.
11	Dacomitinib (21)	27-09-2018	RP-HPLC	Tablets	Mobile phase: 0.1M sodium perchlorate, acetonitrile 20:80 (v/v) Column: Zorbax Eclipse (250x4.6 mm,5 µm). Wavelength: 253 nm Flowrate: 1 ml/min Linearity range: 20-200 µg/mL Retention time: 5.8 min

CONCLUSION:

Hence from the above review, it is observed that HPLC is one of the most important analytical techniques for quality control of various dosage forms. The different columns that were used are Zorbax Eclipse plus C18, Zorbax Eclipse, Intertsil ODS C18 etc. The buffers such as Phosphate buffer and acetonitrile solvent were most commonly used for the method development and the validation of the API and the drugs in the dosage forms.

ACKNOWLEDGMENT

The authors are grateful to Prof. M. Ganga Raju, Principal, Gokaraju Rangaraju College of Pharmacy for providing the required facilities.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

FUNDING

Not applicable

ETHICS STATEMENT

Not applicable. The present study does not involve experiments on humans and animals.

INFORMED CONSENT

Not applicable

REFERENCES:

1. Kumar SD, Harish Kumar D. Importance of Rp-Hplc in Analytical Method Development: A Review. IJPSR. 2012;3 (12):4626–33.
2. Varhadi SD, Gaikwad VA, Sali RR, Chambalwar K, Kandekar V. A Short Review on: Definition, Principle and Applications of High Performance Liquid Chromatography. IJPPR. 2020; 19 (2):628-634.
3. Pooja M, Prakash Babar R, Khatmode RB, Shivanjali M, Mane S, Giri T, et al. A Review on High-Performance Liquid Chromatography Technique. IJCRT. 2022; 10 (5) 963-973.
4. Chawla G, Kr. Chaudhary K. A Review of HPLC Technique Covering its Pharmaceutical, Environmental, Forensic, Clinical and Other Applications. IJPCA; 2019; 6(2):27–39.
5. Timchenko Y V. Journal of Environmental Analytical Chemistry Brief Report Advantages and Disadvantages of High-Performance Liquid Chromatography (HPCL) J Environ Anal Chem. 2021; 8: 335.
6. Jadhao AS, Ambhore DP, Biyani KR. Importance of RP-HPLC in Analytical Method Development: A Review. IJARSCT. 2022; 2 (8): 345-351.
7. Boligon A.A and Athayde M.L. Importance of HPLC in Analysis of Plants Extracts. Austin Chromatogr. 2014; 1(3): 2.
8. Hassanpour SH, Dehghani M. Review of Cancer from Perspective of Molecular. J. Cancer Res. Pract. 2017; 4(4):127–9.
9. Kumar N, Sharma A, Khinchi MP, Kuma C, Singh SP. A Review on Different Types of Cancer. AJPCR. 2017. 5(2):1–08.
10. Wang S, Liu Y, Feng Y, Zhang J, Swinnen J, Li Y, et al. A Review on Curability of Cancers: More Efforts for Novel Therapeutic Options are Needed. Cancers. 2019. 11:1782.
11. Dalvi S, Thakur P, Kumari K, Kumar V, Singh RM, Warde S, et al. Development and Validation of Reverse-Phase High-Performance Liquid Chromatographic Method for Quantitative Estimation of Capmatinib in Tablet Dosage Form. IJPPR. 2021. 21(3): 314-329.
12. Darshna kirit bhai S, Indushri I, Dhwani S. Development and Validation of Stability Indicating RP-HPLC Method for Estimation of Capmatinib in API Form. International Journal of Pharmaceutical Research and Applications. IJPRA. 2022. 7 (3): 712-719
13. Sivaganesh MM, Lathiff MMKMA, Krishnamoorthy G, Senthamarai R, Ramya MS, Ahamed MJI. Analytical Method Development and Validation of Capmatinib in Bulk and Tablet Dosage Form By Rp-Hplc Method. YMER. 2022. 21 (1): 638-662.

14. Chakravarthi KK, Himabindu K. RP-HPLC Method Development and Validation for the Determination of Lorlatinib in Bulk and Its Pharmaceutical Formulation. IJRPR. 2021. 2 (9): 958-963.
15. M. Maithani, D. Dwivedi, Hatwal D, P. Bansal. Development And Validation of a Rp-Hplc Method for Determination of Erdafitinib in Marketed Formulations. J. Biomed. Pharm. Res. 2020.9(3): 29-32.
16. Navya Singamsetty, Raja Sundararajan. Analytical Method Development and Validation for Determination of Selpercatinib by Using RP-HPLC. IJRPS. 2021.12(1):931–9.
17. Kumari MV, Reddy CHB. Stability Indicating Validated Hplc Method for The Determination of Zanubrutinib In Bulk and Pharmaceutical Dosage Form. AJPCR. 2020. 159–62.
18. Suchitra D, Battu S. A Stability Indicating Reverse Phase-HPLC Method Development and Validation for the Estimation of Rucaparib in Bulk and Pharmaceutical Dosage Form. Am J Analyt Chem. 2021. 12(04):96–107.
19. Sudhakar N, Sunitha P, Kuchana V. Stability Indicating Rp-Hplc Method Development and Validation for The Estimation of Talazoparib in Bulk Form and Pharmaceutical Dosage Form. YMER. 2023. 22 (1): 63-76.
20. Satyanaraya V, Sri AK, Rao MP. A Rapid Stability Indicating Method Development and Validation for The Quantification of Talazoparib Tosylate in Bulk Drug and Pharmaceutical Formulation by HPLC Introduction. YMER. 2023. 22 (1): 421-434.
21. Kamani V, Sujatha M, Rao GSNK, Kumar NV. Stability Indicating RP-HPLC Method for the Analysis of Dacomitinib and its Related Impurities in Bulk and Oral Solid Dosage Formulations. J Pharm Res Int. 2021. 33 (40B):187–99.

	Barla Karuna Devi* Department of Pharmaceutical Chemistry, Gokaraju Rangaraju College of Pharmacy, Hyderabad-500 090, Telangana, India.
	Soujanya Chaganti Department of Pharmaceutical Chemistry, Gokaraju Rangaraju College of Pharmacy, Hyderabad-500 090, Telangana, India.

Veluvolu Tejaswini
Department of Pharmaceutical Analysis,
Gokaraju Rangaraju College of Pharmacy,
Hyderabad-500 090, Telangana, India.