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MULTIVARIATE CALIBRATION TECHNIQUE AIDED UV SPECTROPHOTOMETRIC METHOD FOR THE ESTIMATION OF CEFPODOXIME IN PHARMACEUTICALS DOSAGE FORM

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ABSTRACT

According to the current study, a novel methodology should be created and validated in order to ascertain the bulk and formulation amounts of cefpodoxime. This analytical method can be explained as sensitive, exact, and fast. Utilizing a multivariate calibration methodology and a UV spectrophotometer, the analytical approach was executed. A connection between concentration and absorption has been assessed at five different wavelengths, notably the absorbance maximum at 235 nm. This multivariate calibration methodology was established using the aforementioned method. In addition to other mathematical and statistical techniques method was validated by employing linear regression equations under the ICH Q2 (R1) standard. The instructions' validation parameters for linearity, precision, and other factors have all been met. This technology is dependable, sensitive, and economical when used for routine drug and formulation examinations.

Keywords: Cefpodoxime, Multivariate calibration method, UV spectrophotometric, Pharmaceutical compositions, ICH standards, Validation

INTRODUCTION

Cefpodoxime proxetilis (CPDX) is a third-generation oral cephalosporin with an extended spectrum that is semi-synthetic. It has a wide spectrum of potency against bacterial strains that are gram-positive as well as gram-negative. This compound

exhibits exceptional in vitro efficacy against Enterobacteriaceae, Hemophilus species, and Moraxella species, especially those resistant to B-lactamase. CPDX antibacterial activity is achieved by inhibiting the formation of bacterial cell walls, most likely by the acylation of transpeptidase enzymes linked to membranes. This stops the process of peptidoglycan sequence forming connections, which is incredibly important for the strength and rigidity of the cell walls of bacteria **[1-5]**. The active molecule's molecular weight of 557.6 enables unrestricted passage through the proteins found in the cell wall of bacteria. Subsequently, it infiltrates the periplasmic region and binds to the PBP-1 and PBP-3 proteins that attach to penicillin positioned in the cellular membrane. This contact additionally impacts the emergence of peptidoglycan on the cellular membrane, leading to cell injury **[6]**.

It is a prototype of CPDX and is prescribed for treating individuals with minor to mildly serious infections such as Pharyngitis, throat inflammation, as well as Community-imposed pneumonia., Acute microbial amplification of chronic bronchitis, uncomplicated acute vaginal and cervix gonorrhoea, Acute anorectal infections in women that are not complicated, as well as skin and skin structure infections that are not complicated, Short-term inflammation within the maxillary sinus along with common pathogens of the urinary glands **[7-9]**.

The empirical formula of the compound is $CH_{27}N_5O_9S_2$. The component is a white to light brownish powdered material, that's either unscented or has a subtle odor. The compound chemical is racemic. The compound-1-(isopropoxycarbonyloxy)-ethyl (+)-(6R,7R)-7-[2-(2-amino-4-thiazolyl)-2-{(Z)-methoxy-imino} acetamido]-3-methoxymethyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate2, 5The compound exhibits low solubility in water, high solubility in anhydrous alcohol, and solubility in methanol and acetonitrile. Conversely, it has solely restricted solubility in ether. The substance should be stored in hermetically sealed containers at an ambient temperature no higher than 25°C **[10, 11]**.

In the gut wall, it undergoes enzyme-mediated splitting, resulting in the formation of acetaldehyde, cefpodoxime,2-propanol, and carbon dioxide. CPDX has a Half-life of elimination of 1.9 to 2.8 hours. A review of the literature reveals that there are numerous published techniques for determining CPDX in pharmacological or biological formulations. A limited number of hyphenated CPDX procedures were presented, such as LC-MS/MS, LC/MS, and Multiple chromatographic approaches including High-Performance Liquid

Chromatography (HPLC) along with HPLC-UV. There was no context provided for a multivariate calibration technique (MVC) employing UV spectroscopy for this cefpodoxime sample. Thus, the current technique focuses on developing the UV spectrophotometric MVC for the quantification of clomipramine. Under ideal circumstances, the applicable analytical technique provides a robust, quick, sensitive, and affordable quantitative analysis of investing admixtures **[12, 13]**.

