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AN APPROACH TOWARDS GREEN ANALYTICAL CHEMISTRY: SPECTROPHOTOMETRIC METHOD FOR THE DETERMINATION OF CELECOXIB IN CAPSULE FORMULATIONS

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ABSTRACT

Celecoxib (CXB) is a NSAIDs or nonsteroidal anti-inflammatory drug pre-owned in the therapy of knee pain and body inflammation, correlated with inflammatory disorders, and assorted other rheumatoid arthritis. The unprejudiced of this education was to expand an uncomplicated, high diplomatic, selective, and fast quantitative analytical and bioanalytical procedure for evaluation of Celecoxib drug as API. The drug manifest absorption maxima at 253nm. A new uncomplicated, precise, diplomatic, highly certain and economical ultraviolet spectrophotometric (UV) method for the analysis of celecoxib drug in mass or bulk and its pharmaceutical expression or formulation (capsules) has been expended. The absorbance sample of celecoxib in a combination of methanol and 0.1 N sodium hydroxide (1 :1 v/v) were expended or set on at 253 nm. Reducing the usage of solvents is aim in development of green analytical method. Beer's law is bow to above concentration range of 1-13 µg/ml with correlation coefficient r^2>0.998. The conclusions have been verified mathematically and by recovery studies. Method was flourishing employed for the analysis of celecoxib drug in the existence of the expression or formulation, and analytically compared between the suggested procedures. Therefore, the suggested methods can be employed for routine quality control (QC) studies.

Keywords: Celecoxib, UV Spectrophotometry, Analytical method, Spectrophotometry analysis, COX-2 inhibitors.

Introduction

Inflammation is a defensive mechanism against infection or injury, including mechanical harm, ischemia (deprivation of oxygen), hereditary or immune deformities, chemical agents, temperature limits, or ionizing radiation.[1] It is a normal pathological process that can occur in different parts of the body.[2] The most common treatment for inflammation is nonsteroidal anti-inflammatory drugs (NSAIDs).[3] In the researches done by Vane *et al*.[4][5] after it was initially established that cyclooxygenase is the therapeutic target of NSAIDs, additional research revealed that inhibition of cyclooxygenase directly halted the biosynthesis of prostaglandins (PGs), an important mediator of inflammation.

Celecoxib (CXB) is a 1,3,5-trisubstituted pyrazole or nitrogen-containing heterocyclic compound. The chemical name is "4-[5-(4-Methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide" (Figure 1), CAS number: 184007-95-2, formula: $C_{17}H_{14}F_3N_3O_2S$, molar mass: 381.37 g mol^{-1}. CXB can be categorized as BCS class II drugs (High permeability and poor solubility).[6] According to IP[7], it is freely soluble in anhydrous alcohol, soluble in dichloromethane and practically insoluble in water. CXB is a "nonsteroidal anti-inflammatory drug (NSAID) that can be used to treat rheumatoid arthritis and ischemic heart disease".[8] It works by selectively inhibiting cyclooxygenase-2 (COX-2), which is the enzyme that makes prostaglandins, which are necessary for pain and inflammation. CXB is a cyclo-oxigenase-2 (COX-2) selective nonsteroidal anti-inflammatory drug (NSAID) that is widely used in the treatment of osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, acute pain in adults, and familial adenomatous polyposis[9]. Because CXB weakly inhibits COX-1, it may affect platelet function less than aspirin does.[10] COX-2 inhibition may result in apoptosis and a reduction in tumor angiogenesis and metastasis.[11] Additionally, CXB has demonstrated promise as a chemopreventive agent for the treatment of breast, lung, and other types of cancer.[12] CXB was reported to play an important role in inhibiting the proliferation of the Nasopharyngeal (NP) carcinoma cell lines.[13]

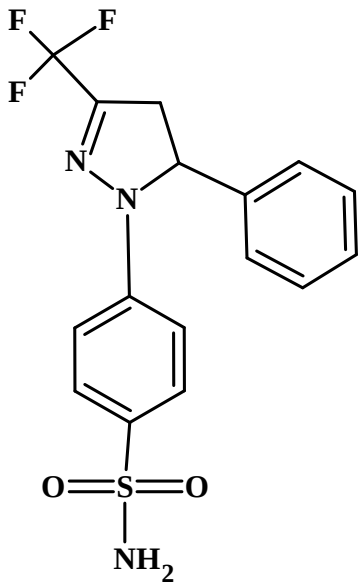

Figure 1: Structure of Celecoxib (CLB)

