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Research Article

Analytical Method Development and Validation of Piracetam by UV Spectroscopic Method for Bulk and Pharmaceutical Dosage Form

S. Gokulraj*, D. Rajalingam, N. Gnanasekar, K. Ganga, U. Prasanna, N. Jayapriya

Kamalakshi Pandurangan College of Pharmacy, Ayyampalayam, Tiruvannamalai 606603.

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ABSTRACT

The present study was carried out to develop and validate a simple, accurate, precise, and economical UV–Visible spectrophotometric method for the estimation of Piracetam in pharmaceutical dosage forms. Piracetam is a nootropic drug belonging to the racetam group and is used for the treatment of cortical myoclonus in certain clinical settings. The proposed method was developed using distilled water as the solvent, and the maximum absorbance of Piracetam was observed at 209 nm. The method showed good linearity over the concentration range of 10–60 µg/ml. The developed method was validated for linearity, precision, accuracy, robustness, limit of detection (LOD), and limit of quantification (LOQ) according to ICH guidelines. The method showed good precision, with %RSD values ranging from 0.885–1.204%. The accuracy study showed good percentage recovery ranging from 99.85–100.08% at 80%, 100%, and 120% levels. The LOD and LOQ were found to be 4.53 µg/ml and 13.73 µg/ml, respectively. The robustness study showed that small changes in wavelength from 208 to 210 nm did not significantly affect the absorbance response. The results obtained from the validation studies indicate that the proposed method is simple, reliable, reproducible, and suitable for the routine estimation of Piracetam in pharmaceutical formulations.

INTRODUCTION

Piracetam is a synthetic drug belonging to the racetam group of nootropic agents. It is chemically related to the neurotransmitter-modulating racetam class and has been studied for various neurological and cognitive disorders. The clinical use and approved indications of piracetam vary between countries. In the United Kingdom, for example, piracetam is licensed for the treatment of cortical myoclonus, in combination with other anti-myoclonic therapies. It is sometimes described as a "memory-enhancing" drug, but evidence supporting its routine use for improving memory in healthy people or treating dementia is limited and inconsistent.[1]

***Corresponding Author:** S. Gokulraj
Address: *Kamalakshi Pandurangan College of Pharmacy, Ayyampalayam, Tiruvannamalai 606603.*
Email ✉: gokulraj952000@gmail.com

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Piracetam belongs to the nootropic/racetam class of drugs. Its ATC classification is N06BX03. Unlike conventional stimulants, piracetam does not act primarily by producing generalized central nervous system stimulation. Its pharmacological actions are complex, and its precise mechanism responsible for therapeutic effects in cortical myoclonus has not been completely established. Cognitive and neurological disorders comprise a broad group of conditions that affect functions such as memory, learning, attention, coordination, behaviour, and other aspects of central nervous system function.[2] These disorders may arise from ageing, neurodegenerative processes, vascular abnormalities, metabolic disturbances, hypoxia, or structural and functional abnormalities of the brain. Because impairment of neuronal function can involve several interconnected mechanisms, various pharmacological agents have been investigated to improve or preserve neurological and cognitive function. Among these agents, nootropic drugs represent a group of compounds developed or investigated for their potential effects on cognitive and neuronal function. Piracetam is one of the best-known and earliest members of this group.[3]

Piracetam is a synthetic compound chemically known as 2-oxo-1-pyrrolidine acetamide and is structurally related to the cyclic derivatives of gamma-aminobutyric acid (GABA). It is regarded as the prototype of the racetam family of nootropic compounds, which subsequently led to the development and investigation of structurally related compounds. Although piracetam has been studied for several neurological and cognitive conditions, its precise mechanism of action remains incompletely understood. The current UK product information classifies piracetam pharmacologically as a nootropic (ATC N06BX03) and specifically indicates its use for cortical myoclonus, where it is administered as an adjunct to other anti-myoclonic therapy.[4]

