World Journal of Pharmaceutical Sciences
ISSN (Print): 2321-3310; ISSN (Online): 2321-3086
Available online at: https://wjpsonline.com/
Review Article

A REVIEW ON ANALYTICAL CHROMATOGRAPHIC METHODS FOR ESTIMATION OF CETILISTAT IN PHARMACEUTICAL FORMULATION AND BULK FORM

Miss. Vrushali M. Pawar[1], Dr. Manoj Kumar Patil[2], Mr. Sagar S. Kale[3]

[1]Research scholar, Department of Pharmaceutical Chemistry, Sahyadri College of Pharmacy, Methawde, Sangola, Dist- Solapur, Maharashtra, India.
[2]Professor and Principal, Department of Pharmaceutical Chemistry, Sahyadri College of Pharmacy, Methawde, Sangola, Dist- Solapur, Maharashtra, India.
[3]Associate Professor, Department of Pharmaceutical Chemistry, Sahyadri College of Pharmacy, Methawde, Sangola, Dist- Solapur, Maharashtra, India.

Received: 30-06-2025 / Revised Accepted: 01-07-2025 / Published: 03-07-2025

ABSTRACT:
Overweight and obesity pose serious health concerns to both individuals and society. Obesity causes a number of physiological, psychological, and social difficulties in addition to visual impairments and abnormal physiological metabolism, Obesity is associated with the development of numerous chronic diseases and is a major risk factor for a number of illnesses, such as diabetes, hypertension, hyperlipemia, cardiovascular disease, and even cancer. Compared to those of normal weight, obese people are more prone to suffer type 2 diabetes, gallbladder disease, and syndrome. Gout, osteoarthritis, hypertension, and coronary heart disease all increase the risk of obesity, and they may also have some effects on reproduction. Pancreatic lipase inhibitors are crucial for the metabolism of fat in humans. This article discusses the many processes needed to develop and validate an HPLC analysis and UV technique. Testing for accuracy, specificity, linearity, range, limit of detection, limit of quantification, robustness, and system adaptability are all part of the ICH Guidelines' validation of an HPLC process. In light of this, the purpose of this review is to present a summary and analysis of HPLC techniques that have been documented in the literature for the estimate of cetilistat in pharmaceutical dosage forms, either alone or in combination. The comparative application of HPLC by UV/PDA techniques for Cetilistat estimation is covered in the review that follows. Future analytical research needs can be adequately met by Cetilistat using the current compilation.
Keywords: Cetilistat, Lipase-Inhibitor, High performance liquid Chromotography, Uv-Spectroscopy.

INTRODUCTION

Cetilistat, the Food and Drug Administration recently approved a weight-loss medication with a unique mode of action to treat obesity.[1] In order to reduce the systemic absorption of dietary fat, it inhibits the pancreatic and gastric lipases in the gastrointestinal tract lumen, Additionally, treatment leads to modest improvements in blood pressure, low-density lipoprotein, total cholesterol, and the levels of insulin and fasting glucose. The main side effects, which typically appear early in therapy and tend to go away with continuing treatment, are gastrointestinal in nature. A conventional multiple-vitamin supplement is advised daily during therapy to avoid anomalies in vitamin serum concentrations since cetilistat may reduce the absorption of fat-soluble vitamins.[2] The moderate amount of weight loss and the possibility of significant gastrointestinal distress could restrict the agent's therapeutic usefulness. Its long-term safety and efficacy for maintaining weight, treatment cost-effectiveness, and overall decrease in morbidity and death associated with obesity are still unknown.[3]

EXPERIMENTAL

Physiochemical properties

Cetilistat (Fig.1), is chemically, (2-hexadecoxy-6-methyl-3,1-benzoxazin-4-one), It is a Benzoxazine derivative and which acts as an inhibitor of gastric and pancreatic lipase.4 The molecular weight and molecular formula of Cetilistat is 401.5821 and C25H39NO3 respectively.[5]

Address for Correspondence: Miss. Vrushali M. Pawar, Research scholar, Department of Pharmaceutical Chemistry, Sahyadri College of Pharmacy, Methawde, Sangola, Dist- Solapur, Maharashtra, India, Email: vrushalip2929@gmail.com.

