International Journal of Pharmaceutical Research and Development
www.pharmaceuticaljournal.net
Online ISSN: 2664-6870; Print ISSN: 2664-6862; Impact Factor: RJIF 5.48
Received: 06-01-2021, Accepted: 21-01-2021, Published: 25-03-2021
Volume 3, Issue 1, 2021, Page No. 18-21

Analytical techniques for the estimation of Celecoxib in capsule dosage form by spectrophotometric method

Kirtimaya Mishra[1], Snigdha Rani Behera[1], Soumyashree Tripathy[1], Biswa Ranjan Biswal[1], Chintapalli Gowri Sankar[2*]
[1] Department of Pharmaceutical Analysis, Jeypore College of Pharmacy, Jeypore, Odisha, India
[2] Department of Pharmaceutics, Jeypore College of Pharmacy, Jeypore, Odisha, India

Abstract
For the determination of Celecoxib in pure formulations and its pharmaceutical formulations, a simple UV-spectrophotometric method was developed. Celecoxib exhibited maximum absorption at 244 nm in ethanol and obeyed linearity in the concentration range of 0.2-40 µg/ml. The method proposed was validated statistically. With good accuracy, all the proposed methods are simple, selective, reproducible, sensitive and precise. Some of the methods were proved to be superior to most of the reported methods. Many of these suggested prediction methods for chosen drugs, such as Celecoxib, have been successfully implemented either in bulk or in prescription formulations. The suggested methods can be used in bulk and prescription dosage formulations as alternative methods to the recorded ones for the routine determination of selected drugs in the sample.

Keywords: methanol, tablets, UV spectroscopy, celecoxib

Introduction
UV-visible spectrophotometric methods that fall in the 200-380 nm wavelength region and fluorimetric methods are very simple, inexpensive, and easy to estimate bulk-form drugs and their formulations. The drawbacks of certain analytical colorimetric or fluorimetric approaches lie in the chemical reaction on which the systems are based rather than the available instruments. Many of the reactions involve a certain drug's color or fluorescence are very selective or may be made selective by adding masking agents, regulating pH, using solvent extraction methods, changing oxidation states or previous elimination of intervening ingredients with the assistance of separate chromatographic ingredients [1, 2, 3]. Celecoxib (CELE) is a non-steroidal anti-inflammatory drug family and is available for oral administration in 5 mg and 10 mg strength tablets. Chemically, it is 4-[5-(4-methylphenyl)-3-(trifluoromethyl) pyrazol-1-yl] benzene sulfonamide. The drug is official in British Pharmacopoeia. It is a highly selective COX-2 inhibitor and primarily inhibits this isoform of cyclooxygenase, whereas traditional NSAIDs inhibit both COX-1 and COX-2. Celecoxib is approximately 7.6 times more selective for COX-2 inhibition over COX-1In theory, this selectivity allows celecoxib and other COX-2 inhibitors to reduce inflammation while minimizing gastrointestinal adverse drug reactions that are common with non-selective NSAIDs. According to the literature survey, it was found that few analytical methods were recorded for estimating CELE, such as UV-Visible analysis [4, 5, 6]. The aim of the approach proposed is to establish simple and precise methods for the determination of Cele in pharmaceutical dosage forms using the UV-Spectrophotometry method. All of these findings have demonstrated the need for a fast and sensitive quality-control study of CELE-containing pharmaceutical formulations. Since these methods are costly, we have tried to establish a more reliable, convenient and economical spectrophotometric approach with greater precision, specificity and sensitivity for the study of CELE in bulk and dosage types.

Materials and Methods
CELE was obtained as gift sample from Elite chemicals and all reagents were purchased from SD Chemicals Chennai. There was an analytical grade of all materials and reagents used.

Method Development
For the identification of CELE in pure form and its pharmaceutical formulation, a simple UV-Visible Spectro photometric method was developed. CELE demonstrated maximal ethanol absorbance at 310nm and obtained linearity in the 0.2 to 40 µg/ml concentration range. The method proposed was validated statistically.

Instrumentation
Spectral and absorbance measurements were made on an Elico SL–159 UV–Visible spectrophotometer by using 1cm quartz cells. Afcoset ER 200A electronic balance was used for weighing the samples.

Selection of Solvent
Methanol was selected an ideal solvent for spectrophotometric analysis of CELE.

Scanning and Determination of Maximum Wavelength (ΛMAX)
Various drug solutions (0.2µg/ml and 40µg/ml) in Methanol were scanned using UV-Visible spectrophotometers within the 200-380nm wavelength region against Methanol as blank in order to determine the wavelengths of maximum absorption (λmax) of the drug. The resulting spectrum was presented in Fig 1 and the absorption curve showed characteristic absorption maximum at 310 nm for CELE.

