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UV-Spectrophotometric Method for Citicoline: Development and Validation

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ABSTRACT

A UV-spectrophotometric technique that is simple, sensitive, specific, rigid, precise, and repeatable was created and verified for the measurement of citicoline in tablet dosage form as well as in its pure form. The highest absorbance of citicoline in 0.1N HCl was observed at 280 nm. Between 10 and 80 µg/mL, the method showed linearity with a linear regression equation of Abs = 0.0111 x Conc and a correlation coefficient of 0.9999. The method's average accuracy was 98.41 ± 0.70%, and its precision was good (%RSD ~2%). It was shown that common excipients did not significantly interfere.

INTRODUCTION

Citicoline (Cytidine-5'-diphosphocholine or CDP-choline) is a naturally occurring compound essential for cellular function. In the body, it hydrolyzes into cytidine and choline, which contribute to phosphatidylcholine synthesis, crucial for neuronal membrane function. [1-2] Citicoline is used clinically as a neuroprotective agent and is available in supplement form. Doses range from 500 to 2000 mg daily via oral or IV routes [3]. Though its exact mechanism is not fully known, it is considered safe and exhibits low toxicity. [4]

2. UV SPECTROSCOPY

UV-visible spectroscopy provides analytical data by measuring light absorbance of compounds in the UV and visible range. [5] The technique is commonly used to study organic and inorganic substances, evaluate coating reflectance, and monitor biochemical changes. The fundamental concept of UV-visible spectroscopy is the absorption, reflectance, and transmission of photons through translucent or opaque solids and liquids in the UV-visible spectrum. It makes use of light photons that fall between the visible (400–800 nm) and ultraviolet (200–400 nm) portions of the electromagnetic spectrum. [6]

3. PRINCIPLE

The method is based on the interaction between light and matter, where molecules absorb UV light leading to electronic excitation. Absorption occurs when the energy of light matches the gap between molecular electronic energy levels, resulting in a characteristic absorbance spectrum. [7-8]

4. MATERIALS AND METHODS

4.1 Selection of Solvent: Citicoline is soluble in 0.1N HCl, selected as the solvent.

4.2 Preparation of Stock Solution (1000 µg/mL): 50 mg of citicoline was dissolved in 50 mL of 0.1N HCl.

4.3 Preparation of Working Solution (100 µg/mL): 5 mL of the stock solution was diluted to 50 mL with 0.1N HCl.

4.4 Selection of Wavelength (280 nm): 10 µg/mL solution was scanned from 200 to 400 nm. λmax observed at 280 nm.

4.5 Calibration Curve Construction: Aliquots of 1–8 mL of working solution were diluted to 10 mL to obtain concentrations from 10 to 80 µg/mL. Absorbance was measured at 280 nm. Linear regression: Abs = 0.0111 x Conc, R = 0.9999.

Table 1: Concentration vs. Absorbance

S. No.	Conc (µg/mL)	Absorbance
1	10	0.1109
2	20	0.2199
3	30	0.3342
4	40	0.4383
5	50	0.5504
6	60	0.6643
7	70	0.7736
8	80	0.8858

5. VALIDATION PARAMETERS

5.1 Precision

5.1.1 Repeatability: Nine replicates of 10 µg/mL were analysed. Mean = 9.58 µg/mL, %RSD = 0.69%

5.1.2 Intra-day Precision: Measured at 0, 3, and 6 hours. Mean %RSD = 1.17%

5.1.3 Inter-day Precision: Measured at 0, 24, and 48 hours. Mean %RSD = 1.20%

5.2 Accuracy: Recovery studies at 80%, 100%, and 120% levels. Mean recovery = 98.41 ± 0.70%

5.3 Specificity: No significant interference from common excipients. Mean interference = 1.40%

5.4 Linearity and Range: Linear range: 10–80 µg/mL, R = 0.9999, Abs = 0.0111 x Conc

6. ESTIMATION OF CITICOLINE

6.1 In Pure Form: Citicoline concentration found to be 97.63 ± 0.75% (n = 3)

6.2 In Pharmaceutical Dosage Form (ECWIN 15 mg): Citicoline content found to be 99.34 ± 0.50% (n = 3)

7. RESULT & DISCUSSION

The UV-spectrophotometric method developed is simple, sensitive, and precise for citicoline estimation. It showed excellent linearity (10–80 µg/mL), accuracy (98.41%), and precision (<2% RSD). The presence of excipients did not interfere with drug analysis, confirming method specificity. The results comply with ICH guidelines. [9-11]

Table 2: Summary of Validation Parameters

S. No.	Parameter	Observation
1	Range	10–80 µg/mL
2	Regression Equation	Abs = 0.0111 x Conc
3	Correlation Coefficient	0.9999
4	Repeatability (%RSD)	0.69
5	Intra-Day Precision	1.17
6	Inter-Day Precision	1.20
7	Accuracy (%Recovery)	98.41±0.70
8	Specificity (%Interference)	1.40

CONCLUSION

The developed UV-spectrophotometric method is easy to use, sensitive, accurate, precise, and specific for determining citicoline. For analytical applications, it is very reliable due to its good linearity, low excipient interference, and adequate precision and accuracy. Because of these established parameters, the method can be used regularly and successfully for the quality control analysis of citicoline in tablet dosage forms as well as bulk drug substances.

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