Piracetam has attracted considerable scientific interest because of its reported effects on neuronal membrane properties, neurotransmission, neuroplasticity, and hemorheological functions. Experimental and pharmacological studies suggest that piracetam can influence membrane fluidity and modulate neurotransmission involving several systems, particularly cholinergic and glutamatergic pathways. However, it is important to note that no single mechanism has been universally accepted as responsible for all of its clinical effects. Reviews of the pharmacology of piracetam have emphasized that its mechanism remains complex and incompletely defined. In addition to its effects on the nervous system, piracetam demonstrates several hemorheological effects. According to the current product information, piracetam increases erythrocyte deformability and decreases platelet aggregation and erythrocyte adhesion to vascular endothelium. It has also been reported to influence blood viscosity and certain coagulation-related parameters. These properties have contributed to investigations of piracetam in various neurological and circulatory disorders. However, these pharmacological effects should not be interpreted as establishing piracetam as an approved treatment for every condition in which such effects have been studied.[5]

Historically, piracetam has been investigated in conditions including cognitive impairment, dementia, vertigo, dyslexia, cortical myoclonus, and other neurological disorders. Nevertheless, the strength of evidence varies substantially between indications, and regulatory approval differs between countries. In particular, evidence supporting piracetam as a general cognitive or memory-enhancing drug is not conclusive. A

recent systematic review and meta-analysis of piracetam in adults with memory impairment found no statistically significant overall improvement in memory compared with placebo, highlighting the need for caution when describing piracetam as a general memory-enhancing medicine.[6]

Piracetam is also characterized by a distinctive pharmacokinetic profile. It is rapidly and almost completely absorbed following oral administration, with oral bioavailability close to 100%. It crosses the blood-brain barrier and is distributed to the central nervous system. Piracetam undergoes minimal metabolism and is eliminated predominantly through the kidneys, with approximately 90% of the administered dose excreted in the urine as unchanged drug. Consequently, renal function is an important consideration in patients receiving piracetam, particularly elderly patients and those with renal impairment. Overall, piracetam remains an important compound in the history and study of nootropic pharmacology. Its unique pharmacological properties, effects on neuronal membranes and hemorheology, and long history of investigation have made it a subject of considerable clinical and experimental research. However, its therapeutic role should be considered according to the specific indication, available clinical evidence, and regulatory status in the relevant country, rather than assuming that it is universally effective for cognitive enhancement or neurological disease.[7]

Piracetam Structure:

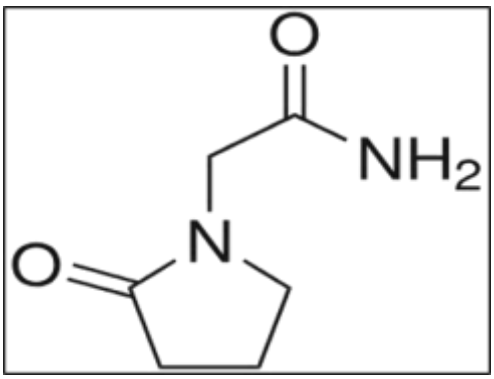

Figure 1: Structure of Piracetam

Piracetam is a nootropic/racetam drug with the IUPAC name 2-(2-oxopyrrolidin-1-yl) acetamide, molecular formula $C_6H_{10}N_2O_2$, and molecular weight 142.16 g/mol. It is a white to almost white crystalline powder with a melting point of approximately 151–154 °C and is very soluble in water. Piracetam is essentially non-ionizable at physiological pH. It was developed by Corneliu E. Giurgea and colleagues at UCB Pharma, Belgium, and was introduced commercially in Europe under the brand name Nootropil.[8,9] Its precise mechanism of action is not fully established, but it is thought to influence neuronal membrane properties and neurotransmission, including cholinergic and glutamatergic pathways. Following oral administration, piracetam is rapidly and almost completely absorbed, with bioavailability approaching 100%. It undergoes minimal hepatic metabolism and is eliminated predominantly unchanged through the kidneys, with an elimination half-life of approximately 5 hours in healthy adults; therefore, dose adjustment may be required in renal impairment. Piracetam is administered orally and, in some countries, by parenteral routes.[10] Its approved therapeutic indications vary between countries; in the UK, it is licensed as an adjunctive treatment for cortical myoclonus. Reported adverse effects include nervousness, agitation, irritability, anxiety, headache, dizziness, sleep disturbances, and gastrointestinal symptoms. Caution is particularly required in patients with renal impairment or

increased risk of bleeding. In India, the exact first approval date of piracetam as a standalone drug is not clearly established in currently accessible CDSCO records; however, CDSCO records document approval of piracetam-containing fixed-dose combinations, including citicoline sodium 500 mg + piracetam 800 mg, approved on 17 July 2015. [11,12]

