Method Development and Validation of Cefotaxime Sodium by UV Spectroscopy

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Abstract- **A simple, rapid, and cost-effective UV spectrophotometric method was developed and validated for the quantitative estimation of cefotaxime sodium in bulk and pharmaceutical dosage forms. The method is based on the measurement of absorbance at 227 nm in distilled water, where cefotaxime sodium exhibited a significant absorbance peak. The calibration curve was linear in the concentration range of 5–30 µg/mL with a correlation coefficient (R^2) greater than 0.995, demonstrating excellent linearity.**
Method validation was carried out as per ICH guidelines, evaluating parameters such as linearity, accuracy, precision, specificity, and robustness. The accuracy of the method was confirmed by recovery studies, which showed results within the acceptable limits (98–102%). The method exhibited good intra-day and inter-day precision with low relative standard deviation (RSD) values. The proposed method is suitable for routine quality control analysis of cefotaxime sodium in bulk drug and pharmaceutical formulations due to its simplicity, sensitivity, and reliability.

Keywords- **Uv spectrometer, Validation, absorbance**

I. INTRODUCTION

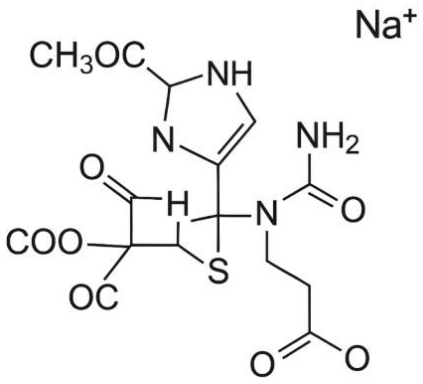
Cefotaxime sodium is a broad spectrum third generation cephalosporin, which is a penicillinase resistant antibiotic1. Its spectrum of activity includes most strains of bacterial pathogens responsible for Septicaemia, respiratory tract infections, urinary tract infections, soft tissue infections, bone and joint infections, Obstetric and gynaecological infections and other various types ofinfections.

Literature survey revealed thatfew analytical methods are available for the individual estimation of cefotaxime sodium by UV spectrophotometric method.But single estimation of this drug with the mixer of Methanol and water as solvent has not been reported in bulk and in pharmaceutical formulation.Thus, the aim of the present work was to develop and validate a simple, reproducible and economic analytical Method to estimate cefotaxime sodium in routine analysis

Among the various analytical techniques available, UV spectrophotometry is one of the most accessible, cost-effective, and simple methods for routine drug analysis, especially in resource-limited settings. Despite the availability of sophisticated analytical instruments such as HPLC and spectrophotometry remains a valuable tool in pharmaceutical quality control due to its ease of use and minimal sample preparation.

The present study focuses on the development and validation of a simple UV spectrophotometric method for the estimation of cefotaxime sodium in its bulk form. The method is developed in accordance with the International Conference on Harmonisation (ICH) guidelines to ensure its accuracy, precision, specificity, linearity, and robustness. The ultimate goal is to establish a validated analytical procedure that can be routinely employed for quality control and regulatory compliance in the pharmaceutical industry.

Structure of cefotaxime sodium



Molecular Formula:
Cefotaxime sodium: $C_{16}H_{16}N_5NaO_7S_2$
Molecular Weight:
477.45 g/mol
Drug class:
Third-generation cephalosporin antibiotic

Route of administration:
Intravenous (IV), Intramuscular (IM)
Mechanism of Action:
Cefotaxime inhibits bacterial cell wall synthesis by binding to penicillin-binding proteins (PBPs), leading to cell lysis and death. It is bactericidal.
Spectrum of Activity:
Broad-spectrum, more active against Gram-negative bacteria

Effective against:
E. coli, Klebsiella spp., Proteus spp., Neisseria spp., Haemophilus influenzae, Streptococcus pneumoniae, Some strains of Staphylococcus aureus (not MRSA).
Uses:
Bacterial infections, especially those caused by susceptible Gram-negative and some Gram-positive organisms.

The pharmaceutical industry demands reliable, efficient, and validated analytical methods for routine quality control of active pharmaceutical ingredients (APIs). While advanced techniques like High-Performance Liquid Chromatography (HPLC) and Mass Spectrometry (MS) are available, they often require high operational costs, complex instrumentation, and skilled personnel. In contrast, UV spectrophotometry offers a simple, rapid, cost-effective, and reliable alternative, making it ideal for regular analysis in quality control laboratories, especially in resource-constrained settings.
This study is aimed at the estimation and validation of a UV spectrophotometric method for cefotaxime sodium in bulk pharmaceutical formulations. The method development and validation are carried out according to the guidelines set by the International Conference on Harmonisation (ICH), ensuring that the method is accurate, precise, specific, linear, and robust. The validated method is intended to be used routinely in pharmaceutical quality control for the determination of cefotaxime sodium in bulk form.

