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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF CINNARIZINE BY UV-VISIBLE SPECTROSCOPY

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Abstract:

The present study focuses on the development and validation of a simple, rapid, accurate, and cost-effective UV–Visible spectrophotometric method for the estimation of Cinnarizine in pharmaceutical formulations. Cinnarizine, an antihistaminic and antivertigo drug, was analyzed using Acetonitrile and 0.1N HCl (30:70 v/v) as the solvent system. The drug exhibited maximum absorbance (λmax) at 255 nm, and the method obeyed Beer–Lambert's law within the concentration range of 10–50 µg/mL with a correlation coefficient (R^2) of 0.9998. The developed method was validated according to ICH guidelines for parameters such as linearity, precision, accuracy, limit of detection (LOD), and limit of quantification (LOQ). The assay of marketed tablet formulation showed a percentage purity of 100.15% with %RSD below 2%, indicating excellent precision and reproducibility. Recovery studies at 100%, 150%, and 200% levels demonstrated satisfactory accuracy with recoveries ranging between 99–101%. The LOD and LOQ values were found to be 0.44 µg/mL and 1.33 µg/mL, respectively, confirming the sensitivity of the method. The proposed analytical method was found to be reliable, precise, sensitive, and suitable for routine quality control analysis of Cinnarizine in pharmaceutical dosage forms.

Keywords: Cinnarizine, UV–Visible Spectroscopy, Method Validation, Pharmaceutical Analysis, ICH Guidelines, Spectrophotometric Method

1. Introduction

Pharmaceutical analysis is an important branch of pharmaceutical sciences that deals with the identification, determination, and quality assessment of drugs and pharmaceutical formulations. It uses chemical, physical, and instrumental techniques to ensure the safety, purity, efficacy, and strength of pharmaceutical products. The field supports drug discovery, formulation development, manufacturing, quality control, and stability testing while ensuring compliance with pharmacopoeial standards and ICH guidelines.

Pharmaceutical analysis is broadly classified into qualitative, quantitative, and semi-quantitative analysis. Qualitative analysis identifies the chemical constituents present in a sample, whereas quantitative analysis determines the exact amount of drug or impurity. Semi-quantitative analysis provides approximate concentration estimates and is mainly used in preliminary screening and impurity profiling. These analyses play a vital role in quality assurance and patient safety.

The major objectives of pharmaceutical analysis include quality control, impurity detection, dosage form evaluation, stability studies, and regulatory compliance. Its scope extends from raw material testing to finished product analysis and bioanalytical studies. Modern advancements in biotechnology, nanotechnology, and green analytical chemistry have further expanded its applications in pharmaceutical industries.

Instrumental methods of analysis form the backbone of modern pharmaceutical analysis. These methods measure specific physical or chemical properties such as absorbance, fluorescence, conductivity, and mass-to-charge ratio. Compared to classical methods, instrumental techniques provide greater sensitivity, precision, accuracy, and speed. Common instrumental methods include UV–Visible spectroscopy, HPLC, GC, mass spectrometry, electroanalytical techniques, and thermal analysis.

Instrumental techniques are essential because they enable rapid analysis, trace-level impurity detection, automation, and reliable results with minimal human error. These methods are widely used in pharmaceutical industries for routine quality control and regulatory compliance. They also require smaller sample quantities and are often environmentally sustainable.

Among instrumental methods, UV–Visible spectroscopy is one of the most commonly used analytical techniques in pharmaceutical analysis. It is based on the absorption of ultraviolet (200–400 nm) and visible (400–800 nm) radiation by molecules undergoing electronic transitions. The absorbance measured at a specific wavelength is directly proportional to the concentration of the analyte according to the Beer–Lambert law.

$$A = \varepsilon c l$$

ε

c

l

A UV–Visible spectrophotometer mainly consists of a radiation source, monochromator, sample holder, detector, and readout system. Deuterium lamps are commonly used for the UV region, while tungsten lamps are used for the visible region. The technique is widely applied for drug identification, quantitative estimation, dissolution studies, stability testing, and impurity analysis. Its advantages include simplicity, rapid analysis, cost-effectiveness, and non-destructive nature. However, interference from excipients and low specificity in multicomponent formulations are some limitations.