UV SPECTROSCOPIC METHODOLOGY

Collection of reagents and solvents:

Piracetam API was received as a gift sample from Linux Life Sciences Pvt. Ltd., Puducherry, India and it was used as the reference standard for the analytical study. Piracetam tablets marketed under the brand name Cognitam-400, containing 400 mg of piracetam per tablet, were procured from a local pharmacy and used as the pharmaceutical dosage-form sample for UV spectrophotometric analysis. Distilled water was used as the solvent and diluent throughout the experimental procedure. Standard laboratory glassware, including volumetric flasks, pipettes, beakers, and measuring cylinders, was used for sample preparation and dilution. The piracetam tablets were accurately weighed, finely powdered, and an appropriate quantity of the powdered sample was transferred into a volumetric flask. The required volume was made up with distilled water to obtain the desired concentration for UV spectrophotometric analysis. The prepared solutions were analysed using a calibrated UV–Visible spectrophotometer with matched quartz cells.

Apparatus and Software:

An analytical weighing balance (Shimadzu AUX-220) was used for accurate weighing of the drug and tablet samples. An ultrasonic sonicator (Equitron, 230 V AC, 50 Hz) was employed for proper dissolution and extraction of the samples. A vacuum pump (Super Fit) and filtration kit (Tarsons) were used for sample filtration. 0.45 µm nylon membrane filters (Merck Millipore) were used for the filtration of solvents and sample solutions. The wavelength detection and UV spectrophotometric analysis were carried out using a double-beam UV–Visible spectrophotometer (Shimadzu UV-1800).

Preparation of Standard and Working Solutions of Piracetam:

The standard stock solution of piracetam (Stock-I) was prepared by accurately weighing 25 mg of piracetam and transferring it into a 25 mL volumetric flask. The drug was dissolved in distilled water, and the volume was made up to the mark with the same solvent to obtain a final concentration of 1000 µg/ml. The prepared stock solution was then sonicated for 5 minutes using a sonicator to ensure complete dissolution and uniformity. A secondary stock solution (Stock-II) having a concentration of 100 µg/ml was prepared by accurately transferring 10 mL of Stock-I into a 100 mL volumetric flask. The solution was diluted up to the mark with distilled water and mixed thoroughly.

From Stock-II, six working standard solutions of piracetam having concentrations of 10, 20, 30, 40, 50, and 60 µg/mL were prepared by appropriate dilution with distilled water. The required volume of Stock-II was transferred into individual volumetric flasks and diluted up to the respective final volume with distilled water. The prepared working standard solutions were then sonicated for 5 minutes to ensure homogeneity. The absorbance of each working standard solution was subsequently measured using a UV–Visible spectrophotometer at the predetermined wavelength of maximum absorption (λ max) of piracetam, using distilled water as the blank. The absorbance values obtained for the different

concentrations were used to construct the calibration curve of piracetam by plotting absorbance against concentration.

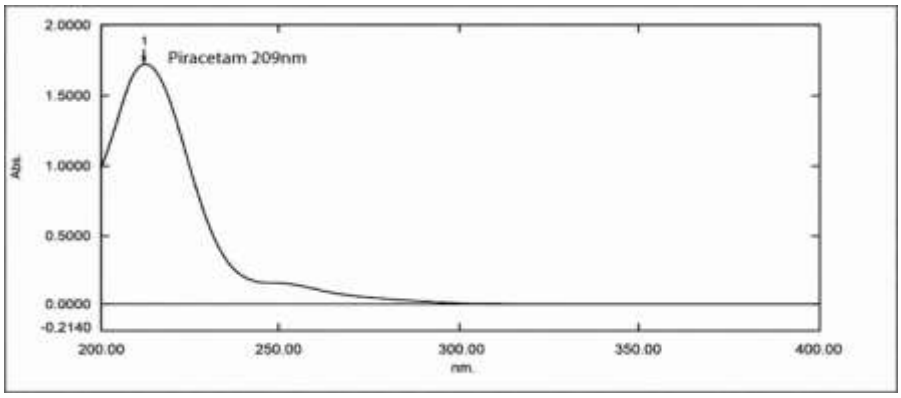

Figure 2: UV Absorption maxima of piracetam

VALIDATION PARAMETERS:[13]