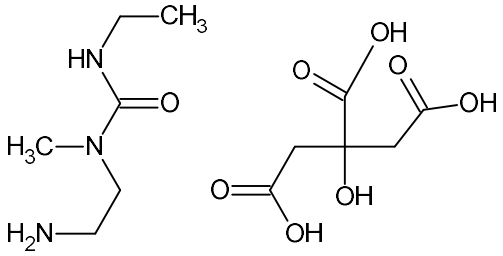

Figure 1: Structure of cefpodoxime

The following equations may be generated for each chosen wavelength when the sample absorbance(x) is measured at various wavelengths (λ), namely at 231, 233, 235, 237, and 239nm.

$A_{\lambda 231}$= a X C_X + k1 …… (1)

$A_{\lambda 233}$ = b X C_X + k2…… (2)

$A_{\lambda 235}$ = c X C_X + k3 ……..…….. (3)

$A_{\lambda 237}$ = d X C_X + k4 …… (4)

$A_{\lambda 239}$ = e X 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 variables stated above can be organized in the following manner:

A_T = a x C_X + b x C_X + c x C_X + d x C_X + e x C_X + K_T…… (6)

Therefore, mentioned equation may be reduced even more to

A_T = C_X (a+b+c+d+e) + K_T……. (7)

While as,

- A_T = The sum of the acquired absorbances
- K_T = The total of intercepts in the equation for regression.

To quantify the level 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

- Distilled water
- Methanol
- The Ralipod 100 DT Tablet Form, produced by Astra Laboratory Co,

includes a label claim of 100 mg of CPDX. The medicine preparations accessible for sale are imported from various geographic areas.

Solubility

- Easy to disintegrate in methanol, chloroform, and water.

Equipment

- Ultra sonicator (model 160T, The barton-Australia).
- The laboratory equipment India 3092 -uv is a UV-Vis double-beam spectrometer.
- The electronic balance utilized is an AY-220 Shimadzu.

METHOD DEVELOPMENT

Selection of solvent

Methanol, the solvent used to demonstrate drug dissolution in the analysis, exhibited prompt solubility.

Standard solution preparation

100 mg of the drug component was diluted in 100 mL of Methanol to create the CPDX standard stock solution. We adjusted the concentration of this solution (5-15g/mL) and utilized it for further investigation.

Preparation of sample solution

Measure the weight of ten tablets by using a powder and scale. The precise weight of the tablet.

Approximately equivalent to 100 mg of CPDX. Subsequently, it was introduced into a volumetric flask with a capacity of 50 ml. Ten minutes were spent sonicating the mixture after 30 ml of methanol was added. A volume of 50 ml (1000 µg mL^{-1}) was the resulting volume. The amount of CPDX in the resultant solution is determined by measuring its absorbance at 235 nm. Consequently, the resulting solution was solubilized with the use of solvent to provide concentrations varying from 5 to 15 µgmL^{-1}.

Measurement of λ_{max} for multivariate calibration

The cefpodoxime standard solutions that work was compared to methanol as the blank solution, which has the highest absorbance at 235 nm, across the uv region that ranges from 200 to 400 nm. In determining this, the wavelength of the method's MVC has been estimated to be between these absorption peaks, at 231, 233, 235, 237, and 239 nm.

METHOD VALIDATION

In complying with the recommendations provided by ICH, the linearity, accuracy, and precision of the demonstrated approach were assessed **[14]**.

Linearity

The linearity and spectral area of CPDX were analyzed following the ideal dilution of the stock solution using Methanol to obtain concentrations within the range of 5 to 15 µg mL^{-1}. The approach for MVC involved evaluating and measuring the absorption of

linearity solutions at the optimum wavelength.

Limit on Quantification and Detection

The calibration curve's gradient and the deviation of standard responses at the stipulated wavelength were taken into consideration in the following computations to Evaluate the LOQ and LOD for cefpodoxime.

.

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

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

Precision

The precision's repetition was assessed using both intraday and inter-day measurements. A cefpodoxime solvent with a concentration of 10 µgmL^{-1} was Employed to assess different levels of accuracy. To evaluate repeatability, six solutions were analyzed at five distinct wavelengths. For the inter-variation scenario, the absorbance of prepared solutions was measured three times at different times on the same day. To account for intra-variation, the absorbance was used for three additional days.

Accuracy

The recovery percentages were calculated. The degree of accuracy of the CPDX technique was assessed at 80, 100, and 120 percent of the concentrations of the previously examined sample solutions.