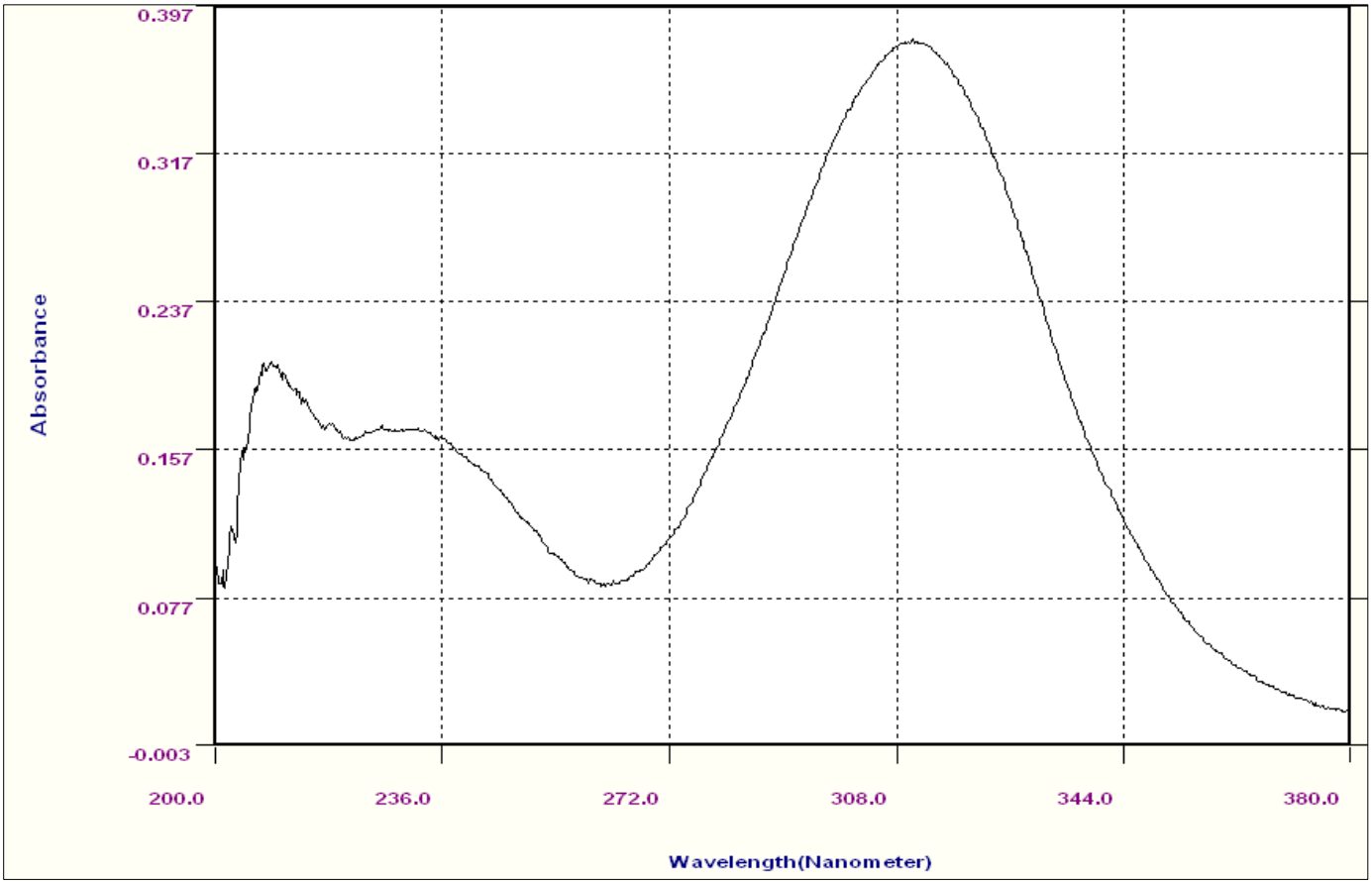

Fig 1: Absorption Spectrum of Celecoxib in Methanol

Preparation of Stock Solution

Standard stock solution of CELE was prepared by dissolving 10mg of CELE drug in 10ml of Methanol in 10ml of volumetric flask to get a concentration of 1mg/ml solutions.