This is evident that researchers reported various analytical methods for the determination of CXB in different matrices by spectrophotometry[14-35], chromatography[36-74], and electroanalytical methods[75-80]. CXB is an BCS class II drug[6], having solubility in solvents, and is a reason of high proportion in diluents or mobile phase (for HPLC methods)

used by various scientists and researchers. For example, the last six published[30-35] spectrophotometric methods are based on either ethanol, methanol or acetonitrile because of its poor solubility in water (4.3 mg/L at 25 °C). However, there were few attempts to overcome this problem by developing hydrotophy solubilization (using sodium benzoate)[21] or by decreasing the composition of solvent.[20,33] The researchers are using methanol in most of the case, the reasons may be low UV cutoff (205 nm) and economy. The chromatography method reported by uses 50% acetonitrile and buffer[43] for method development is another attempt to reduce solvent concentration, but the drawback is higher cost (ACN costlier than methanol) and time-consuming process because it requires additional step in preparation of buffer. The chromatographic methods are more specific and sensitive and can be used for separation of drug and its components, impurities or related substances. The chromatographic methods are tedious, time consuming and require skilled operator to understand and interpretation of results.[81-84]

The concept of green analytical methodologies is not new, and commonly aimed at the reduction of solvent proportions, fast and more ecofriendly analytical method development without compromising the accuracy of results.[84] This is the background of our study, and the development of more environment friendly, specific, simple and economic method development for determination of CXB in its capsule dosage forms. CXB is BCS class II drug, and development of analytical methodology using aqueous phase is quite difficult. The only published research by hydrotrophy solubilization[21] require 12 hrs for proper solubilization of drug. In this study, our approach was to minimize the solvent and proposed more environment friendly usage of methanol and 0.1N NaOH in the ratio of 1:1 as diluent and validated the proposed method as per ICH guidelines. The methanol and NaOH used directly for dilution of the preparations after sonication, and then further used for analysis. Direct use of the solvent methanol and NaOH as diluents for formulations in quantitative analysis minimizes the usage of solvents require for extraction procedures.

Material and Method

The celecoxib pure was procured from Clearsynth Labs (P) Ltd. (Mumbai, India). The shimadzu double beam UV 1800 spectrophotometer was used to conduct the study. Methanol was purchased from Merck and distilled water was prepared by inhouse distillation assembly. Sodium hydroxide AR grade procured from Central Drug House.

Identification of drug

The identification of CXB was performed by IR (Figure 2) and NMR spectrum (Figure 3).

