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MULTIVARIATE CALIBRATION TECHNIQUE AIDED UV SPECTROMETRIC METHOD FOR THE ESTIMATION OF CEFIXIME IN PHARMACEUTICALS DOSAGE FORM

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ABSTRACT

The current study suggests developing and testing a novel methodology to determine the bulk and formulation concentrations of Cefixime (CEFI). This analytical method can be described as sensitive, precise, and rapid. The investigation was carried up employing a multivariate calibration technique and a UV spectrophotometer. This multivariate calibration approach depends on the proven connection among drug concentration and absorbance that are at 289 nm . Along with other mathematical and statistician instruments, the linear regression equations are used to determine the process to the ICH Q2 (R1) guidelines. Validation parameters linearity, accuracy, and other aspects were all met. This technique, which is used in the routine analysis of therapeutics and formulations, is dependable, cost-effective, and responsive.

Keywords: Cefixime, Multivariate calibration technique, UV spectrophotometric, ICH Guidelines

INTRODUCTION

Cefixime (CEFI), is a third-generation cephalosporin antibiotic taken internallyt is chemical [carbomethoxy]amino] [4.2.0]3-ethenyl-8-oxo-5-thia azabicyclocarboxylic acid, oct-2-ene-2 **[1] (Figure 1)**. Is employed in handling the management of illnesses that are susceptible, such as urinary tract infections, bronchitis, pharyngitis, otitis media, and gingivitis **[2, 3]**. It's an antibiotic that corresponds to the identical

class as and this drug, which are third-generation cephalosporins. When certain gram-negative bacteria create beta-lactamase enzymes, it remains extremely stable. Because of the presence of beta lactamases, a large number of organisms that are resistant to penicillin and some cephalosporins may be sensitive to CEFI. The medication can be taken orally for the treatment of illnesses that are susceptible, such as pharyngitis, otitis media, a condition known as respiratory tract infections, and urinary tract infections. It comes in tablet and capsule forms, with 200 mg and 400 mg of each available **[4]**. As to research carried out by Britain *et al*. 1985and Risser *et al*. 1987 CEFI is a semi-synthetic, third-generation cephalosporin that is exceptionally effective against a variety of gramme negative and certain gramme positive aerobic bacteria when taken orally. The stability of CEFI is quite high when beta lactamase enzymes are present. The medication was granted a patent in 1979 and became authorised for use in medicine in the US in 1989. Cefixime is to treat throat infections, gonorrhoea, of via to the lungs **[5, 6]**.

Several analytical procedures have been cre ated to determine CEFI in different pharma ceutical dosage forms.

Numerous analytical methods, including mi crobiological methods and high-performance liquid chromatography (HPLC) , are used in these operations **[7]**, CEFI is an antibiotic that is classified as part of the third-generation cephalosporin class. It maintains its outstanding stability even when beta-lactamase enzymes are present. Along with its stability, cefixime can effectively combat organisms that have developed resistance to beta-lactamases and penicillins as well as certain other cephalosporins. When CEFI is used to treat gram-ve&+ve, it inhibits formation mucopeptides in the cell wall of bacteria, which has an antibacterial effect. One typical antibiotic used to treat an array of bacterial infections is CEFI. It works well against a variety of diseases, ranging including strep throat, pneumonia, a condition called (middle ear infection), and urinary tract infections **[8]**. Since CEFI is not a USP medicament and is accessible and in frequent use since of its spectrum although not being included in the monograph, it is essential to create an analytical approach that conforms with these validation requirement **[9]**. For this sample of CEFI, no multivariate calibration technique (MVC) utilizing UV spectrophotometry was obtained. Therefore, the current technique emphasises upon creating the UV spectrophotometric MVC for CEFI determination. Applied analytical technique provides a quantitative investigation into investing admixtures under ideal circumstances that is powerful,

quick, sensitive, and affordable. absorbance of a sample (x) is measured multiple wavelengths (λ), at 286, 288, 290, 292, and 294nm.

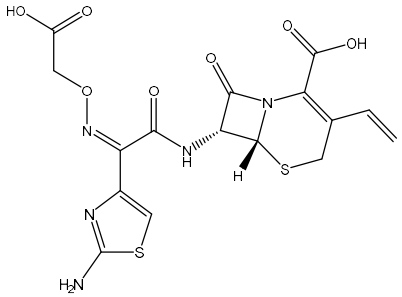

Figure 1: Structure of CEFI

The following equations may be generated for each chosen wavelength when the absorbance of a sample(x) is measured at various wavelengths (λ), namely at 286, 288, 290, 292, and 294 nm.