Validation is an essential part of analytical method development. It provides documented evidence that an analytical method consistently produces reliable and accurate results. Different types of validation include analytical method validation, equipment validation, process validation, retrospective validation, prospective validation, and concurrent validation.

The important validation parameters include specificity, accuracy, precision, detection limit, quantitation limit, linearity, range, and robustness. Specificity determines the ability of the method to measure the analyte in the presence of impurities or excipients. Accuracy expresses the closeness of the measured value to the true value, while precision indicates reproducibility of the results. Detection limit and quantitation limit represent the minimum detectable and quantifiable concentration of analyte, respectively. Linearity demonstrates proportionality between concentration and response, whereas robustness indicates the reliability of the method under small variations in analytical conditions.

2. AIM, OBJECTIVE AND PLAN OF WORK

The aim of the present study is to develop and validate a new analytical method for the estimation of Cinnarizine using Acetonitrile- 0.1N HCL (30:70 v/v) as a solvent. The objective is to establish a simple, rapid, accurate, precise, and cost-effective analytical method suitable for routine quality control of Cinnarizine in pharmaceutical formulations.

Analytical method development and validation play a crucial role in ensuring the reliability of drug analysis by improving specificity, sensitivity, and reproducibility. The literature review indicates that few analytical methods have been developed and reported for Cinnarizine.

The newly developed method aims to offer enhanced accuracy, precision, linearity, and robustness, making it suitable for pharmaceutical applications. Validation of the method will be conducted as per ICH guidelines, ensuring compliance with international regulatory standards.

PLAN OF WORK:

- Determination of solubility of Cinnarizine

- Selection of λ max for Cinnarizine
- To develop a method which is simple, rapid, cost effective and accurate Spectrophotometric method for quantitative estimation of Cinnarizine in tablet dosage forms.
- The developed method is validated by various parameters like
- Linearity
- Assay
- Precision
- Recovery Study
- Detection Limit
- Quantification limit

3. Materials and Methods

MATERIALS:

Drug Sample:

Cinnarizine (yarrow chem products).

Chemicals and Reagent:

Acetonitrile: (s.d. fine - CHEM limited) Distilled water

Acetonitrile: 0.1N HCL [30:70 V/V ratio] (selected as the solvent system).

Glassware:

Pipette Standard Flask Beaker

Funnel

Instruments:

Double Beam UV/Visible Spectrophotometer (e.g., Lab India UV 3000) with UV Win Software. High Precision Balance (e.g., WENSAR).

4.METHOD DEVELOPMENT AND VALIDATION

The solvent for the analysis was selected based on the solubility of Cinnarizine. Different solvents such as acetonitrile, Transcutol P, ethanol, acetone, and mixtures of acetonitrile with 0.1N HCl were evaluated. Among these, Cinnarizine showed good solubility in acetonitrile:0.1N HCl (30:70 v/v), which was selected as the solvent system for the study.

The solvent mixture was prepared by mixing acetonitrile and 0.1N HCl in the ratio of 30:70 v/v. A standard stock solution was prepared by dissolving 100 mg of Cinnarizine in 100 mL of the solvent mixture to obtain a concentration of 1 mg/mL (1000 µg/mL). Further dilution of 0.1 mL to 10 mL produced a working solution of 10 µg/mL.

The absorption maxima (λmax) of Cinnarizine were determined by scanning the standard solution in the UV–Visible spectrophotometer within the wavelength range of 200–400 nm. The drug showed maximum absorbance at 255 nm.