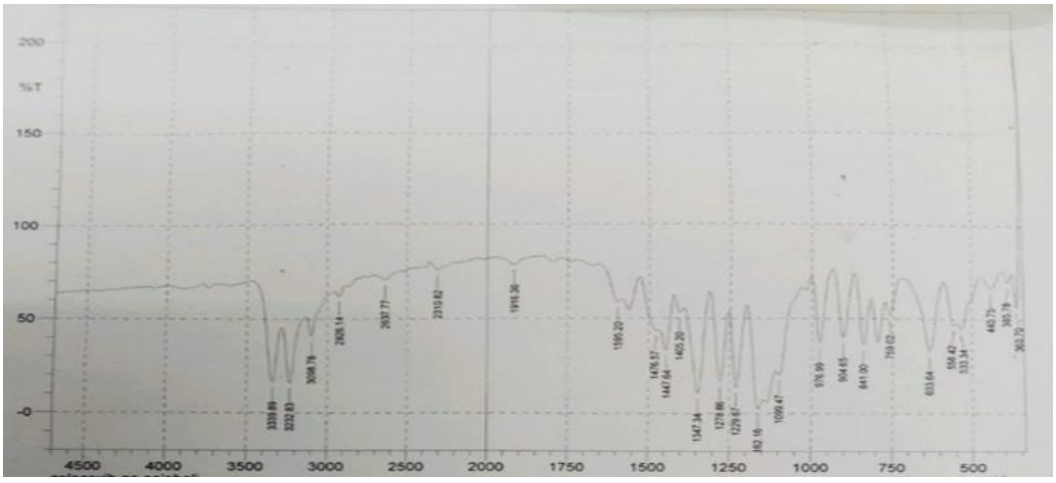

Figure 2: IR spectrum of CXB

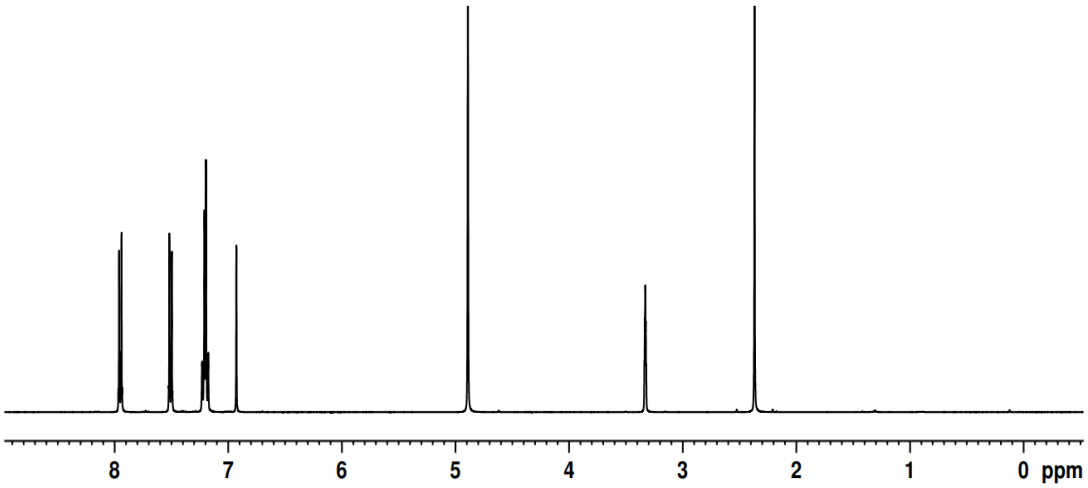

Figure 3: NMR spectrum of CXB

Development of UV method

The celecoxib is BCS class II drug, with low solubility and high permeability. The analytical methods available are based on dilutions prepared in solvents or solvents in higher proportion. This is also evident that the solubility increases with decrease in pH. The initial aim was to select the diluent with minimum solvent ratio.

Preparation of diluent solution

Methanol and 0.1 N NaOH mixed in the ratio 50:50 ml transferred to 200 ml volumetric and sonicated it for 5 min.

Optimization of the reaction conditions

The reaction was adapt using 3 parameter, namely, the volume(ratio) of NaOH in the solution, the solubility of diluent(methanol), and the amount of time the mixture was sonicate (in minutes). To ensure the greatest stability of the methanol and sodium hydroxide, 50:50ml were used, with the total volume and sonicating duration being 10 minutes. The wavelength selected was 253 nm and was used for further development of method.

Sonication-time

As the medication was soluble in Methanol and water. Therefore, the sonicating duration should be substantial enough medicine and become transparent in 10 min sonicating period.

Preparation of stock solution

Accurately weighed 100 mg of *Celecoxib* was weighted and transfers into 100 ml calibrated volumetric, volume make up with diluent and sonicated it for 10 min to prepare clear solution. The 10 ml of this solution was then transferred to another calibrated 100 ml volumetric flask and diluted upto the mark with same diluent to ger 100 µg/ml dilution.

Preparation of calibration curve

Suitable aliquots of 1 ml to 9 ml of stock solution were transferred to previously calibrated 100 ml volumetric flasks and diluted with same composition to prepare 1 to 13 µg/ml solution. These dilutions were scanned under UV range to prepare calibration curve.