$A_{\lambda 248} = a \times C_X + k1$ …… (1)

$A_{\lambda 250} = b \times C_X + k2$…… (2)

$A_{\lambda 252} = c \times C_X + k3$ …….. (3)

$A_{\lambda 254} = d \times C_X + k4$ …… (4)

$A_{\lambda 256} = e \times C_X + k5$ …… (5)

Whereas,

- A_λ= Absorbance of the sample;
- a, b, c, d, e = Slope of the straight regression functions of a sample;
- k_1, k_2, k_3, k_4, k_5 = Intercept of the straight regression;
- C_X = Concentration of the sample

The five equations mentioned before can be arranged as follows:

$A_T = a \times C_X + b \times C_X + c \times C_X + d \times C_X + e \times C_X + K_T$…… (6)

The aforementioned equation may be reduced even more to

$A_T = C_X (a+b+c+d+e) + K_T$……. (7)

Whereas,

- A_T = Sum of the absorbances acquired
- K_T = Sum of intercepts of regression equation

To determine the amount of analyte X in a solution, use the formula.

$$Cx = \frac{A_T - K_T}{(a+Ab+c+d+e)} \quad \text{……(8)}$$

MATERIALS AND METHODS

Chemicals and solvents employed

- Methanol
- CEFIX® TABLETS: produced by Zeiss Pharma Limited, the label promises that it has 100 mg of CEFI. The medicinal formulations that were put on sale were acquired domestically.

Solubility:

- Freely Dissolved in methanol

Instrumentation:

- UV-Vis double beam Spectrophotometer (Lab India UV-3092).
- Electronic balance (SHIMADZU AY-220H).
- Soniclean sonicator (model 160T, Thebarton-Australia).

METHOD DEVELOPMENT

Selection of solvent

It was discovered that methanol, the solvent used to dissolve the medicine while the analysis, was readily soluble **[10]**.

Preparation of the standard solution

The CEFI 100 mg of the pharmaceutical component has been diluted in 100 mL of methanol to create the standard stock solution. We altered the concentration of this solution (5–15 µg mL^{-1}) and utilised it for more research.

Preparation of sample solution

CEFI was precisely quantified resulting in 100 mg, which was then added to a 50 ml volumetric flask. After adding 25 mL of methanol, the solution was Sonicated for 20 minutes. The final capability was 50 mL. The mixture solvent to offer around (5 and 15µg mL^{-1}.)

λ_{max} determination and selection of wavelength for multivariate calibration

Over the 200–400 nm wavelength range, the operational standard solutions for CEFI scanned against methanol, at 289 nm. at 286,288,290,292,294 nm, the wavelength of the MVC technique was discovered to be within between these absorption peaks**.**

METHOD VALIDATION

The proposed method's linearity, accuracy, and precision were verified in accordance with ICH recommendations **[10]**.

Linearity

Solution diluted with methanol to 5 -15µg mL^{-1}. CEFI 'S linearity and the spectrum area were then evaluated. linearity solutions at the was measured and examined employing the MVC method.

Limit of Quantification and Detection

For determining the LOD and LOQ for CEFI, the slope of the calibration curve and SD of responses for certain wavelengths were utilised, as illustrated below.

$$LOD = \frac{3.3 \text{ x standard deviation}}{\text{Slope}} \quad \text{..... (10)}$$

$$LOQ = \frac{10 \text{ x standard deviation}}{\text{Slope}} \quad \text{..... (11)}$$

Precision

The repeatability of precision assessed using intraday and interday precision. A CEFI solution with a concentration of 10 µg mL^{-1} was used for evaluating accuracy levels. Five solutions have been evaluated at five distinct wavelengths to establish repeatability. the absorbing capacity of solutions was verified six time at different intervals on same day. Three more days of absorbance were used to account for intravariation.

Accuracy

The CEFI methodology's precision was assessed at 80, 100, and 120 percent of the concentrations of the previously examined sample solutions, while recovery value were estimated.

Assay

Weigh and Powder 10 tablets and adequately a quantity of tablet powder that equals nearly 25 mg of CEFI, add 25 mL of methanol, and sonicate for a period of 20 minutes. Add sufficient to 50 mL. solution mentioned earlier is filtered and diluted with

methanol achieve a concentration of 10 µg mL^{-1} of CEFI. It is determined by measuring the resultant solution's absorbance at 289 nm.

RESULTS AND DISCUSSION

CEFI standard solution was initially scanned at 200–400 nm. The peak performance wavelength of CEFI is 289 nm. The UV spectrum of CEFI standards & samples was recorded using pure methanol as a blank and a 252nm MVC wavelength. **Figure 2** shows the standard spectra of CEFI at 10µg mL^{-1}.