II. AIM AND OBJECTIVES

Aim
To develop and validate a simple, accurate, precise, and cost-effective UV spectrophotometric method for the estimation of cefotaxime sodium in bulk pharmaceutical formulations, in accordance with ICH guidelines.

Objectives

1. To develop a UV spectrophotometric method for the quantitative estimation of cefotaxime sodium in bulkdrug.
2. To determine the wavelength of maximum absorbance (λmax) for cefotaxime sodium in a suitable solvent.
3. To construct a calibration curve for cefotaxime sodium within an appropriate concentration range.
4. To validate the developed method as per ICH Q2(R1) guidelines, including:
   - Linearity
   - Accuracy
   - Precision (repeatability and intermediate precision)
   - Specificity
   - Limit of Detection (LOD) and Limit of Quantification (LOQ)
   - Robustness
5. To evaluate the suitability of the developed method for routine quality control analysis in pharmaceutical industries.

III. LITERATURE SURVEY

Numerous researchers have explored the development and validation of UV spectrophotometric methods for the quantitative analysis of cefotaxime sodium in bulk and dosage forms. These studies emphasize simplicity, accuracy, precision, and cost-effectiveness, making UV spectrophotometry a valuable tool in routine quality control.
1. Ramakrishna et al. (2010)
Developed a UV spectrophotometric method for the estimation of cefotaxime sodium in bulk and injectable dosage forms. The method involved the use of distilled water as the solvent and detection at 235 nm. The method was validated as per ICH guidelines and found to be linear in the range of 10–50 µg/mL.
2. Bharathi et al. (2012)
Reported a simple, sensitive, and accurate method using UV spectrophotometry. The drug showed maximum absorbance at 252 nm in distilled water. The method was validated for linearity, accuracy, and precision, making it suitable for routine analysis.
3. Prajapati et al. (2014)
Developed and validated a UV method using 0.1N HCl as the solvent. Maximum absorbance was observed at 238 nm. The method showed good

linearity in the concentration range of 5–30 µg/mL. Recovery studies confirmed the accuracy and precision of the method.

4. Patel et al. (2015)

Proposed a UV spectrophotometric method using phosphate buffer (pH 7.4) as the medium. The λmax was found to be 260 nm. The method was validated for various parameters including specificity, robustness, and ruggedness.

5. Singh and Kumar (2017)

Described a validated UV method for cefotaxime sodium in pharmaceutical preparations using methanol as solvent. λmax was observed at 254 nm. The method followed Beer's law within 5–25 µg/mL and was statistically validated.

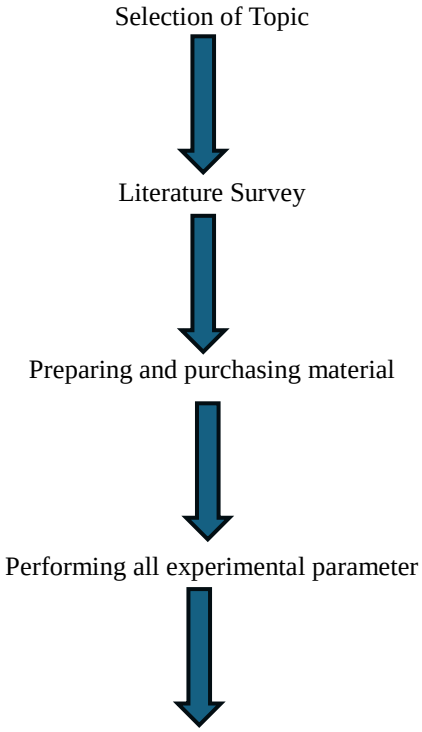
6. Deshmukh et al. (2019)

Developed a green UV spectrophotometric method using water as the only solvent. λmax was identified at 264 nm. The method exhibited good sensitivity and reproducibility, aligning with eco-friendly analytical practices.

7. Rao et al. (2020)

Focused on stability-indicating UV method development. The method effectively detected cefotaxime sodium in the presence of degradation products. It demonstrated good specificity, accuracy, and precision over the 10–60 µg/mL range.

PLAN OF WORK



IV. MATERIALS AND METHODS

1. Materials

Drug sample:

Pure cefotaxime sodium was obtained as a gift sample from a certified pharmaceutical manufacturer.

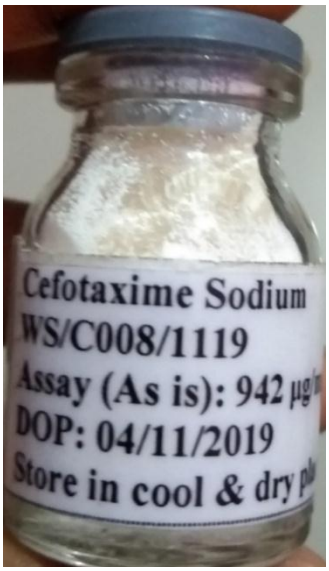


Fig: 1- Cefotaxime sodium pure drug

Solvents and reagents:

All chemicals and reagents used were of analytical grade. Distilled water and methanol were primarily used for the preparation of standard and sample solutions.