Assay

Powder and Weigh Ten tablets. Accurately weigh out 50 mg of CPDX worth of tablet powder. After that, incorporate 25 ml of methanol and subject the mixture to sonication for 10 mins. An adequate amount of methanol was added to attain 50 ml. Filtered and diluted with methanol, the above solution yields a 10µg mL^{-1} concentration of CPDX.
An amount measuring CPDX in the last solution formed is determined by measuring its absorbance at 235 nm.

RESULTS AND DISCUSSION

The initial detection range for CPDX standard solution was 200–400 nm. CPDX maximum spectrum has a wavelength of 235 nm. Methanol was used as a blank, and a wavelength of 235 nm was used for MVC while recording the UV spectra of cefpodoxime standards and samples. **Figure 2** shows the typical CPDX spectrum at 10 µg mL^{-1}.

Linearity

The relative linearity of the developed technique of CPDX was assessed within the quantification range of 70 to 130 percent for a concentration of 10g mL^{-1} (equivalent to 5 to 15 µgmL^{-1}), as per the requirements of ICH Q2 R1. In **Figure 3,** the linearity spectrum of CPDX is depicted. By estimating the absorption of reference samples that have been distilled at five distinct frequencies (231,233,235,237,239), the calibration curve was produced. The first

table illustrates what has been noticed in a form that is tabulated. All of the standard curves were found to be linear within the selected quantity range. **Figure 4-8** and the **Table 2** exhibit the calibration plots and analyses of regression, subsequently.

LOQ AND LOD

The LOQ and LOD in CPDX were determined using the linearity slope, and numerous sample analyses have validated this method. CPDX LOD was estimated using the mean of all absorption values, and it yielded a value of 0.4707 µg mL^{-1}. A LOQ for CPDX has yielded a value of 1.4264 µg mL^{-1} by averaging all of the absorbances

Precision

A system's precise spectra on CPDX are illustrated in **Figure 9**. **Figures 10 and 11** display the inter-day and intraday precision spectra for CPDX, consequently. The RSD % for the system's inter-day and intraday precision of CPDX was determined. The approach method's precision occurred by the finding that it was less than 2%. This proposed approach showcases exceptional precision in contrast to outcomes obtained from alternative accurate methods.

Accuracy

Figure 12 displays the accuracy of the cefpodoxime overlay spectra were estimated at 80, 100, and 120%. **Table 3** presents the results of the CPDX analysis, which had been assessed to fall by acceptable parameters.

A marketed formulation for assay:

A present study looked at the amount of CPDX in tablet preparation using the recommended spectrophotometer technique. Thrice analyses were conducted on a commercial medication's UV absorption spectrum. The pharmaceutical production ideal analytic rate of recovery held consistent throughout on extraction and filtration process. The results are shown in **Table 4**.