Linearity

By Using the prepared working standard solution of piracetam, six standard solutions having concentrations of 10, 20, 30, 40, 50, and 60 µg/mL were prepared separately by appropriate dilution with distilled water. For each concentration, six replicate solutions were prepared independently using distilled water as the diluent.

The absorbance of each prepared working solution of piracetam was measured using a UV–Visible spectrophotometer at a wavelength of 209 nm, with distilled water used as the blank. Six replicate measurements were performed for each concentration, and the corresponding absorbance values were recorded. The mean absorbance values obtained were used to construct the calibration curve of piracetam by plotting absorbance versus concentration. The calibration curve was subsequently evaluated for its linearity over the selected concentration range.

The absorbance of each prepared standard solution was measured using a UV–Visible spectrophotometer at a wavelength of 209 nm, with distilled water used as the blank. The absorbance values obtained for the six replicates at each concentration were recorded and used for the construction of the calibration curve of piracetam, by plotting absorbance against the corresponding concentration.

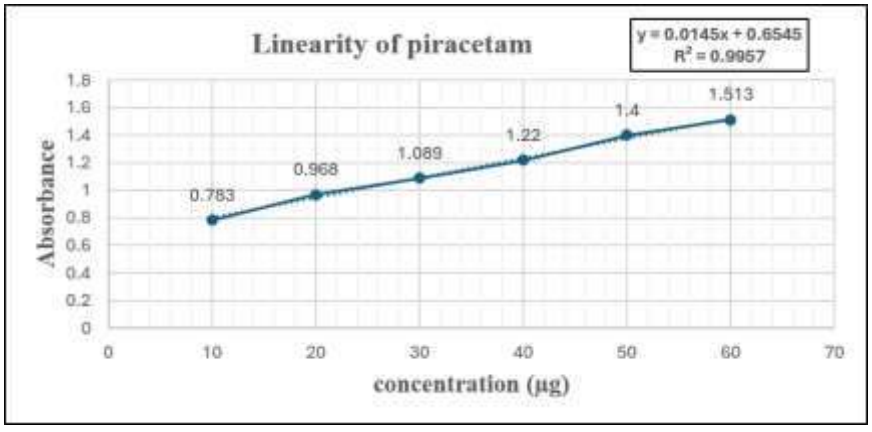

Figure 3: Linearity graph of Piracetam

Precision

The precision of the assay was evaluated in terms of intra-day and inter-day variation in the peak area of piracetam. A standard drug solution at a concentration of 40 µg/mL was analyzed six times on the same day to determine intra-day precision. For inter-day precision, the same concentration of the drug solution was analysed six times on each of two different days. The precision was expressed as percentage relative standard deviation (%RSD), calculated from the mean and standard deviation of the obtained peak-area values. The low %RSD values indicated good precision and reproducibility of the analytical method.

Accuracy

The accuracy of the proposed analytical method was determined by the standard addition method at three concentration levels, namely 80%, 100%, and 120%. The required quantities of pure piracetam were added to a fixed quantity (25 mg) of the formulation. The accuracy solutions were prepared using methanol as the diluent.

The following quantities were used for the preparation of the accuracy solutions:

- 80% Accuracy Level: 20 mg of pure piracetam was added to 25 mg of the formulation.
- 100% Accuracy Level: 25 mg of pure piracetam was added to 25 mg of the formulation.
- 120% Accuracy Level: 30 mg of pure piracetam was added to 25 mg of the formulation.

The prepared solutions were subsequently diluted as required and analysed using the proposed UV–Visible spectrophotometric method. The accuracy of the method was evaluated by calculating the percentage recovery of piracetam at each concentration level.