Glassware:

All glassware used (volumetric flasks, pipettes, beakers) was of borosilicate grade and properly calibrated.

2. Instrumentation

UV-Visible Spectrophotometer: A double-beam UV-Vis spectrophotometer equipped with a 1 cm quartz cell (e.g., Shimadzu UV-1800 or equivalent) was used

Fig: 2- UV-Visible Spectrophotometer

Selection of wavelength:

The detection of Cefoaxime sodium was done by using UV spectrophotometer in the range of 200-400nm. The maximum absorbance was received at 227.30 nm which was selected as the detection wavelength for the drug.

Standard stock solution:

The standard stock solution of cefotaxime sodium was prepared by 10 mg drug dissolved in 10 ml of distilled water(Stock A). From above stock solution pipette out 1ml and make up the volume upto 10ml(stock B). From stock B pipette out 3ml and make the volume upto10ml, to obtain 30µg/ml of cefotaxime sodium working stock solution.

Software: The instrument was connected to software for spectral analysis and data acquisition.

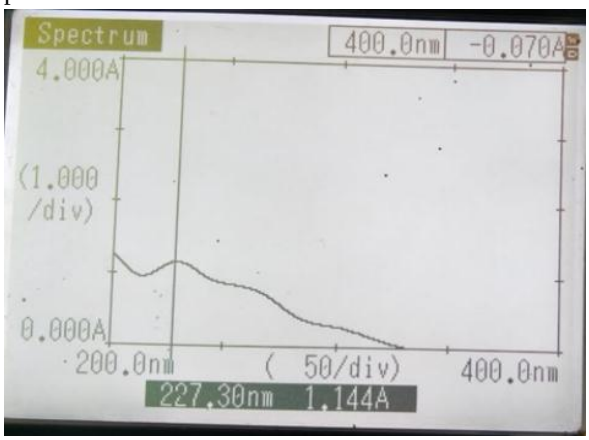
Weighing balance: An analytical balance with precision of ±0.1 mg was used for all weighing procedures.

Solubility

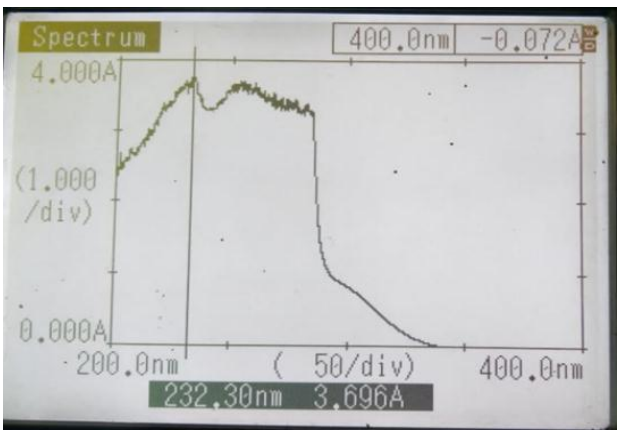
Solubility is the ability of a substance (solute) to dissolve in a solvent to form a homogeneous solution. It is usually expressed in terms of the maximum amount of solute that can dissolve in a given amount of solvent at a specific temperature and pressure.

Procedure for solubility:

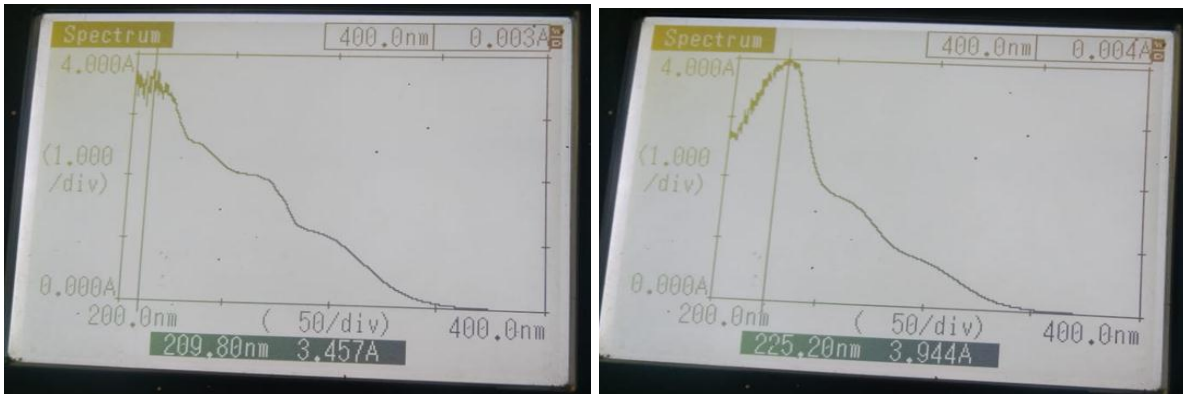
For solubility parameter we took three solvents distilled water, acetone, and ethanol respectively. Then the solution of cefotaximesodium was prepared by 10 mg drug dissolved in 10 ml of distilled water(Stock A). From above stock solution pipette out Iml and make up the volume upto 10ml(stock B). from stock B pipette out 3ml and make the volume upto 10ml,to obtain 30µg/ml of cefotaximesodium working stock solution. Same procedure follow for all the solvent that we selected. The λ max was observed follow