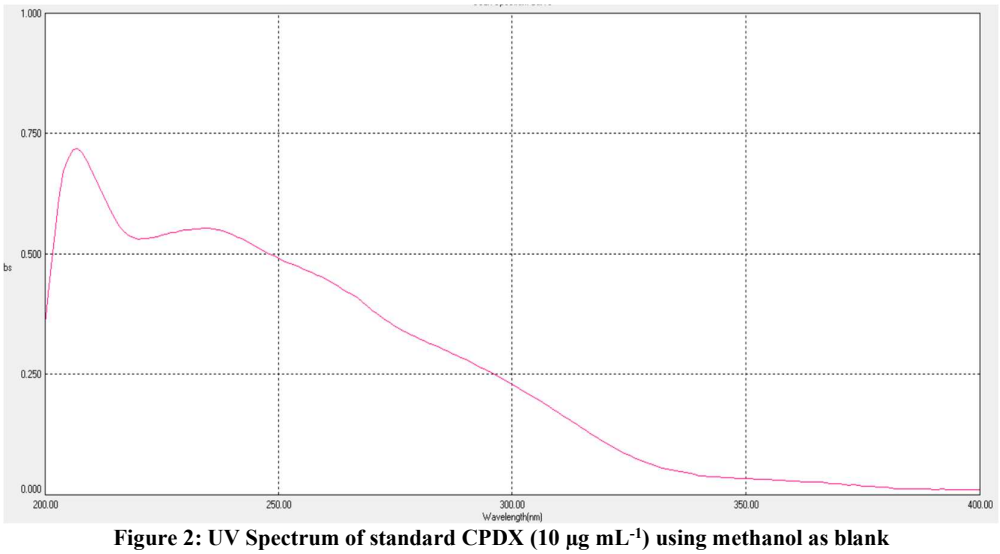

Figure 2: UV Spectrum of standard CPDX (10 µg mL^{-1}) using methanol as blank

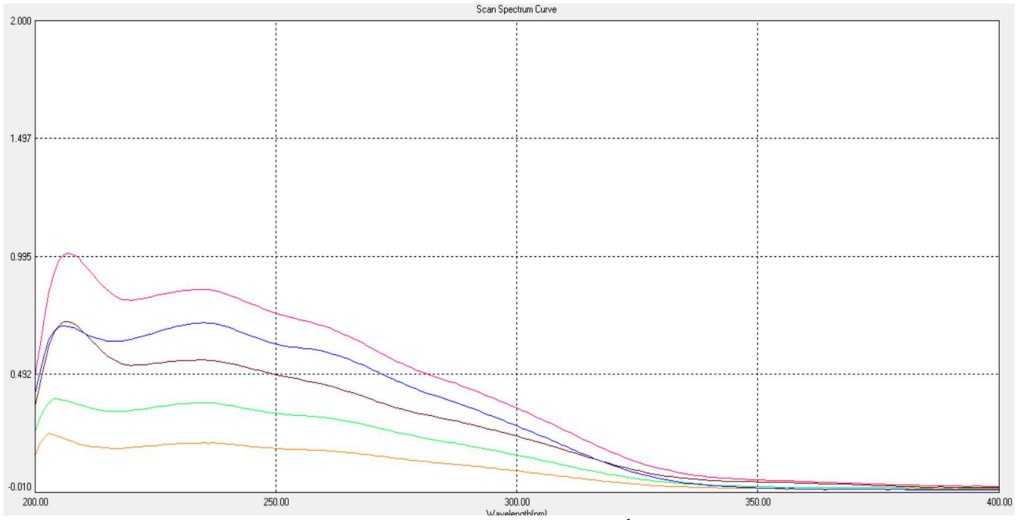

Figure 3: Linearity spectrum of CPDX (5-15 µg mL^{-1}) using methanol as a blank

Table 1: Multivariate UV calibration data at five selected wavelengths

Concentration (µgmL^{-1})	231nm	233nm	235nm	237nm	239nm
5	0.197	0.198	0.199	0.200	0.197
7.5	0.367	0.370	0.372	0.370	0.367
10	0.531	0.545	0.550	0.544	0.547
12.5	0.693	0.705	0.703	0.708	0.702
15	0.849	0.853	0.861	0.851	0.849