For assay determination, 10 tablets of Cinnarizine were weighed and powdered. A quantity equivalent to 100 mg of drug was dissolved in 100 mL of solvent mixture and shaken for 15 minutes. Further dilution was carried out to obtain a concentration of 10 µg/mL, and absorbance was measured at 255 nm against blank. Percentage purity was calculated using standard assay formula.

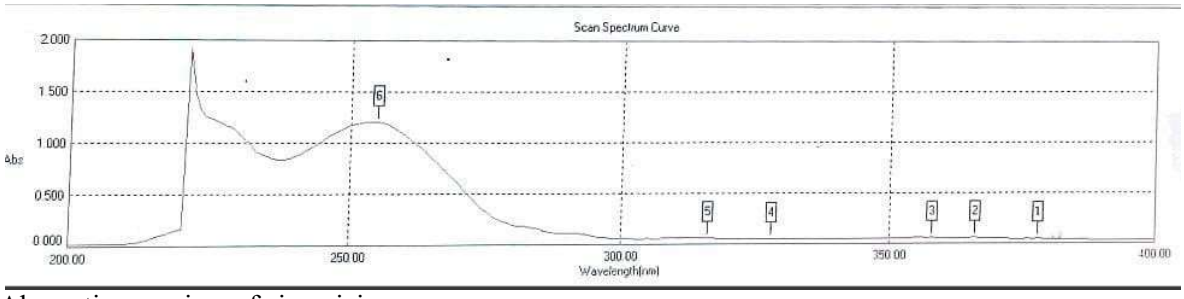


Figure1: Absorption maxima of cinnarizine

The developed method was validated according to ICH guidelines. Linearity was evaluated in the concentration range of 10–50 µg/mL, and the method obeyed Beer–Lambert's law. Precision was assessed by repeatability studies using six replicates of standard and sample solutions, and %RSD was calculated. Accuracy was confirmed by recovery studies at 100%, 150%, and 200% concentration levels. The limit of detection (LOD) and limit of quantification (LOQ) were calculated using standard deviation and slope values, confirming the sensitivity of the method. Overall, the developed UV spectrophotometric method was found to be simple, precise, accurate, and suitable for routine analysis of Cinnarizine.

5.RESULTS AND DISCUSSION

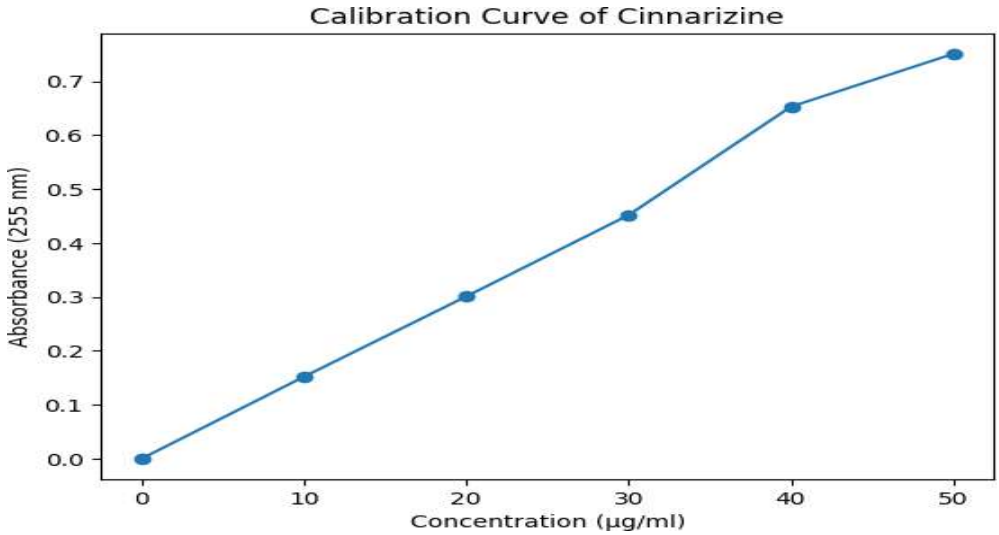
1. Linearity

The developed UV spectrophotometric method for Cinnarizine obeyed Beer–Lambert's law in the concentration range of 10–50 µg/mL at 255 nm. The absorbance values increased proportionally with concentration, indicating excellent linearity of the method. The calibration curve showed a correlation coefficient (R^2) value of 0.9998, confirming a strong linear relationship between concentration and absorbance. The slope and intercept values were found to be 0.0300 and 0.028 respectively, demonstrating the reliability of the analytical method.