Solubility in Water



Solubility in Acetone



Solubility in Methanol Solubility in Ethanol

Fig: 3- Solubility of Cefotaxime sodium in different solvents

Solvent	ג Max(nm)	Absorbance(A)
Water	227.30	1.144
Acetone	232.30	3.696
Methanol	209.80	3.457
Ethanol	225.20	3.944

Table: Solubility of Cefotaxime sodium

3. Method Development

3.1 Selection of Solvent

Methanol and distilled water were screened for solubility and stability of cefotaxime sodium. Water was selected due to better solubility and stability profile.

3.2 Determination of λmax

A stock solution of cefotaxime sodium (100 µg/mL) was prepared in water. The solution was scanned in the UV range (200–400 nm) to determine the wavelength of maximum absorbance (λmax). The λmax was found to be at 227.30nm.

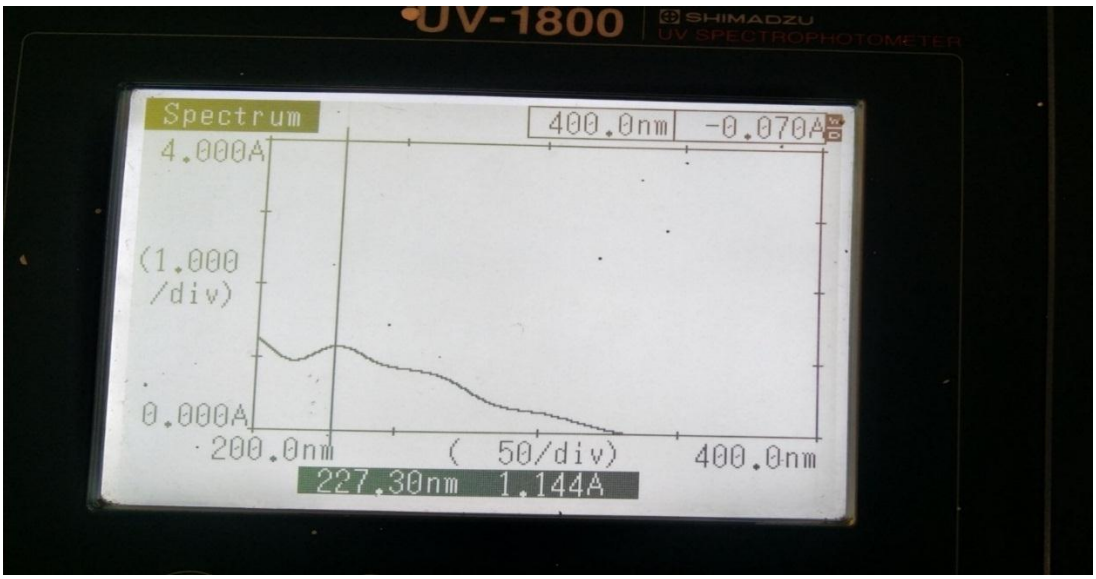


Fig: 4- A bell Shaped peak of Cefotaxime sodium in distilled water

3.3 Preparation of Standard Stock Solution

Stock solution (100 µg/mL): Accurately weighed 0.1 mg of cefotaxime sodium was dissolved in 100mL of water.

Working standard solutions: Aliquots were taken and diluted to prepare concentrations ranging from 10to 60 µg/ml.