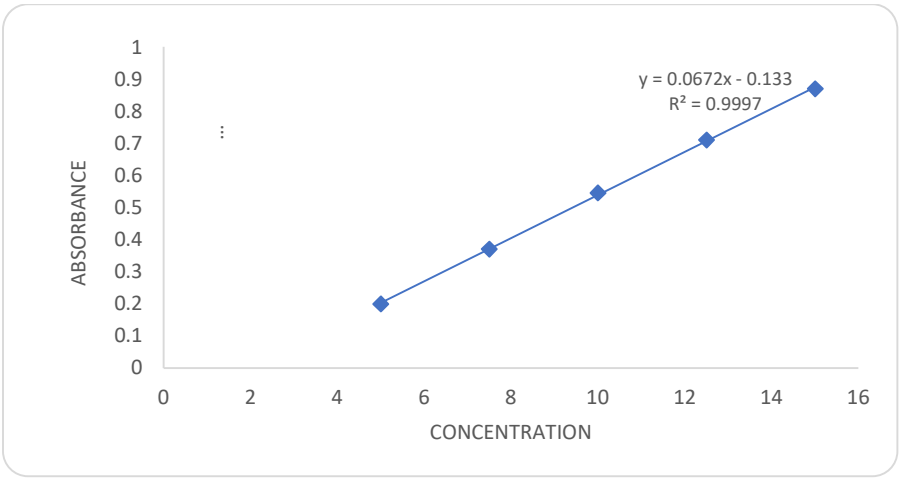

Figure 4: Calibration curve at 231nm

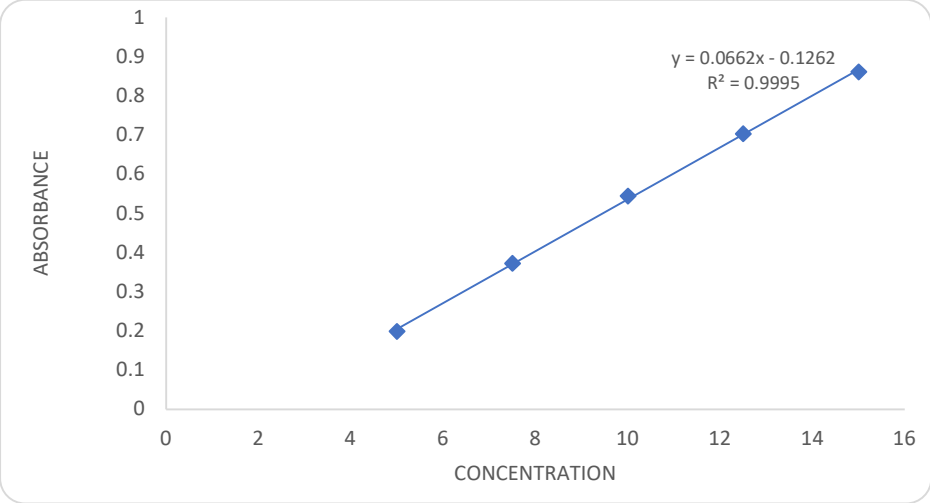

Figure 5: Calibration curve at 233nm

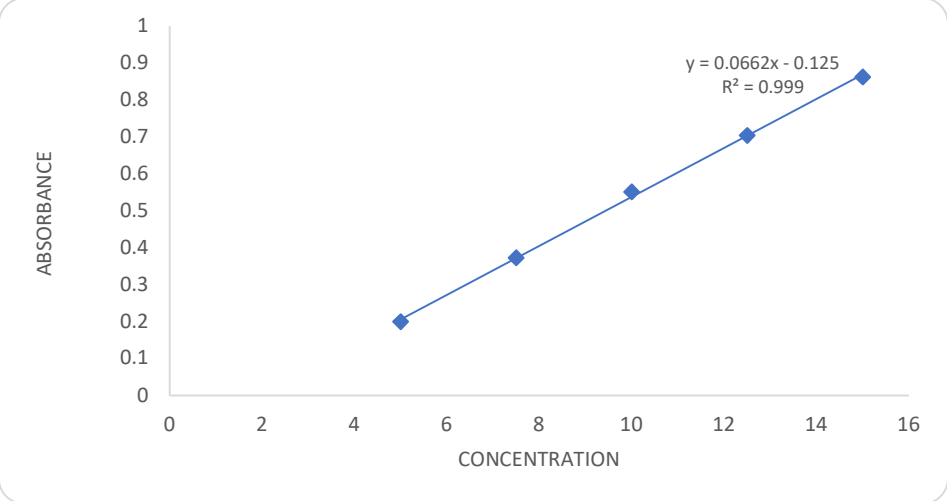

Figure 6: Calibration curve at 235nm

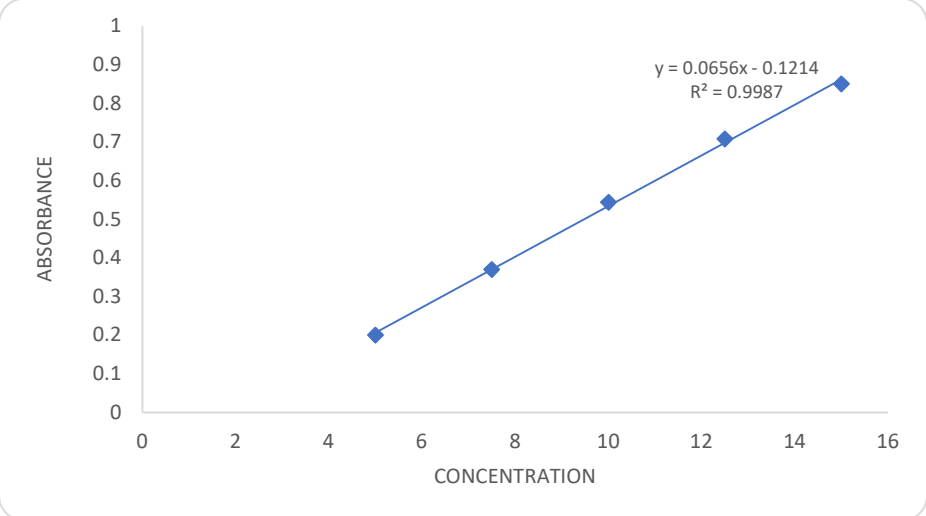

Figure 7: Calibration curve at 237nm

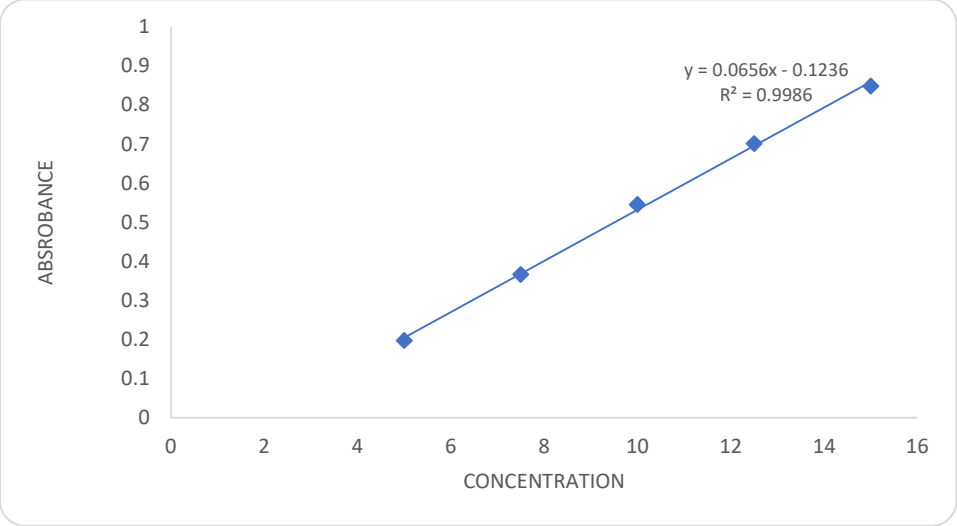

Figure 8: Calibration curve at 239nm