Linearity

The linearity of the CEFI process has been examined as part of the concentration range between 80 to 120% for 10g ml (5 - 15 µg mL^{-1}), satisfying the requirements in the ICH Q2R1 guidelines**. Figure 3** depicts the spectrum of linearity for CEFI. A calibration curve was established by computing the absorbance of a diluted reference at various wavelengths (286, 288, 290, 292, 294 nm). Table one presents the observed results in a tabular format. The analysis revealed that all of the standard curves exhibited linearity within the prescribed concentration range. The calibration graphs and regression analysis are displayed in **Figures 4-8** and **Table 2**, respectively.

Limit of Detection and Limit of Quantification

The linearity slope used to calculate the LOD and LOQ for CEFI, and numerous sample investigations have validated this method. CEFI's limit of detection (LOD) was 1.06 µg $mL^{-1,}$ calculated by taking the average of all absorbance values. CEFI's LOQ was 3.23 µg $mL^{-1,}$ calculated by averaging all absorbances**.**

Precision

Figure 9 shows the system's precision spectrum for CEFI. **Figure 10** depicts the CEFI interday precision spectra. **Figure 11** for CEFI depicts the intraday precision spectra. For CEFI the percentage RSD of the system's intraday and interday precision was calculated. It was discovered to be less than 2%, demonstrating the precision the approach method. Comparing the results acquired from other accuracy approaches, the suggested method exhibits good precision.

Accuracy

Figure 12 shows the overlay spectra for CEFI, were verified at 80, 100, and 120%. The CEFI findings are displayed in **Table 3**, and it was determined that the results were within acceptable bounds.

Assay of marketed formulations:

The suggested spectrophotometric approach aims to accurately determine the amount of CEFI present in tablet formulations. UV absorption spectra a commercial medicine have been examined three times. During extraction and filtration, The pharmaceutical formulation expressed consistent and outstanding analytical recovery values. The results are outlined in **Table 4**.