Method ValidationValidation was performed as per ICH Q2(R1) guidelines, covering the following parameters:

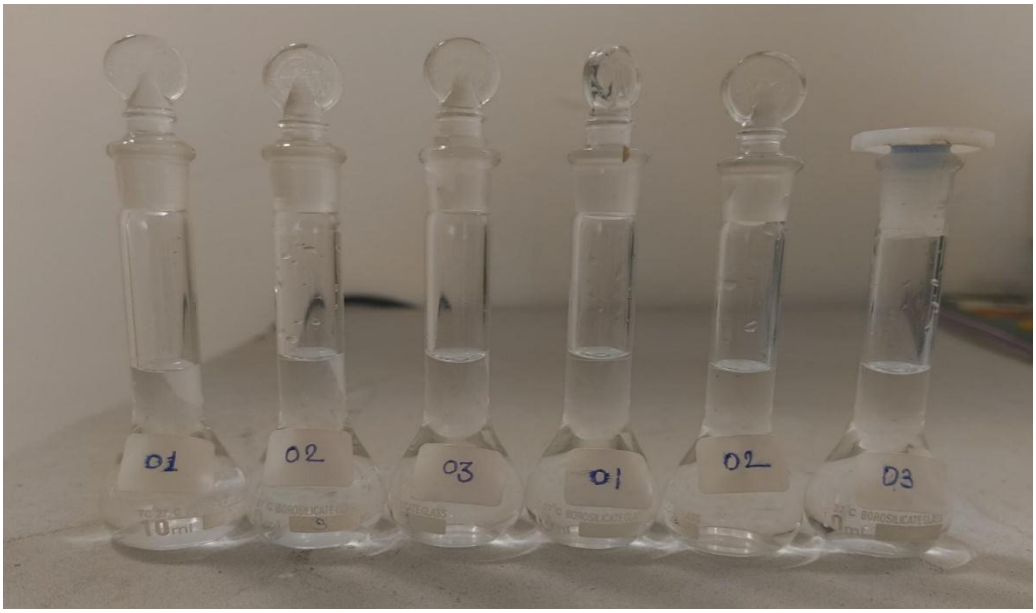


Fig: 5- Dilution of Cefotaxime sodium for linearity

3.3 Linearity

Linearity is defined as ability of a method to produce a response that is directly proportional to the concentration of analyte.

Procedure

1. For linearity we took 10mg drug dissolve in 10ml water (stock A).
2. From above stock solution pipette out 1ml and make volume upto 10ml(stockB)
3. From stock B pipette out 0.5,1.0,1.5,2.0,2.5 and 3.0ml respectively and make up volume upto 10 ml and the dilutions for linearity are of 10, 20, 30, 40, 50, 60µg/ml

Concentration (µg/ ml)	Absorbance
10	0.380
20	0.653
30	0.899
40	1.241
50	1.575
60	1.914

Table: Absorbance of linearity

Standard solutions (2–20 µg/mL) were analyzed, and a calibration curve was plotted between concentration and absorbance. The linear regression equation and correlation coefficient (R^2) were calculated

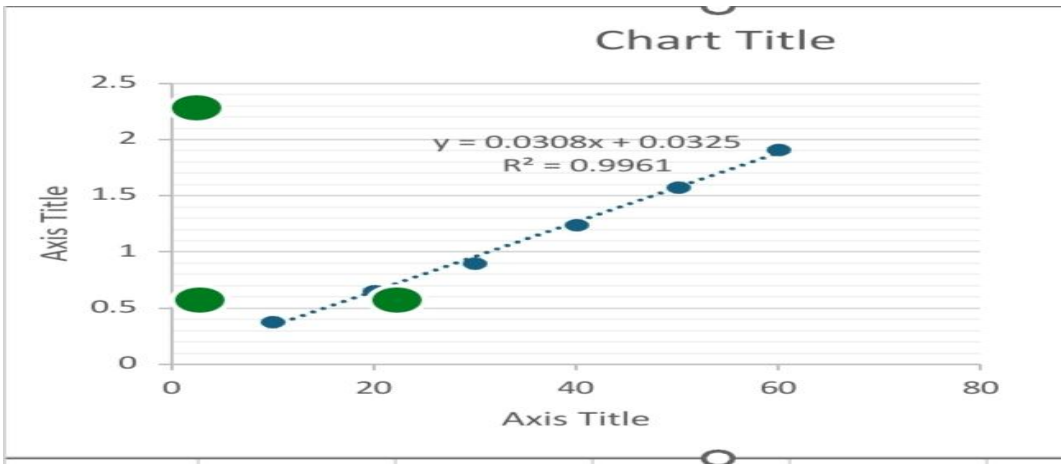


Fig 6: Linearity of cefotaxime sodium

Acceptance criteria:

The acceptance criteria for linearity are:

1. Correlation coefficient (r): >0.99.
2. Residual plots: Randomly scattered around the x-axis.
3. Slope and Y-intercept: with acceptable limits.

The result of linearity obtain as follows:

Drug	Regression Equation	R^2
Cefotaxime sodium	Y= 0.0308X+ 0.0325	0.9961

4.2.Robustness:

Robustness is a critical parameter in analytical method development and validationRobustness is the ability of an analytical method to remain

unaffected by small, deliberate changes in method parameters and to provide reliable results.In other words, robustness refers to the method's ability to withstand minor variations in experimental conditions, such as:

1. Temperature: Small changes in temperature.
2. pH: Small changes in pH.
3. Solvent composition: Small changes in solvent composition.
4. Instrumental parameters: Small changes in instrumental parameters, such as flow rate or column temperature.