Preparation of Working Standard Solutions and construction of standard graph

To achieve working quality solutions of 10ug/ml and 100ug/ml, the formulated stock solution was further diluted with Methanol. Different aliquots of CELE were taken and diluted to 10 ml with Methanol to create Beer's law plot for CELE to get the working normal solutions as shown in Table1. The absorbances of each solution were measured at lmax 244 nm against Methanol as blank. The results were shown in table1. The standard graph for CELE was plotted by taking concentration of drug on x-axis and absorbance on y-axis and was shown in Fig 2. The drug has obeyed Beer's law in the concentration range of 0.2-40ug/ml [7].

Estimation of Celecoxibe in commercial formulations

For analysis of commercial formulations, 20 Tablets containing CELE were taken and powdered. The powder equivalent to 0.010g of CELE was taken in a 10ml volumetric flask, containing 7ml of Methanol and sonicated for 30 minutes. The volume was made up to 10ml with Methanol and filtered to get a solution of concentration 1000µg/ml. This was further diluted with Methanol to get a concentration within the linearity range and the absorbances were measured against the blank at 244nm. The results were shown in Table 3.

Table 1: Linearity table of Celecoxib (pure drug) in Methanol at 310nm

S.NO	Concentration(ug/ml)	Absorbances
1	0.2	0.011
2	0.4	0.018
3	0.5	0.019
4	1	0.041
5	2	0.094
6	4	0.146
7	5	0.193
8	10	0.361
9	20	0.652
10	40	1.254

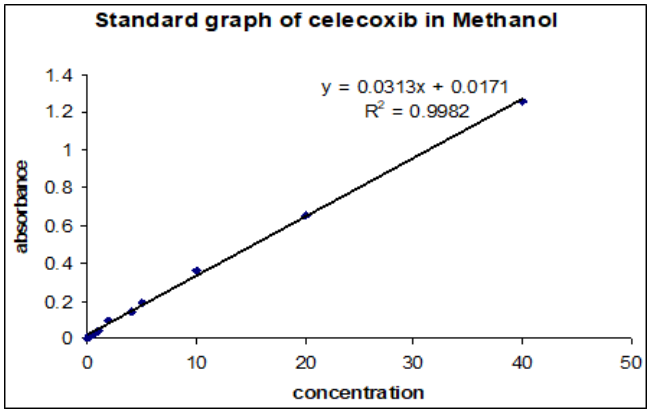

Fig 2: Linearity graph of Celecoxib

Table 2: Optical characteristics of proposed method.

S.NO	Parameter	Celecoxib
1	lmax (nm)	310nm
2	Beer's Law limit (mg/ml)	0.2-40
3	Regression equation (Y)	0.0313x+0.0171
4	Slope (a)	0.0313
5	Intercept (b)	0.0171
6	% Range of error 0.05 confidence limits 0.01 confidence limits	 0.18809 0.24759
7	Correlation co-efficient	0.9982

Validation

Precision

The precision of the proposed method was ascertained by actual determination of six replicates of fixed concentration of the drug within the Beer's range and finding out the absorbance's by the proposed method [8]. From this absorbance's Mean, Standard deviations, %R.S. D were calculated. The readings were shown in Table 4.

Accuracy

Recovery experiments were performed to determine the accuracy of the proposed procedure by applying varying concentrations (80 %, 100 %and 120 %) of bulk samples of CELE within the linearity range and adding 10mg/ml to the pre-analyzed concentration formulation [9]. From that % recovery values were calculated. The results were shown in Table 5.

Table 3: Amount of Celecoxib in formulation by proposed method.

S. No	Formulation	Drug	Labeled amount(mg)	Observed amount	% Recovery
1	Zycel (Zydus health care)	Celecoxib	200	198.01	99

Table 4: Precision data

S.NO	Concentration (ug/ml)	Absorbance At 310nm
1	10	0.365
2	10	0.367
3	10	0.361
4	10	0.365
5	10	0.366
6	10	0.361
7	10	0.364
8	10	0.365
Mean		0.36425
S. D		±0.002188
%R.S. D		0.60069

Table 5: Accuracy data

80%						
S.NO	Conc(bulk)	Conc(formln)	%Recovery	Mean	S. D	%R.S. D
1	8	10	99.84	99.84	0.01448	0.0145
2	8	10	99.85			
3	8	10	99.82			
100%						
4	10	10	99.904	99.90	0.0015	0.0015
5	10	10	99.901			
6	10	10	99.902			
120%						
7	12	10	99.91	99.93	0.02171	0.02172
8	12	10	99.95			
9	12	10	99.95			

Summary

Pharmaceutical research basically means that pharmaceuticals are analysed. Today, pharmaceutical research requires much more than an analysis of active pharmaceutical ingredients or a manufactured substance. The pharmaceutical industry is subject to heightened government and public stakeholder oversight to reduce costs and to reliably bring healthy, efficient drugs to the consumer that address unmet patient needs. In maintaining the origin, safety, effectiveness, purity, and consistency of a drug product, the pharmaceutical analyst plays a significant role [10]. The need for pharmaceutical analysis is primarily motivated by regulatory specifications. In general, the widely used pharmaceutical research tests include the development of compendia testing system, establishing criteria and evaluation of methods. One of the most interesting ways for scientists to take part in the quality process is by empirical research, which offers real evidence on the identification, substance and purity of drug products. With a great deal of commitment to global harmonization, new approaches are now being developed. As a consequence, it is possible to ensure that emerging goods have similar consistency and can be taken more easily to foreign markets.