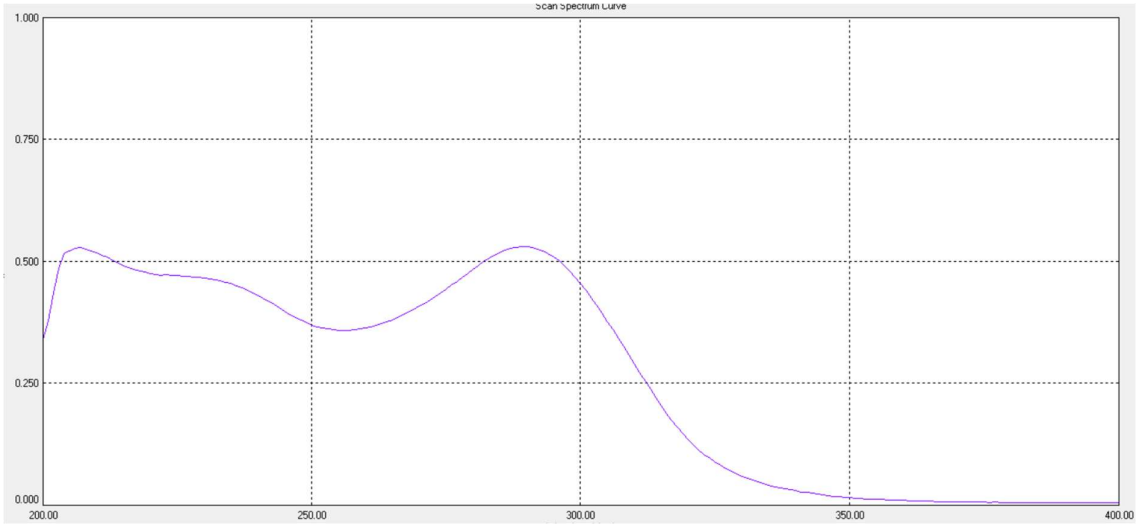

Figure 2: UV spectrum of standard CEFI (10 µg mL^{-1}) using methanol as blank

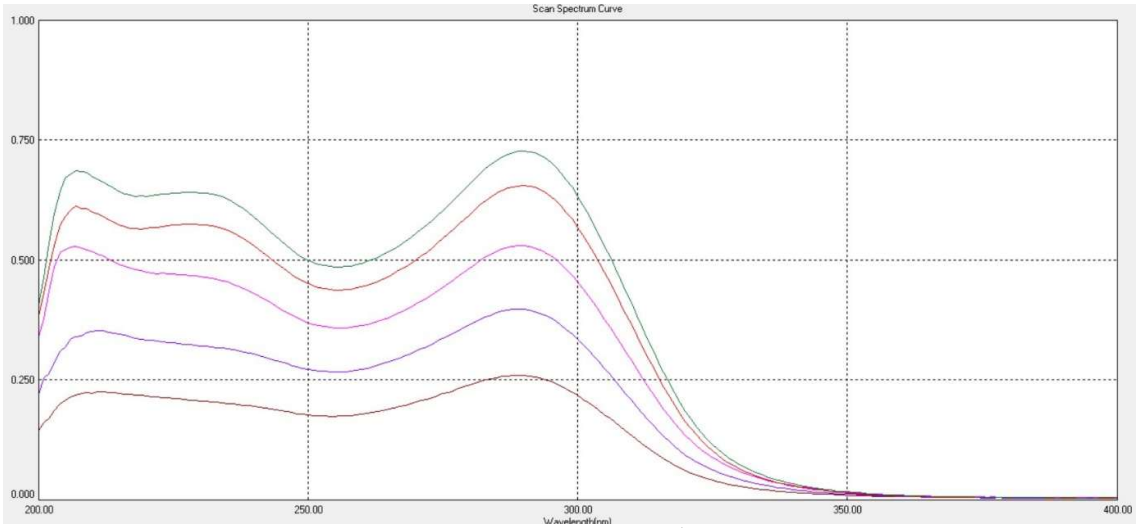

Figure 3: Linearity spectrum of CEFI (5-15µg mL^{-1}) using methanol as a blank

Table 1: Multivariate UV calibration data at five selected wavelengths

Concentration (µg mL^{-1})	286 nm	288 nm	290 nm	292 nm	294 nm
5	0.249	0.281	0.256	0.251	0.252
7.5	0.360	0.398	0.380	0.380	0.378
10	0.470	0.512	0.530	0.513	0.505
12.5	0.600	0.621	0.622	0.610	0.601
15	0.721	0.726	0.741	0.723	0.696