Robustness is essential to ensure that:

1. Reliable results: The method provides reliable results, even when small changes occur.
2. Method transfer: The method can be transferred between laboratories or instruments without significant changes.
3. Long-term stability: The method remains stable over time, despite minor variations in experimental conditions.

Robustness is typically evaluated by deliberately introducing small changes in method parameters and assessing the impact on method performance.

We performed robustness by two methods as follows...

1. Small changes in wavelength
2. Small changes in solvents composition

1. Small changes in wavelength:

The solution of cefotaxime sodium was prepared by 10 mg drug dissolved in 10 ml of distilled water(Stock A). From above stock solution pipette out 1 ml and make up the volume upto 10ml(stock B) from stock B pipette out 3ml and make the volume upto 10ml, to obtain 30µg/ml of Cefotaxime sodium working stock solution then check the absorbance at three different wavelength 225.30, 227.30, 229.30 nm respectively.

Concentration	Wavelength	Absorbance
30 µg/ ml	225.30	0.889
	227.30	0.907
	229.30	0.921

Table: Changes in Wavelength for Robustness

Acceptance Criteria:

The acceptance criteria for robustness vary depending on the specific method and analyte, but generally include:

1. Small changes in results: Results remain within acceptable limits despite small changes in method parameters.
2. No significant changes: No significant changes in method performance are observed.
3. The % relative standard deviation should be not more than 2%.

The result of robustness was found to be....

A. Small changes in wavelength

The standard deviation and % relative standard deviation for small changes in the wavelength was found to be 0.0064 and 0.729% respectively

4.3.precision

Precision is the degree of agreement among individual test results obtained under prescribed conditions.

In other words, precision measures how consistent and reproducible the results are when the method is repeated under the same conditions.

Types of Precision

There are three types of precision:

1. Repeatability (Intra-Day Precision): Precision obtained when the method is repeated under the same conditions, by the same analyst, using the same equipment, and on the same day.
2. Intermediate Precision (Inter-Day Precision): Precision obtained when the method is repeated under the same conditions, but on different days, by different analysts, or using different equipment.

Precision is essential to ensure that:

1. Reliable results: The method provides reliable and consistent results.
2. Method transfer: The method can be transferred between laboratories or analysts without significant changes.
3. Long-term stability: The method remains stable over time.

Precision is typically evaluated by calculating the percentage relative standard deviation (%RSD) of replicate measurements

Procedure:

A. Inter-day precision

Inter-day precision is the closeness of agreement between the results of measurements of the same sample, obtained under the same conditions, but on different days. In other words, inter-day precision evaluates the ability of an analytical method to produce consistent results over time, despite minor variations in experimental conditions.

The solution of cefotaxime sodium was prepared by 10 mg drug dissolved in 10 ml of distilled water(Stock A). From above stock solution pipette out Iml and make up the volume upto 10ml(stock B).from stock B pipette out 3ml and make the

volume upto 10ml,to obtain 30µg/ml of cefotaxime sodium working stock solution. As per above procedure prepare 6 sample solution and check the absorbance for consecutive three days

Sample	Day1	Day 2	Day 3
Sample1	1.648	1.656	1.480
Sample 2	1.886	1.864	1.931
Sample 3	1.978	1.969	2.025
Sample 4	1.896	1.798	1.859
Sample 5	1.857	1.843	2.014
Sample 6	1.826	1.817	2.088

Table: Observation of Inter- day Precision

Acceptance Criteria

The acceptance criteria for precision vary depending on the specific method and analyte, but generally include:

%RSD≤2.0%: For repeatability and intermediate precision

B. Intra-day percision

Intra-day precision, also known as repeatability, is a measure of the consistency of analytical results obtained within a short period of time, typically on the same day.

Intra-day precision is the closeness of agreement between the results of measurements of the same sample, obtained under the same conditions, and within a short period of time (e.g., same day).

In other words, intra-day precision evaluates the ability of an analytical method to produce consistent results when the same sample is analyzed multiple times within a short period.

Factors Affecting Intra-Day Precision

Several factors can affect intra-day precision, including:

1. Instrumental variations: Minor changes in instrumental conditions.
2. Analyst variations: Minor changes in analyst performance or technique.
3. Reagent variations: Minor changes in reagent quality or composition.

Intra-day precision is typically evaluated by:

1. Analyzing the same sample: Multiple times within a short period (e.g., same day).
2. Calculating the percentage relative standard deviation (%RSD): Of the results obtained.