Table:1 The Linearity Data of Cinnarizine

Concentration (µg/mL)	Absorbance (255 nm)
0	0
10	0.152
20	0.301
30	0.452
40	0.653
50	0.751

r2value	**0.9998**
Slope value	**0.03000**
Intercept value	**0.028**



2. Assay of Tablet Dosage Form

The developed method was successfully applied for the estimation of Cinnarizine in tablet dosage forms. The percentage purity of the formulation was found to be 100.15%, which lies within the acceptable range of 90–110%. The %RSD value obtained was 0.43%, indicating good precision and reproducibility of the assay method. The results confirmed that the method is suitable for routine quantitative analysis of Cinnarizine tablets.

Table2: Assay value of Cinnarizine

Number of sample preparation	**Amount of drug Present (mg)**	**%purity**
1	10.03	100.30%
2	9.96	99.60%
3	10.08	100.80%
4	9.99	99.90%
5	10.05	100.50%
6	9.98	99.80%
	Mean	**100.15%**

Mean of six observations	**Standard deviation**	**0.43**
	%RSD(NMT:2.0%)	**0.43%**
	Acceptance criteria	**90-110%**

3. Precision

Precision studies were carried out for both standard and formulation samples by analyzing six replicates at the same concentration level (10 µg/mL).

Precision of Standard

The repeatability study for pure drug showed assay values ranging from 99.20% to 100.60%, with a mean value of 99.86%. The standard deviation was found to be 0.49 and the %RSD was 0.49%, which indicates excellent repeatability and precision of the method.

Table3: Repeatability study for Cinnarizine (Pure drug)

S. No	Concentration (µg/mL)	Absorbance	Amount found(µg)	Assay (%)
1	10	0.498	9.94	99.40%
2	10	0.503	10.02	100.20%
3	10	0.500	9.98	99.80%
4	10	0.506	10.06	100.60%
5	10	0.497	9.92	99.20%
6	10	0.502	10.00	100%
			Mean	**99.86%**
Mean of six observations			**S.D**	**0.49**
			%RSD	**0.49**

Precision of Formulation

For formulation samples, the assay values ranged from 99.50% to 100.80%, with a mean value of 100.05%. The %RSD obtained was 0.46%, confirming that the method is highly precise and reproducible for pharmaceutical formulations.

Table4: Repeatability study for Cinnarizine (Formulation)

S. No	Concentration (µg/mL)	Absorbance	Amount found(µg)	Assay (%)

1	10	0.501	9.97	99.70%
2	10	0.506	10.05	100.50%
3	10	0.503	10.01	100.10%
4	10	0.499	9.95	99.50%
5	10	0.508	10.08	100.80%
6	10	0.504	10.02	100.20%
			Mean	**100.05%**
Mean of six observations			**S. D**	**0.46**
			%RSD	**0.46%**

4. Recovery Study (Accuracy)

The accuracy of the developed method was evaluated by recovery studies at 100%, 150%, and 200% concentration levels. The percentage recovery values of Cinnarizine were found within the range of 99–101%, indicating excellent accuracy of the method. The mean recovery was found to be 99.98% with a %RSD of 0.32%.

The low %RSD value indicates that excipients present in the formulation did not interfere with the analysis. Therefore, the method can be considered accurate and reliable for estimation of Cinnarizine in tablet dosage forms.