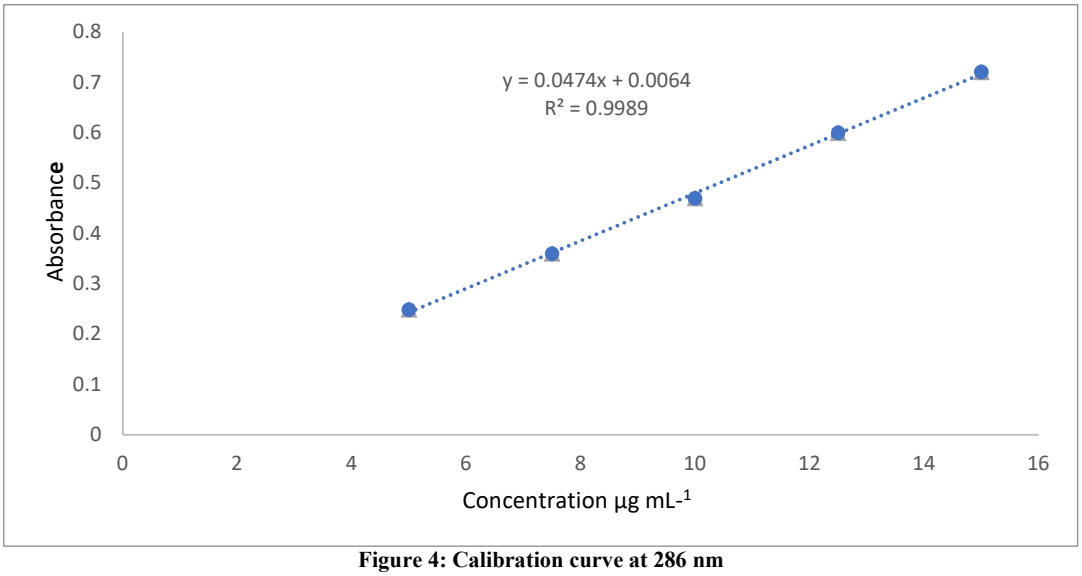

Figure 4: Calibration curve at 286 nm

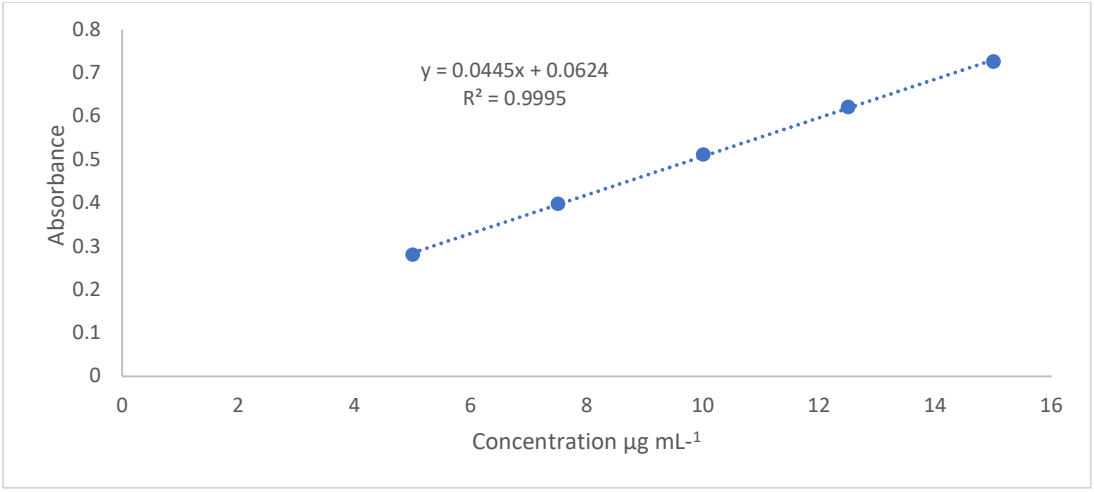

Figure 5: Calibration curve at 288 nm

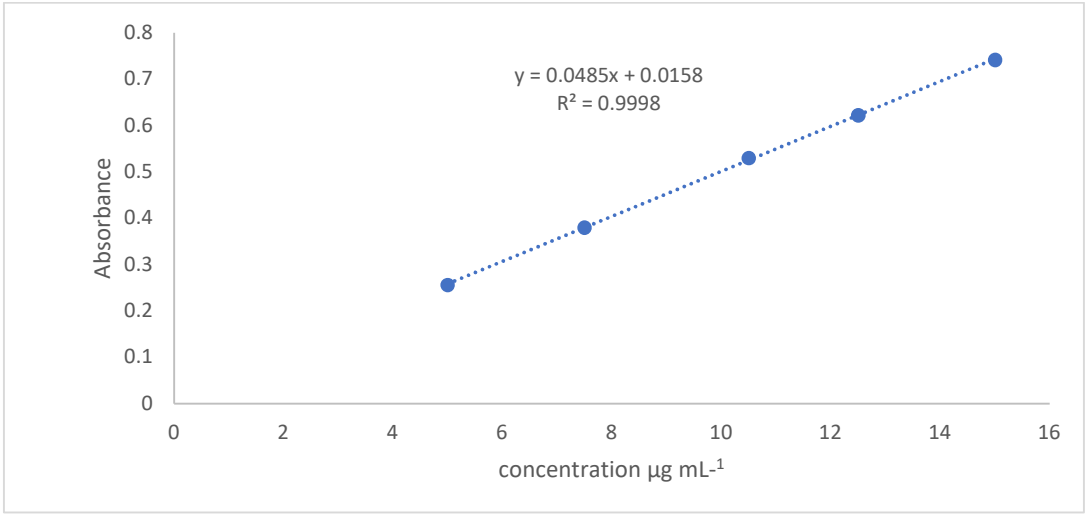

Figure 6: Calibration curve at 290nm

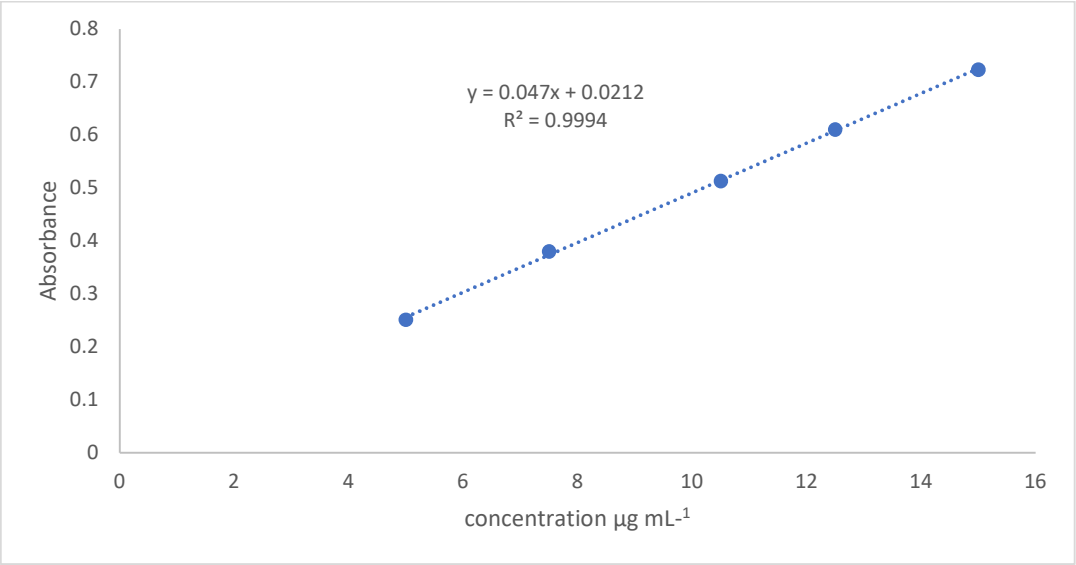

Figure 7: Calibration curve at 292nm

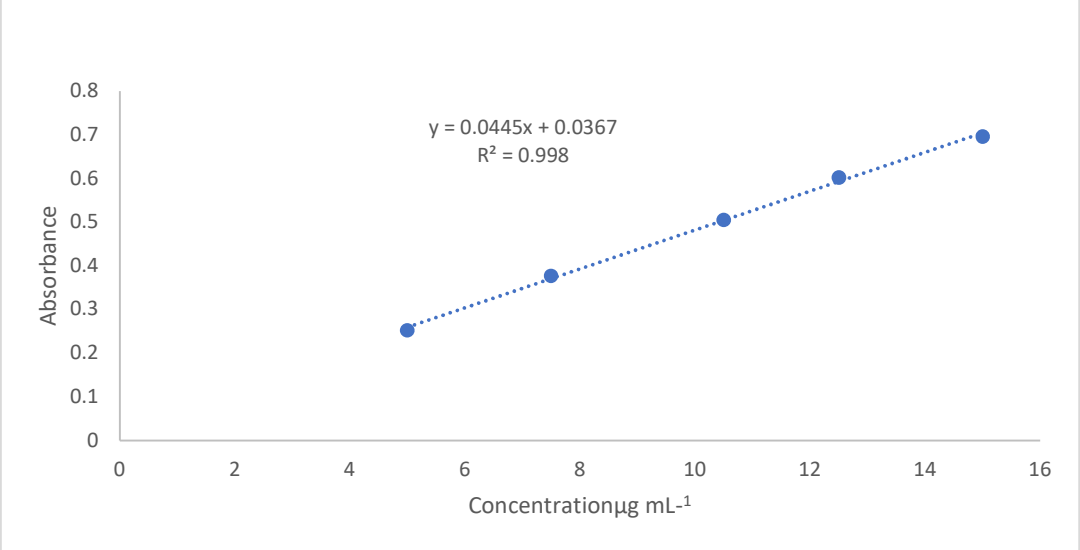

Figure 8: Calibration curve at 294nm

Table 2: Linearity data shows statistical parameters at the selected wavelengths

Wavelength(nm)	Regression equation	Slope	Intercept	R^2	LOD (µg mL^{-1})	LOQ (µg mL^{-1})
286	y = 0.0474x+0.0064	0.0474	0.0064	0.9989	0.5031	0.8343
288	y =0.0445x+0.0624	0.0445	0.0445	0.9995	0.3323	1.0070
290	y = 0.0485x+0.0158	0.0485	0.0485	0.9998	1.0679	3.2361
292	y = 0.047x+0.0212	0.047	0.047	0.9994	0.8754	2.6528
294	Y=0.0445x+0.0367	0.0445	0.445	0.998	1.1122	3.3705