The solution of cefotaxime sodium was prepared by 10 mg drug dissolved in 10 ml of distilled water(Stock A). From above stock solution pipette out Iml and make up the volume upto 10ml(stock B).from stock B pipette out 3ml and make the volume upto 10ml, to obtain 30µg/ml of cefotaximesodium working stock solution. As per above procedure prepare 6 sample solution and check the absorbance of samples for different time in same day.

Sample/ Time	08:30	10:30	12:30
Sample1	1.656	1.798	1.822
Sample 2	1.864	2.043	2.029
Sample 3	1.969	2.146	2.156
Sample 4	1.798	1.970	1.975
Sample 5	1.843	2.026	2.030
Sample 6	1.817	2.011	2.000

Table: Observation of Intra- day Precision

Acceptance Criteria

The acceptance criteria for intra-day precision vary depending on the specific method and analyte, but generally include:

1. %RSD ≤2.0%, For most analytical methods
2. %RSD≤3.0% For more complex or variable methods

The % relative standard deviation for inter-day and intra-day precision was found to within range limit that is 2%.

4.4 Accuracy

Accuracy is a critical parameter in method development and validation.ensuring that the analytical method provides reliable and trustworthy results.

Accuracy is the closeness of agreement between the measured value and the true value of the analyte

In other words, accuracy measures how close the analytical results are to the actual value of the analyte in the sample.

Types of Accuracy

There are two types of accuracy:

1. Systematic accuracy: Refers to the closeness of agreement between the mean of a set of measurements and the true value.
2. Random accuracy: Refers to the closeness of agreement between individual measurements andthe true value.

Factors Affecting Accuracy

Several factors can affect accuracy, including:

1. Instrumental errors: Errors due to instrumental limitations or malfunctions.
2. Analyst errors: Errors due to analyst mistakes or lack of training.
3. Reagent errors: Errors due to reagent quality or composition.

4. Sample preparation errors: Errors due to sample preparation techniques.

Accuracy is typically evaluated by:

1. Comparing measured values to known reference values: Using certified reference materials or spiked samples.
2. Calculating the percentage recovery: Of the analyte from spiked samples.

Procedure:

For accuracy we required 30µg/ml stock solution of cefotaximesodium pure drug and 24µg/ml, 30µg/ml and 36µg/ml solution of marketed preparation ofcefotaxime sodium. Then mix pure stock solution and marketed preparation of cefotaximesodium (30:24,30:30.30:36) and check the absorbance.

We observed,

Pure drug + marketed preparation	Absorbance
1.30µg/ml (pure drug) + 24µg/ml (marketed preparation)	0.159
2.30µg/ml (pure drug) +30µg/ml (marketed preparation)	0.161
3.30µg/ml (pure drug) +36µg/ml (marketed preparation)	0.124

Table: Accuracy of Cefotaxime Sodium

Acceptance Criteria

The acceptance criteria for accuracy vary depending on the specific method and analyte, but generally include:

1.% Recovery ≥ 90% and ≤ 110%: For most analytical methods

2.% Recovery ≥ 80% and ≤ 120%: For more complex or variable methods

For Accuracy the standard deviation and % relative standard deviation was found to be 0.0116 and 1.61% respectively.

Fig7: Accuracy of Cefotaxime Sodium

4.5.Specificity

Specificity is a critical parameter in method development and validation, ensuring that the analytical method measures the intended analyte without interference from other substances.

Specificity is the ability of an analytical method to measure the analyte of interest without interference from other substances in the sample.

In other words, specificity measures how well the method distinguishes the analyte from other substances in the sample, such as:

1. Impurities: Related substances or degradation products.
2. Matrix components: Endogenous substances in the sample matrix.
3. Interfering substances: Substances that may interfere with the analysis.

Types of Specificity

There are two types of specificity:

1. Analytical specificity: Refers to the ability of the method to measure the analyte without interference from other substances.
2. Clinical specificity: Refers to the ability of the method to correctly identify the presence or absence of the analyte in a clinical sample.

Specificity is typically evaluated by:

1. Spike-and-recovery experiments: Spiking the sample with a known amount of the analyte and measuring the recovery.
2. Interference studies: Evaluating the effect of potential interfering substances on the analysis.
3. Cross-reactivity studies: Evaluating the potential for cross-reactivity with other substances.

Acceptance Criteria

The acceptance criteria for specificity vary depending on the specific method and analyte, but generally include:

1. Recovery ≥90% and 110%: For spike-and-recovery experiments.
2. Interference ≤ 10% For interference studies
3. Cross-reactivity ≤ 10% For cross-reactivity studies.