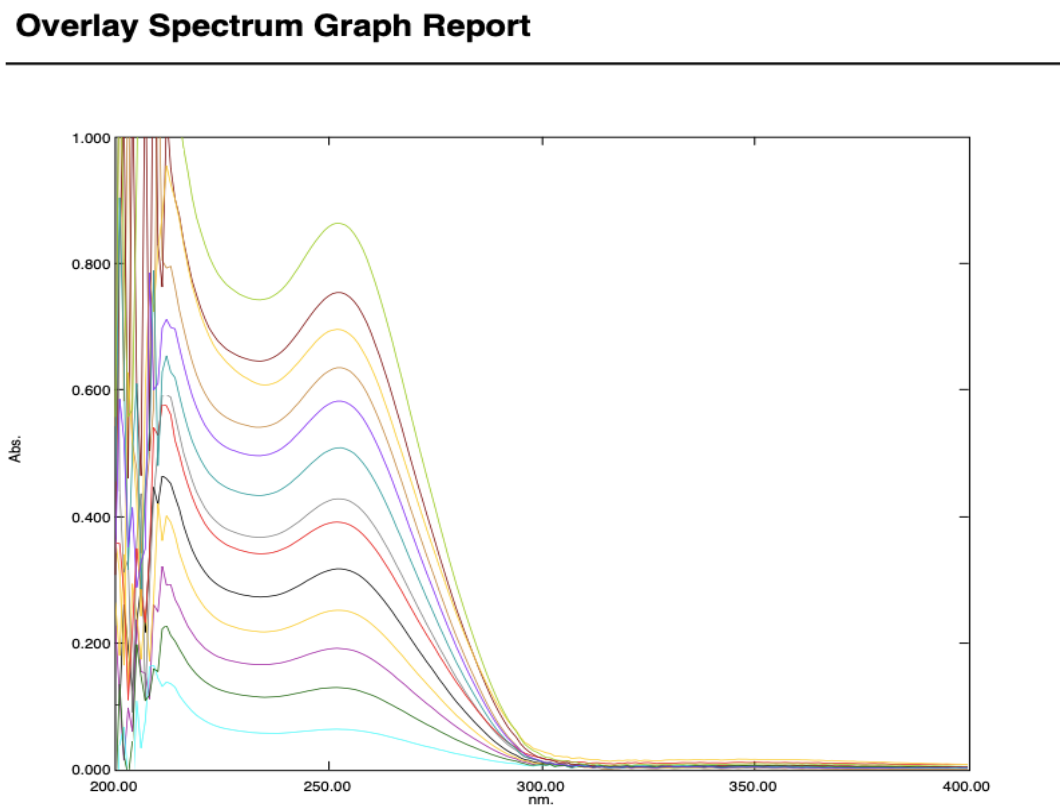

Figure 4: Overlay graph of Standard Curve of Celecoxib (1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13 µg/ml)

Validation of proposed method

Linearity

In the analytical chemistry province, linear stratagem is designated as approach that convey test detecting that are straight proportional to the concentration of analyte in a particular test or illustrative. We executive continuous solutions of the asset's solution of Celecoxib as a test for the linearity of the detector outcome. Celecoxib was process and explored at thirteen different concentrations, including 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, and 13 µg/ml. The regression equation and correlation coefficient found was y = 0.0655x - 0.008 and 0.9983 respectively.