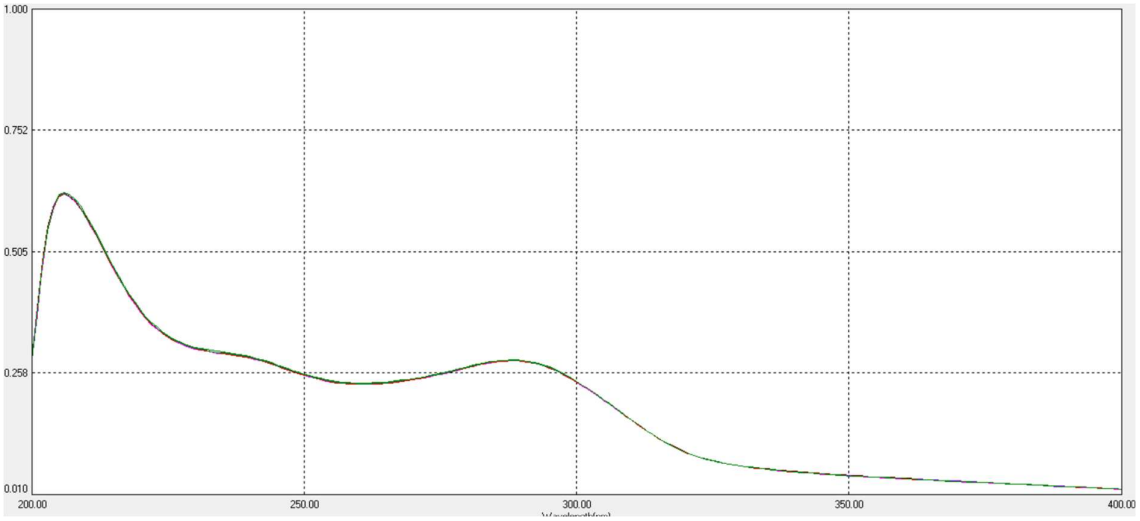

Figure 9: System precision overlay spectra of CEFI

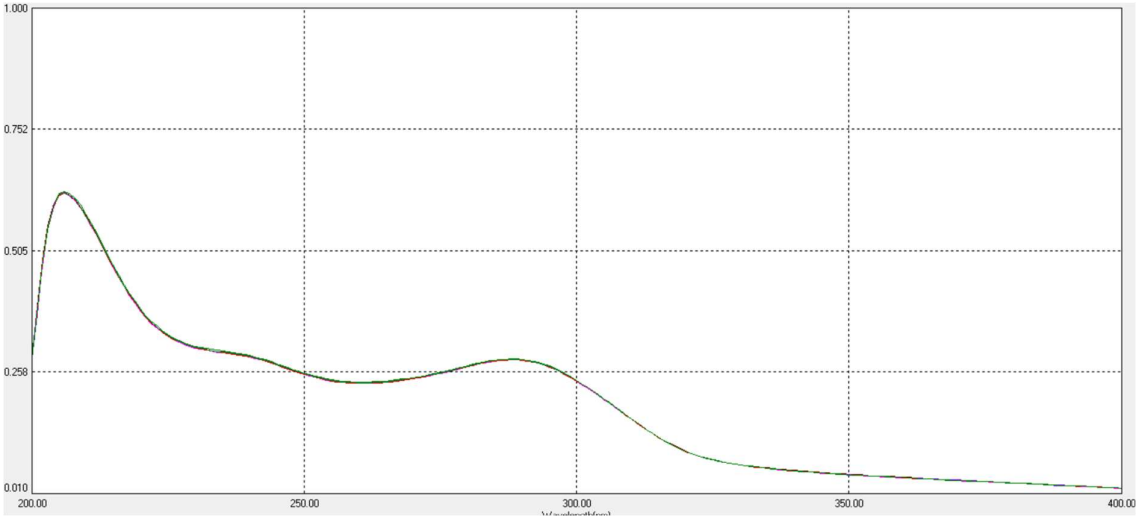

Figure 10: Interday precision overlay spectra of CEFI

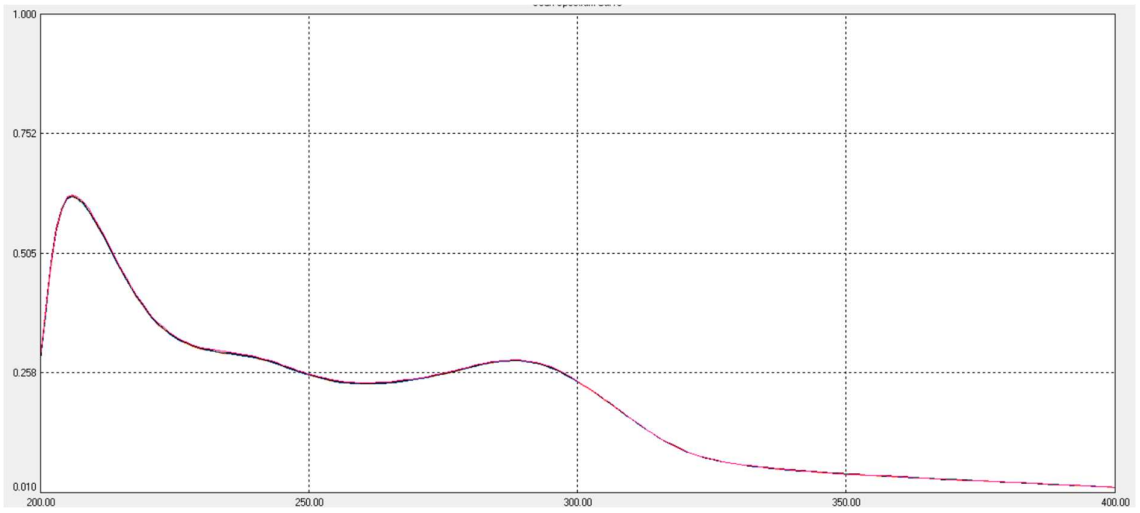

Figure 11: Intraday precision overlay spectra of CEFI

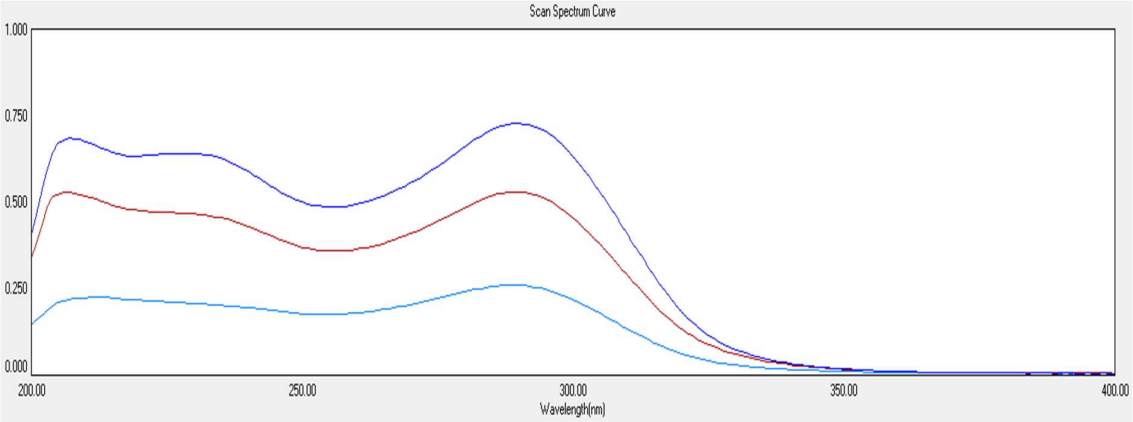

Figure 12: Overlay spectra of accuracy of CEFI 80, 100, 120 % raising

Table 3: Recovery Studies

Wavelength (nm)	Amount present (µg mL^{-1})	Amount added (µg mL^{-1})	Amount recovered (µg mL^{-1})	% Recovery
286	5	2.5	7.47	98.66
		5	9.94	99.4
		7.5	12.6	100.8
288	5	2.5	7.42	98.93
		5	9.97	99.7
		7.5	12.65	101.2
290	5	2.5	7.57	100.9
		5	9.97	99.7
		7.5	12.42	99.2
292	5	2.5	7.45	99.3
		5	9.97	100.17
		7.5	12.50	100
294	5	2.5	7.44	99.2
		5	9.88	98.8
		7.5	12.64	101.1

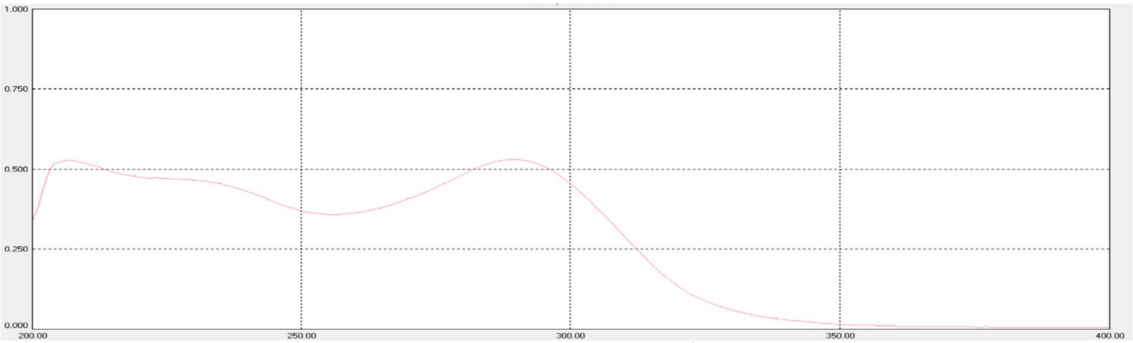

Figure 13: UV spectrum of standard CEFI (10µg mL^{-1}) using methanol as a blank

Table 4: Assay of CEFI

Label claim (mg)	Amount estimated (mg)	% Assay
100	99.67	99.67
100	100.4	100.40
100	99.32	99.80
Average	99.80	99.80
SD		0.5510
% RSD		0.5522

CONCLUSION

The newly developed spectrophotometric technique for quantifying CEFI was validated by a number of validation criteria and determined to be within acceptable ranges under ICH recommendations. Using the recommended approach, CEFI was measured in its tablet formulation and found to be These qualities include being sensitive, it can detect even small changes; accurate, meaning it provides correct results; exact, meaning it gives consistent and reliable measurements; and reproducible, meaning it can be repeated and yield the same outcomes. We highly encourage utilizing the suggested methodology for regular study on CEFI in pharmaceutical formulations due to its superior accuracy compared to current UV spectrophotometric methodologies, as well as its incorporation of straightforward mathematical capabilities.

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STATEMENT OF ETHICS

There are no animal or human participants used in this study's trials.

DISPUTE OF INTEREST

There are no financial interests that could be at odds with this content.

FUNDING SOURCES

No financing has been reported.

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