How to Cite this Article: Miss. Vrushali M. Pawar, A REVIEW ON ANALYTICAL CHROMATOGRAPHIC METHODS FOR ESTIMATION OF CETILISTAT IN PHARMACEUTICAL FORMULATION AND BULK FORM, World J Pharm Sci 2025; 13(02): 221-224;https://doi.org/10.54037/WJPS.2022.100905

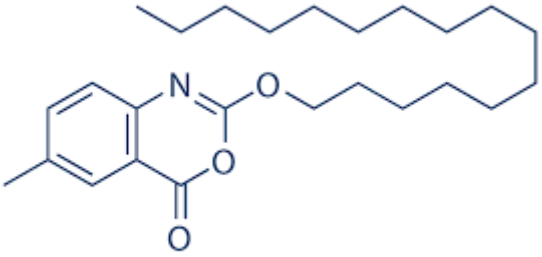

Fig.1 Chemical structure of Cetilistat

Mechanism of Action

A gastrointestinal lipase inhibitor called cetilistat prevents the breakdown and absorption of fat, which lowers calorie intake and causes weight loss. It differs from the majority of other anti-obesity medications in that it acts peripherally rather than on the brain to decrease hunger. The substance does not significantly enter the body and stays in the gastrointestinal tract.[6]

Quantitative & Qualitative Analytical Techniques.

With the use of quantitative and qualitative analysis techniques, it is possible to exactly ascertain the concentration of each variable and the kind of drug included in the sample.

High-Performance Liquid-Chromatography (HPLC)

In high pressure liquid chromatography (HPLC), a sample solution in a mobile phase is pumped through a stationary phase-containing column. The elements contained in a combination can be resolved, identified, and quantified using this instrumental analytical approach. Many industrial and scientific applications, such as the examination of chemicals, pharmaceuticals, environmental materials, and forensic investigations, have been made possible by HPLC's ability to detect samples at trace concentrations as low as parts per trillion. Several researchers worked together to create the HPLC method for identifying Cetilistat from pharmaceutical dosage forms and bulk material in either single analysis or combination.[6]

In this review paper, we have tried to give an overview of the many chromatographic conditions that are utilized to build HPLC methods, their outcomes, and a conclusion. The C18 column was found to have the maximum degree of hydrophobicity and a sorbent phase that retained the ligand molecules, making it the sole HPLC technique used to separate cetilistat out of all those evaluated, Table 1 displays various HPLC methods and their properties as they are described in the literature.

Samie Sable and Kanchan Chauhan. Examined Cetilistat in the pharmaceutical dosage form. Separation of Cetilistat was accomplished on a BDS Hypersil C-18 by using acetonitrile and phosphate buffer of pH 4.0 in the ratio 60:40 as a solvent system with flow rate kept at 1.0 ml/min. Cetilistat was discovered to have a retention duration of 2.73 minutes at a wavelength of 228 nm. With a correlation coefficient of 0.9986, the technique was determined to be linear over the concentration range of 20–100µg/ml. The cetilistat sample solutions' mean recovery percentage was 100.26%. Cetilistat detection and quantification limits were determined to be 1.961µg/ml and 5.944µg/ml, respectively. On the same line, Omkar S. Bidkar et all., A reliable and verified RP-HPLC method was created in this study to quantify cetilistat in biological fluids. Optimizing chromatographic conditions, such as choosing appropriate solvents, wavelengths, and mobile phase composition, was part of the technique development process. The last technique used a C18 column with a mobile phase made up of trifluoroacetic acid, water, and methanol (85:15:0.1). With a correlation coefficient (R2) of 0.9996, the technique demonstrated good linearity over a concentration range of 25–75 µg/ml. The detection limit (LOD) and the results showed that the limit of quantification (LOQ) was 4.47 µg/ml and 1.48 µg/ml, respectively.

Table 1: Performance attributes of HPLC method [7-12]

Author	Drug	Stationary phase	Mobile phase	Application	Wave length
Samie Sable et al.,	Cetilistat	BDS Hypersil C-18 (250×4.6µm)	acetonitrile and phosphate buffer of pH 4.0 in the ratio 60:40	Tablet Dosage Form	228nm
Omkar S. Bidkar et al..,	Cetilistat	C18 (Hypersil BDS) (4.6× 250mm, 5µm)	Methanol: Water: Trifluloroacetic acid, 85: 15:0.1	Bioanalytical	222 nm

UV Visible spectroscopy

Spectroscopic techniques based on UV absorption and chemical reactions can support pharmacopoeia. Spectrophotometry is the quantitative study of a material's wavelength-dependent transmission or reflection characteristics. One benefit of these approaches is that they take less time and effort. These techniques are also very precise and exact. The use of UV-vis spectrophotometry in the process of developing pharmaceutical dosages has grown significantly in recent years. We can learn a lot about atomic and molecular structure (EMR) by looking at how atoms and molecules interact with light. EMR spectrum areas offer a wide variety of information as a result of these interactions. Table 3 lists various UV techniques and their characteristics as they are described in the literature.

Up till now, only a few UV-Spectrophotometric methods have been reported for Cetilistat S. A. Kshirsagar et all.., Cetilistat was determined in pharmaceutical dosage forms and API using a straightforward, quick, sensitive, accurate, and specific UV spectrophotometric method that was developed and validated. Cetilistat solutions were made in n-hexane using this approach. Within a 1cm quartz cell in a twin beam UV spectrophotometer, cetilistat standard solution was scanned in the UV range (400-200 nm). The wavelength at which the cetilistat standard solution exhibited the highest absorption was 320.0 nm. The technique complies with Beer's law when the concentration is between 20 and 100 µg/ml. The regression of the curve revealed Y=0.0096x+0.0012 with excellent recovery of 96-99%, and the correlation coefficient was determined to be 0.9996. The results showed that the limits of quantification and detection were 8.2677µg/ml and 2.7283µg/ml, respectively.