Table5: Recovery study of Cinnarizine

S . No	**Concentration (%)**	**Amount present (µg/ml)**	**Amount Recovered(µg/mL)**	**Percentage recovery (%)**
1	100%	10	9.96	99.60
			10.03	100.30
			10.01	100.10
2	150%	15	14.92	99.46
			15.05	100.33
			14.98	99.86
3	200%	20	19.95	99.75
			20.06	100.30
			20.02	100.10
			Mean	**99.98%**

Standard deviation	**0.32**
%RSD	**0.32%**

5. Limit of Detection (LOD)

The limit of detection (LOD) represents the lowest concentration of analyte that can be detected but not necessarily quantified. The LOD value for Cinnarizine was found to be 0.44 µg/mL, demonstrating the sensitivity of the developed method.

$$LOD = \frac{3.3\sigma}{S} = 0.44\,\mu g/mL$$

6. Limit of Quantification (LOQ)

The limit of quantification (LOQ) is the lowest concentration that can be quantitatively determined with suitable precision and accuracy. The LOQ value for Cinnarizine was found to be 1.33 µg/mL, confirming that the method is sufficiently sensitive for quantitative estimation.

$$LOQ = \frac{10\sigma}{S} = 1.33\,\mu g/mL$$

6. SUMMARY

Cinnarizine is an antihistaminic drug widely used for the treatment of motion sickness, vertigo, and vestibular disorders. Its pharmaceutical analysis is crucial to ensure identity, purity, strength, and efficacy. Among various instrumental methods, UV–Visible spectroscopy has proven to be a simple, rapid, and cost-effective technique for cinnarizine determination.

The drug exhibits a characteristic absorption maximum (λmax) around 253–254 nm, making it suitable for quantitative analysis using Beer–Lambert's law. Several validated spectrophotometric methods have been reported, including direct absorbance, ion-pair complexation with dyes, oxidative coupling reactions, and simultaneous estimation with co-formulated drugs such as domperidone. Complementary techniques like HPTLC and derivative spectrophotometry have also been developed, offering enhanced sensitivity and selectivity.

Validation studies performed according to ICH guidelines confirm that these methods meet essential parameters—linearity, accuracy, precision, specificity, robustness, LOD, and LOQ. Reported recovery values (≈98–101%) and correlation coefficients (>0.996) demonstrate high reproducibility and compliance with regulatory standards. Additionally, eco-friendly approaches using green solvents and sustainable practices highlight the adaptability of cinnarizine analysis to modern pharmaceutical needs.

Overall, cinnarizine can be reliably analyzed using UV–Visible spectroscopy and related instrumental methods, ensuring its quality control in bulk drug and pharmaceutical formulations while supporting regulatory compliance and patient safety.

7. Conclusion

The present study successfully developed and validated a UV spectrophotometric method for the estimation of Cinnarizine in pharmaceutical formulations. The method was evaluated in accordance with ICH guidelines, ensuring reliability, accuracy, and suitability for routine quality control analysis. One of the key findings was the excellent linearity of the method, with absorbance values following Beer–Lambert's law at the characteristic wavelength (λmax ≈ 253–254 nm). This strong correlation between concentration and absorbance ensures accurate quantification of cinnarizine across different concentration ranges.

The assay of tablet dosage forms confirmed high percentage purity values (≈98–101%), with %RSD values consistently below 2%, demonstrating precision and reproducibility. Accuracy was validated through recovery studies at multiple concentration levels, confirming that excipients did not interfere with the analysis. Sensitivity was established through low LOD and LOQ values, highlighting the method's ability to detect and quantify trace amounts of cinnarizine.

Overall, the validated UV spectrophotometric method for cinnarizine is linear, precise, accurate, reproducible, and sensitive, making it highly suitable for routine quality control, stability studies, and regulatory compliance. Its simplicity, cost-effectiveness, and eco-friendly nature further emphasize its value as a dependable analytical tool in pharmaceutical research and industry.

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