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})
231	y = 0.0672x - 0.133	0.0672x	0.133	0.9997	0.2359	0.71501
233	y = 0.0662x - 0.1262	0.0662x	0.1262	0.9995	0.2602	1.9099
235	y = 0.0662x - 0.125	0.0662x	0.125	0.999	0.4707	1.4264
237	y = 0.0656x - 0.1214	0.0656x	0.1214	0.9987	0.5473	1.6587
239	y = 0.0656x - 0.1236	0.0656x	0.1236	0.9986	0.6033	1.8284

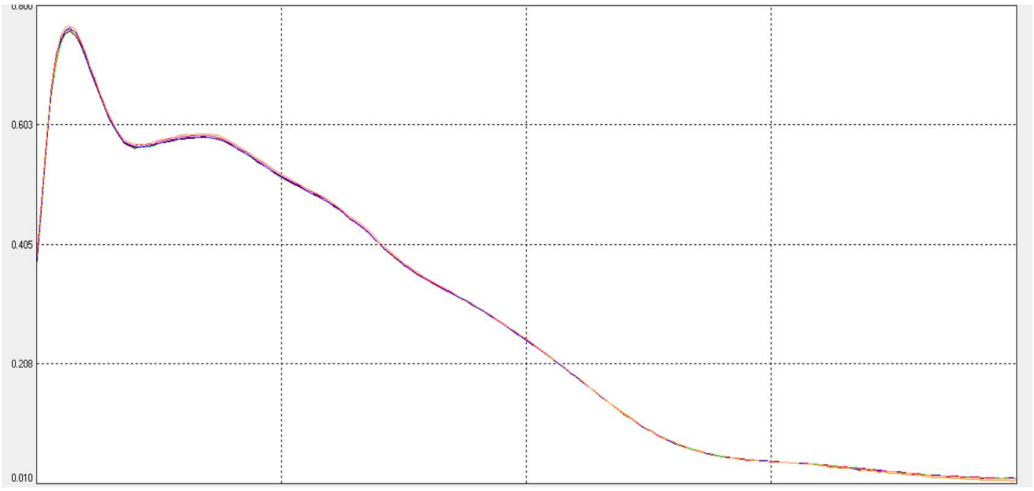

Figure 9: System precision overlay spectra of CPDX.