Table 2: Performance attributes of UV spectroscopy method[13]

Author	Drug	Buffer & Diluent	Linearity range (µg/ml)	Application	Wave length
S. A. Kshirsaga et al	Cetilistat	5 ml n-hexane	20-100µg/ml	API and in Pharmaceutical Dosage Form	320.0 nm

ACKNOWLEDGEMENT: The author expresses sincere thanks to Sahyadri college of Pharmacy Methawade, Sangola.

CONCLUSION: The current research outlined the overview of HPLC techniques that have been documented in the literature for the estimation of Cetilistat in bulk pharmaceutical formulations such as Cetilistat, as well as in single dose and mixed dosage forms. The main goal of the review compilation is to gather as much information as possible about the HPLC analytical procedures of Cetilistat and conduct a thorough analysis of it. In conclusion, pharmacokinetic research, quality control, and regulatory compliance for Cetilistat still rely significantly on high performance liquid chromatography (HPLC), since our survey indicates that very few analytical methodologies are available on HPLC techniques. It is a fine standard in pharmaceutical analysis since it may be customized for both ordinary and sophisticated analytical applications.

REFERENCES

1. Fontaine KR, Barofsky I. Obesity and health-related quality of life. Obesity reviews. 2001 Aug;2(3):173-82.
2. Djalalinia S, Qorbani M, Peykari N, Kelishadi R. Health impacts of obesity. Pakistan journal of medical sciences. 2015 Jan;31(1):239.
3. Liu TT, Liu XT, Chen QX, Shi Y. Lipase inhibitors for obesity: A review. Biomedicine & Pharmacotherapy. 2020 Aug 1;128:110314.

4. Tucci SA, Boyland EJ, Halford JC. The role of lipid and carbohydrate digestive enzyme inhibitors in the management of obesity: a review of current and emerging therapeutic agents. Diabetes, metabolic syndrome and obesity: targets and therapy. 2010 May 10:125-43.
5. Birari RB, Bhutani KK. Pancreatic lipase inhibitors from natural sources: unexplored potential. Drug discovery today. 2007 Oct 1;12(19-20):879-89.
6. Kopelman P, Bryson A, Hickling R, Rissanen A, Rossner S, Toubro S, Valensi P. Cetilistat (ATL-962), a novel lipase inhibitor: a 12-week randomized, placebo-controlled study of weight reduction in obese patients. International journal of obesity. 2007 Mar;31(3):494-9.
7. Padwal R. Cetilistat, a new lipase inhibitor for the treatment of obesity. Current Opinion in Investigational Drugs (London, England: 2000). 2008 Apr 1;9(4):414-21.
8. Yuan S, Chan JF, Chik KK, Chan CC, Tsang JO, Liang R, Cao J, Tang K, Chen LL, Wen K, Cai JP. Discovery of the FDA-approved drugs bexarotene, cetilistat, diiodohydroxyquinoline, and abiraterone as potential COVID-19 treatments with a robust two-tier screening system. Pharmacological research. 2020 Sep 1;159:104960.
9. Kotecha N. DEVELOPMENT & VALIDATION OF ANALYTICAL METHODS FOR THE ESTIMATION OF ANTI-DIABETIC DRUGS (Doctoral dissertation, GUJARAT TECHNOLOGICAL UNIVERSITY AHMEDABAD).
10. Nasr EM, Wong LC. DEVELOPMENT AND VALIDATION OF A REVERSE PHASE-HIGH PERFORMANCE LIQUID CHROMATOGRAPHY-ULTRAVIOLET METHOD FOR SIMULTANEOUS DETECTION OF CAFFEINE AND PHENOLPHTHALEIN IN WEIGHT REDUCING SUPPLEMENTS. Malaysian Journal of Analytical Sciences. 2017;21(3):605-18.
11. Samie Sable and Kanchan Chauhan, Development And Validation Of Stability Indicating Rp-Hplc Method Of Drug Cetilistat In Bulk And Pharmaceutical Formulation, WJPLS, wjpls, 2023, Vol. 9, Issue 2, 112-118.
12. Borman P, Elder D. Q2 (R1) validation of analytical procedures: text and methodology. ICH quality guidelines: an implementation guide. 2017 Sep 27:127-66.
13. Reynolds DW, Facchine KL, Mullaney JF, Alsante KM, Hatajik TD, Motto MG. Conducting forced degradation studies. Pharm Technol. 2002 Feb;26(2):48-56.