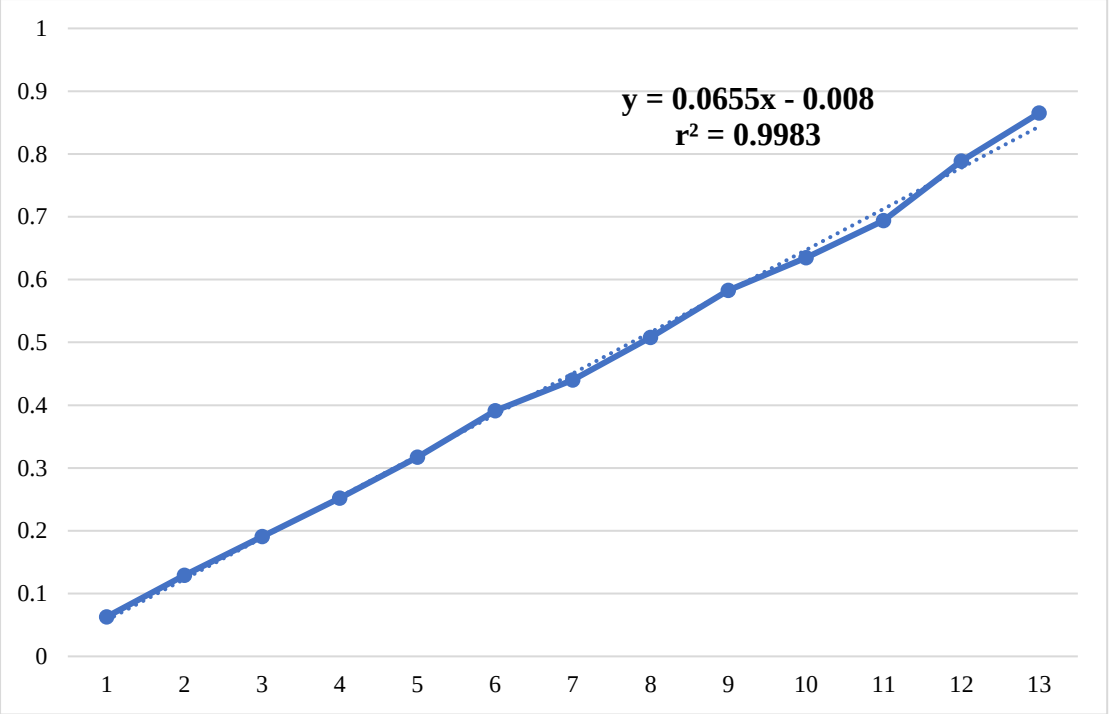

Figure 5: Standard curve of proposed method

Precision

Repeatability

The selected test concentration of 7 µg/ml was scanned six times under UV range using UV spectrophotometer at 253 nm. The %RSD found was 0.14374.

Interday

The 5, 7 and 9 µg/ml dilutions were scanned using same methodology three times a day at different timings (*n* = 3). Results are given under Table 1.

Table 1: Interday reading of CXB

S. NO.	Sample no.	0hrs	SD	RSD	3hrs	SD	RSD	6hrs	SD	RSD	MEAN RSD
1.	5	0.317 0.319 0.317	0.001155	0.363494	0.316 0.317 0.317	0.0000577	0.182321	0.316 0.317 0.317	0.0000577	0.182321	0.221541
2.	7	0.428 0.426 0.424	0.002	0.469484	0.428 0.425 0.424	0.002082	0.489037	0.426 0.425 0.423	0.001528	0.3597	
3.	9	0.583 0.586 0.584	0.001528	0.261413	0.583 0.586 0.584	0.001528	0.261413	0.582 0.583 0.584	0.001	0.171527	

Intraday

In this, 5, 7 and 9 µg/ml dilutions were scanned using same methodology in three consecutive days and same results mentioned under Table 2.

Table 2: Intraday Reading of CXB

S. NO.	**Sample no.**	**0hrs**	**SD**	**RSD**	**24hrs**	**SD**	**RSD**	**48hrs**	**SD**	**RSD**	**MEAN RSD**
1.	5	0.317 0.319 0.317	0.001155	0.363494	0.315 0.316 0.316	0.000577	0.182899	0.312 0.313 0.312	0.000577	0.184851	0.32594
2.	7	0.428 0.426 0.424	0.002000	0.469484	0.425 0.425 0.421	0.002309	0.545099	0.423 0.422 0.418	0.002646	0.628444	
3.	9	0.583 0.586 0.584	0.001528	0.261413	0.581 0.583 0.583	0.001155	0.198289	0.580 0.581 0.580	0.000577	0.099486	

Accuracy

Samples of 5, 7, and 9 µg/mL of the capsule solution of marketed preparations of celecoxib were foregather and explored by using the suggested procedure for establishment of trueness.

Table 3: Result of Accuracy

S.No	**Conc. µg/mL**	**Result**	**Recovery**
1.	5	0.317	100%
		0.318	100.31%
		0.318	100.31%
2.	7	0.434	98.63%
		0.432	98.18%
		0.433	98.40%
3.	9	0.582	99.82%
		0.582	99.82%
		0.584	100.17%

LOD & LOQ

This was performed as per the literature published by Shrivastava & Gupta, 2012[85], using standard deviation of readings and slope. Results given in Table 4.