Pharmaceutical research plays a pivotal role in the statutory approval, either by industry or by regulatory bodies, of medicines and their formulations. In industry, the divisions of quality assurance and quality management play a significant role in delivering a safe and reliable type of prescription or dose. The latest Good Manufacturing Practices and the recommendations of the Food Drug Administration (FDA) insist that sound analytical methods with greater specificity and reproducibility be followed. The sophistication of the problems encountered in pharmaceutical research is therefore critical for achieving the selectivity, speed, low cost, simplicity, specificity, sensitivity, accuracy and precision of drug estimation.

Conclusion

The method proposed was simple, sensitive and accurate with good precision and accuracy. The proposed approach is precise when calculating commercial formulations without intervention from excipients and other additives. This approach can also be

used for the regular assessment of CELE in bulk samples and pharmaceutical formulations.

Acknowledgement
The authors express their gratitude to the Management, Jeypore College of Pharmacy, Jeypore for providing their continuous support throughout the work. The authors are also grateful to Mrs. Sunita Agastin for her continuous encouragement and valuable inputs and cooperation while carrying out this study.

References

1. Babbota S, Faiyaz S, Ahuja A, Shafiq S, Ahmad S. Development and validation of a stability-indicating HPLC method for analysis of celecoxib in bulk drug and micro emulsion formulations. Acta chromatographica. 2007; 18:116-129.
2. Emami J, Fallah R, Ajami A. Rapid and sensitive HPLC method for the analysis of Celecoxib in human plasma: application to pharmacokinetic studies. DARU Journal of Pharmaceutical Sciences. 2008; 16(4):211-17.
3. Dasari S, Sastry BS, Rajendra Prasad Y, Om Prakash G. Separation and determination of process-related impurities of celecoxib in bulk drugs using reversed phase liquid chromatography. Farmacia. 2012; 60(3):436-447.
4. Jadhav KG, Gowekar NM, Gowekar SN. A validated RP-HPLC method for determination of Celecoxib in bulk and pharmaceutical dosage form. International Journal of Research in Pharmaceutical and Biomedical Sciences. 2012; 3(3):1312-16.
5. Kirtimaya M, Aditya Prasanna K, Snigdha Rani B. Simultaneous Estimation of Sacubitril and Valsartan in Bulk and Pharmaceutical Dosage Form by Using RPHPLC. Research Journal of Pharmacy and Life Sciences. 2020; 1(2):25-32.
6. Kirtimaya M, Snigdha Rani B, Gowri Sankar CH, Sujit Kumar M. Development and Validation of Stability Indicating Assay Method (Siam) for Rabeprazole in Rabeprazole Sodium Delayed Release Tablets Using HPLC. Research Journal of Pharmacy and Life Sciences. 2020; 1(3):89-97.
7. Kirtimaya M, Snigdharani B, Sruti Ranjan M, Somesu M, Kiran Kumar B. A. Validated Stability Indicating RP-HPLC Method Development for Platelet Aggregation Inhibitor Ticagrelor in Bulk and Tablet Formulation. Journal of Global Pharma Technology. 2019; 11(12):12-18.
8. Kirtimaya M, Saragi B, Kiran Kumar B. Simultaneous Estimation of Sertraline and Alprazolam in its Bulk and Tablet Dosage Form by RP-HPLC Method. Asian Pacific Journal of Pharmacy and Phytochemistry. 2016; 1(1):25-32.
9. Kirtimaya M, Kiran Kumar B, Muthu Kumari M, Subrah manyam BSS. New Analytical Method Development and Validation of Chlorpheniramine Maleate by Using Uv-Visible Spectrophotometry. Indo American Journal of Pharmaceutical Sciences. 2016; 3(7):767-772.
10. Kirti maya M, Balamurugan K, Suresh R. Linagliptin: A Literature Review on Analytical and Bioanalytical Methods. International Journal of Pharmaceutical Quality Assurance. 2018; 9(3):225-230.