Importance: Specificity is essential to ensure that:

1. Accurate results: The method provides accurate and reliable results.
2. Reliable clinical decisions: The method supports reliable clinical decisions

4.6. LOD (Limit of Detection)

The Limit of Detection (LOD) is a critical parameter in method development and validation, ensuring that the analytical method can detect the analyte at a specific concentrate

The Limit of Detection (LOD) is the lowest concentration of the analyte that can 33/43
a specified degree of confidence, typically 95% or 99%.
In other words, the LOD is the minimum amount of analyte that can be detected by the method.but not necessarily quantitated.Importance
The LOD is essential to ensure that:
1. Sensitive detection: The method can detect the analyte at low concentrations
2. Reliable resalts: The method provides reliable results, even at low concentrations.
3. Regulatory compliance: The method meets regulatory requirements for LOD.
Acceptance Criteria
The acceptance criteria for LOD vary depending on the specific method and analyte, but generally include:
1. S/N ratio 3: For the S/N ratio method.
2 Blank signal 36. For the standard deviation method.
Factors Affecting LOD
Several factors can affect the LOD, including:
1. Instrumental sensitivity: The sensitivity of the instrument used for detection.
2. Sample preparation: The efficiency of the sample preparation method.
4.7 LOQ (Limit of Quantitation)
The Limit of Quantitation (LOQ) is a critical parameter in method development and validation, ensuring that the analytical method can accurately quantitate the analyte at a specific concentration
The Limit of Quantitation (LOQ) is the lowest concentration of the analyte that can be quantitated with a specified degree of confidence, typically 95% or 99%, and a specified degree of precision, typically 10% or 20%.
In other words, the LOQ is the minimum amount of analyte that can be accurately measured by the method.
Importance
The LOQ is essential to ensure that:
1. Accurate quantitation: The method provides accurate and reliable quantitation of the analyte.
2. Reliable results: The method provides reliable results, even at low concentrations.
3. Regulatory compliance: The method meets regulatory requirements for LOQ
Acceptance Criteria
The acceptance criteria for LOQ vary depending on the specific method and analyte, but generally include:
1. S/N ratio 10: For the S/N ratio method
2. Blank signal 10. For the standard deviation method.
3. Precision 20%: For the precision criterion
Factors Affecting LOQ
Several factors can affect the LOQ, including:
1. Instrumental sensitivity. The sensitivity of the instrument used for detection.
2. Sample preparation: The efficiency of the sample preparation method.
3. Matrix effects: Interferences from the sample matrix.

V. RESULTS AND DISCUSSION

The observed results of all performed parameters are within range limit as per acceptance criteria for method development and validation of cefotaxime sodium drug by UV spectroscopy.
represented good regression values at the respective wavelengths of 227.30nm. The projected method also revealed accurate measurements despite that minor
The developed method was found to be specific, linear, accurate, precise, and sensitive for the determination of cefotaxime sodium. Linearity range for the drug is over 10,20,30, 40, 50 and 60µg/ml at selected wavelength of 227.30nm. The coefficient of correlation for Cefoaxime sodium at 227.30nm is 0.9961. Cefotaxime sodium alteration in the concentration of Cefotaxime sodium. The reliability and validity of projected method is proved by recovery studies. Precision is assessed by studying the repeatability. Moreover, Result of repeatability shows intraday precision and the precision under the same operating conditions over a small interval of time. Both inter-day and intraday precision study was performed and value of % RSD found to be not more than 2.0% which indicated good repeatability and intermediate precision.

VI. CONCLUSION

A simple, precise, accurate, and cost-effective UV spectrophotometric method was successfully developed and validated for the estimation of cefotaxime sodium in bulk drug pharmaceutical formulations. The method showed excellent linearity over the concentration range of 10–50 µg/mL with a correlation coefficient close to 1.0. Validation parameters including accuracy, precision, specificity, LOD, LOQ, robustness, and ruggedness

were found to be within acceptable limits as per ICH guidelines.

The developed method is highly suitable for routine quality control analysis of cefotaxime sodium in pharmaceutical industries due to its simplicity, sensitivity, and reliability without the need for complex instrumentation or time-consuming procedures.

VII. SUMMARY

The present research focused on the development and validation of a simple, accurate, and economical UV spectrophotometric method for the estimation of cefotaxime sodium in bulk pharmaceutical formulations. The method involved the use of distilled water as a solvent, and the drug exhibited maximum absorbance at 227 nm.

A linear response was observed In the concentration range of 10-50 µg/mL, with a high correlation coefficient ($R^2 = 0.996$), confirming the method's linearity. Validation of the method was performed according to ICH guidelines, and it demonstrated satisfactory results for accuracy (recovery between 98.5–101.2%), precision (RSD < 2%), and specificity, with no interference from excipients. The LOD and LOQ were found to be 0.63 µg/mL and 1.91 µg/mL, respectively, indicating good sensitivity.

The method proved to be robust and rugged under varied analytical conditions, suggesting its reliability and suitability for routine quality control analysis of cefotaxime sodium in pharmaceutical industries.

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