Table 4: Result of LOD & LOQ

S.No	**Blank Reading**	**SD**	**Slop**	**LOD**	**LOQ**
1.	0.000	0.000548	0.0552	0.0327	0.099

2.	0.000				
3.	0.001				
4.	0.001				
5.	0.001				
6.	0.000				

Application of the proposed method

The CXB procured from the market contains 200 mg (labelled amount). The dilution was prepared by taking 50:50 mixture of 0.1N NaOH and dist. water. The prepared solution was further diluted in 0.1N NaOH to prepare target concentration. The standard solution was also prepared using pure celecoxib as per method already described in the material and method section. The analysis was performed by comparing both results.

Discussion

The measurement of how light interacts with different materials is the focus of spectrophotometry. The quantitative analysis of spectra to compare the relative absorption or emission of various wavelengths of light is referred to as it. Because light can be "reflected, transmitted, scattered, or absorbed", one of the main objectives of the analytical chemistry community over the past two decades has been to implement green analytical methods. Methods for sample preparation and extraction are two parts of the development of an analytical method that can be best adapted to adhere to the tenets of green analytical chemistry [89]. A material can also emit light because it has absorbed some light and reemitted it [86,87]. Green analytical chemistry (GAC)'s incredible success at the end of the twentieth century was unimaginable to anyone.[89]

The present study was carried out to develop a sample, accurate and sensitive UV spectro photometric method for the determination of celecoxib in capsules. In the present investigation, methanol and 0.01 N sodium hydroxide in the ratio 1:1 v/v was found to be better solvent. The optical characteristics are: Beer's law limit (1-13 ppm), absorbance maxima (253nm), correlation coefficient(0.998), slope (0.0655) and intercept (c= 0.008), %relative standard deviation (0.14374). LOD and LOQ found were 0.00327 and 0.099 respectively.

The method was found to be precise as percentage relative standard deviation for inter-day and intra-day precision were 0.22 and 0.32 respectively. Accuracy of the method was calculated by percentage mean recovery is 98.18 to 100.31%. The recoveries studies were carried out by the additional of standard analyte to the pre analyzed sample. The concentrations of standard spiked to the sample were 5,7 and 9µg/ml of celecoxib. The mean percentage recovery was found to be 100% for capsule. This proposal aims to be cost-effective, straightforward, precise, less risky (hazardous), and precise. UV spectrophotometric methods with combination of methanol with 0.1 N NaOH, for determination of CXB in pharmaceutical formulations.

These techniques are time-consuming and labor-intensive, and they need the growth of additional enzymes. Other chemical processes may be used to determine celecoxib, which allows it to be detected using UV spectrophotometers. Even while other chromatographic technologies, such as "high-performance liquid chromatography (HPLC)", make use of an aqueous mobile phase, these procedures are expensive, time-consuming, and require the use of a particular kind of column. Furthermore, a few described techniques include non-aqueous phases in mobile phases in some percentage. It was discovered that the proposed method was easy, precise, accurate, and highly sensitive. The high percentage of recovery indicated that the

formulation's excipients did not interfere with the method. The proposed method was able to analyze the drug both in its pharmaceutical formulation and in bulk, as evidenced by the values of LOD and LOQ.As a result, the proposed approach is suitable for routine laboratory quality control analysis.

Conclusion

The developed method is simple UV spectrophotometric determination of Celecoxib successfully utilised in capsule formulations. The validation parameters were linearity, precision, accuracy, limit of detection and limit of quantitation. The linearity studies show that developed method can be used for determination of Celecoxib from 1 to 13 µg/ml. The validation studies shown all results within specified range, thus, the developed method is specific, precise and accurate for determination of Celecoxib in capsules formulation. The reduction of solvent (methanol) in this study is an attempt for green analytical method. The details of validation studies are given under Table 5.

Table 5: Summary of results of validation studies.

S. No.	Validation parameter	Observations
1	Linearity	1-13µg/ml
2	Precision Repeatability Interday Intraday	 0.14374
3	Accuracy	98.18 to 100.31%
4	Correlation Coefficient	0.9983
5	Limit of detection (LOD)	0.0327
6	Limit of Quantitation (LOQ)	0.099

Conflict of Interest

None declared

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