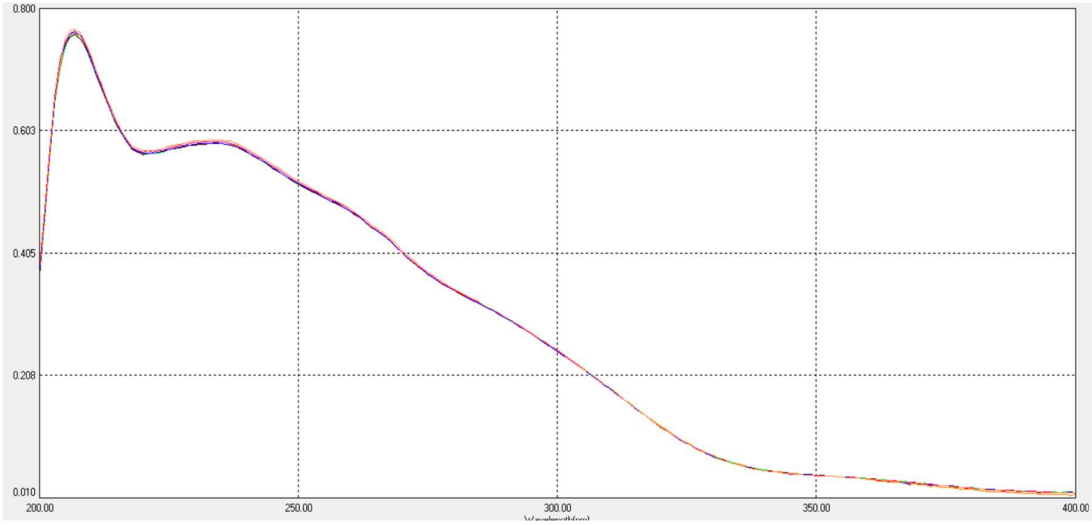

Figure 10: Interday precision overlay spectra of CPDX

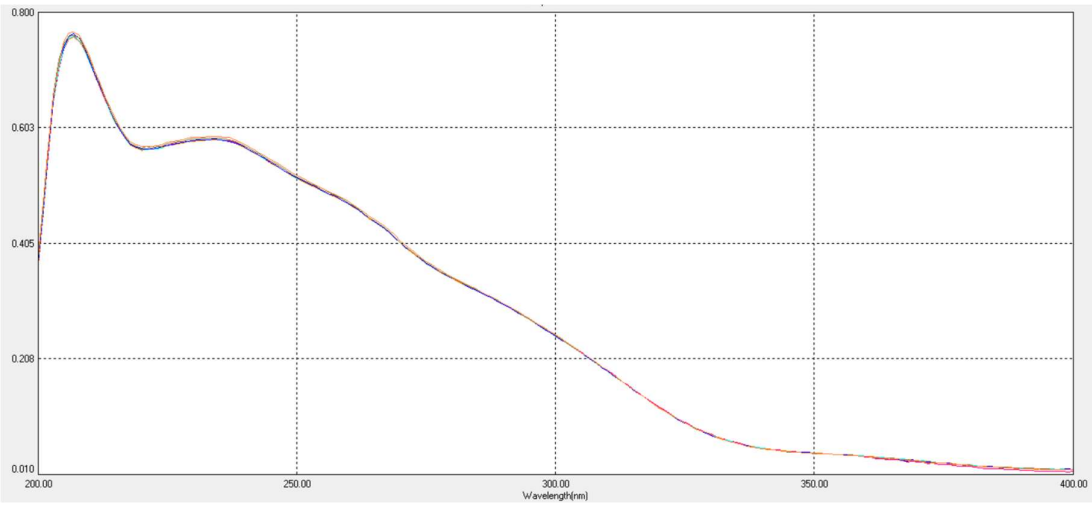

Figure 11: Intraday precision overlay spectra of CPDX

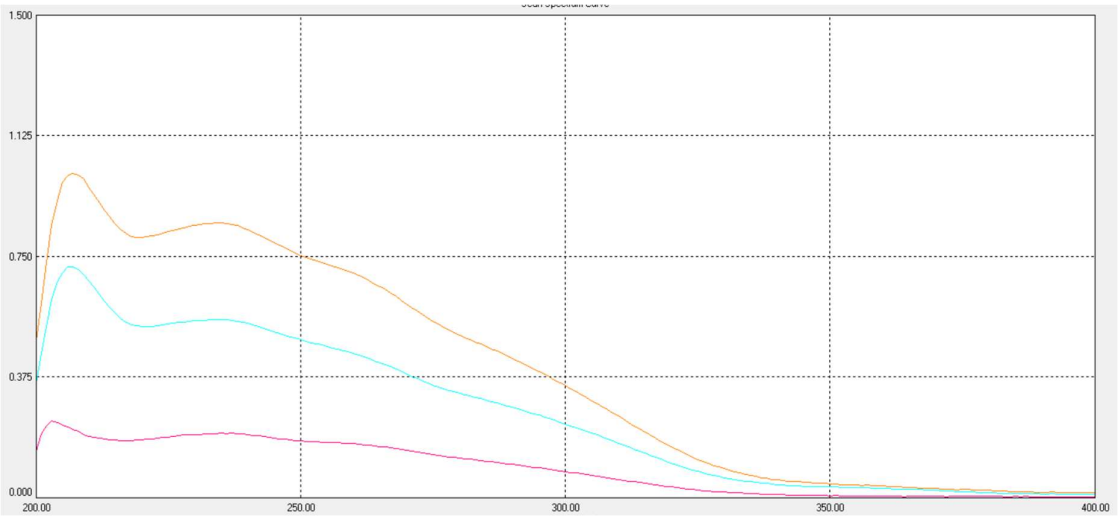

Figure 12: Overlay spectra of the accuracy of CPDX 80, 100, 120 % raising

Table 3: Recovery Studies

Wavelength (nm)	Amount present (µg mL^{-1})	Amount added (µg mL^{-1})	Amount recovered (µg mL^{-1})	% Recovery
231	5	2.5	7.46	99.46
		5	9.95	99.5
		7.5	12.4	99.2
233	5	2.5	7.41	98.8
		5	9.98	99.8
		7.5	12.46	99.68
235	5	2.5	7.58	101.6
		5	10.01	100.1
		7.5	12.43	99.44
237	5	2.5	7.45	99.33
		5	9.97	99.7
		7.5	12.51	100.8
239	5	2.5	7.43	99.06
		5	9.86	99.6
		7.5	12.53	100.16

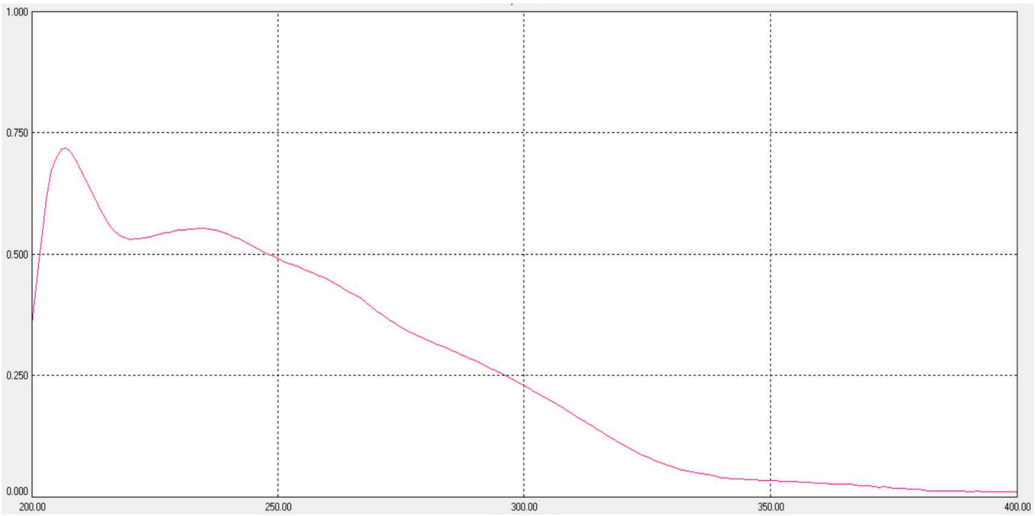

Figure 13: UV spectrum of standard CPDX (10µg mL^{-1}) using Methanol as a blank

Table 4: Assay of cefpodoxime

Label claim(mg)	Amount estimated (mg)	% Assay
100	99.54	99.54
100	98.99	98.99
100	100.05	100.05
Average	99.52	99.52
SD		0.5301
% RSD		0.5326

CONCLUSION

The study effectively created and verified a UV spectrophotometric technique for measuring the amount of CPDX in pharmaceutical formulations. This approach exhibited exceptional sensitivity, precision, and accuracy, per the ICH standards for validating analytical methods. The validation experiments and testing for precision within a single day validated the method's reliability and consistency. In addition, the method was assessed,

highlighting its environmental friendliness through the reduction of toxic solvents and chemicals. This newly devised technique offers a direct, economical, and ecologically sound way for the regular examination of cefpodoxime in quality control labs. This makes it a significant resource for guaranteeing the safety and effectiveness of pharmaceutical products that contain cefpodoxime.

STATEMENT OF ETHICS

This study's trials do not involve any animal or human subjects.

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DISPUTE OF INTEREST

There are no conflicting financial interests associated with this article.

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