Robustness

According to the International Council for Harmonisation (ICH), robustness is the ability of an analytical procedure to remain unaffected by small and deliberate variations in method parameters, thereby demonstrating the reliability of the method under normal operating conditions. The robustness of the proposed UV–Visible spectrophotometric method for the determination of piracetam was evaluated by introducing a deliberate variation in the wavelength. The absorbance of the standard piracetam solution was measured at 208, 209, and 210 nm, corresponding to a variation of ±1 nm from the selected analytical wavelength of 209 nm. The standard drug solution was analysed under the same experimental conditions at each selected wavelength, and the corresponding absorbance values were recorded. The results obtained at the different wavelengths were compared to assess the effect of the deliberate wavelength variation on the analytical response. The method was considered robust if the change in wavelength did not produce a significant variation in the absorbance response or adversely affect the analytical results.

Limit of detection and limit of quantification

The LOD and LOQ of piracetam were determined by UV–Visible spectrophotometry using the signal-to-noise approach. Standard solutions of piracetam at low concentrations were analysed and their absorbance responses were compared with the blank response. The LOD was considered at a signal-to-noise ratio of approximately 3:1, while the LOQ was considered at a signal-to-noise ratio of approximately 10:1.

RESULT AND DISCUSSION:

Results:

1. Linearity

The linearity study for piracetam was performed over a concentration range of 10–60 µg/ml. The required concentrations were prepared from the working standard solution using distilled water as the diluent. Standard solutions at concentrations of 10, 20, 30, 40, 50, and 60 µg/ml were prepared separately. Six replicate dilutions of each concentration were prepared and analysed using a UV–Visible spectrophotometer at 209 nm, with distilled water used as the blank. The absorbance of each solution was measured and recorded. The mean absorbance values were calculated for each concentration. The calibration curve was constructed by plotting the mean absorbance values against the corresponding concentrations of piracetam. The linearity of the method was evaluated based on the linear regression equation and correlation coefficient (R^2) obtained from the calibration curve.

Table 1: Linearity data for Piracetam

Linearity of Piracetam	
Concentration (µg/ml)	**Absorbance**
10	0.783
20	0.968
30	1.089
40	1.22
50	1.4
60	1.513

2. Precision

The precision of the analytical method was studied by analysis of multiple sampling of a homogenous sample. The inter-day (between 2 days) and intraday (on the same days: morning and evening) precision were carried out. The variation of results was calculated and % RSD was determined.

Table 2: Intraday and Interday Precision Data for Piracetam

Precision Sample	Morning	Afternoon	Day-1	Day-2
Piracetam 40 µg/ml – Replicate 1	1.214	1.237	1.226	1.241
Piracetam 40 µg/ml – Replicate 2	1.229	1.208	1.239	1.218
Piracetam 40 µg/ml – Replicate 3	1.221	1.243	1.214	1.232
Piracetam 40 µg/ml – Replicate 4	1.196	1.225	1.241	1.205
Piracetam 40 µg/ml – Replicate 5	1.235	1.216	1.229	1.244
Piracetam 40 µg/ml – Replicate 6	1.207	1.231	1.218	1.223
Average	1.2170	1.2267	1.2278	1.2272
SD	0.01438	0.01309	0.01087	0.01477
%RSD	1.182%	1.067%	0.885%	1.204%

3. Accuracy

The accuracy for estimation of Telmisartan and Azelnidipine using methanol was determined by adding a known amount of the analyte. The accuracy was calculated from the test results as the percentage of the analyte recovered by the assay.

Table 3: Accuracy for Piracetam

PIRACETAM			
Level of Percentage recovery	80%	100%	120%
Amount present (mg/tablet)	25	25	25
Amount of standard drug added (mg)	20	25	30
Absorbance	1.081	1.232	1.376
	1.090	1.235	1.380

	1.096	1.237	1.383
Mean	1.089	1.235	1.380
Standard Deviation	0.00755	0.00252	0.00361
RSD	0.6933	0.204	0.261
Total amount recovery (mg)	44.97	50.04	49.99
% Recovery	99.85%	100.08%	99.98%

4. Limit of detection (LOD) and Limit of quantification (LOQ)

LOD and LOQ were calculated according to ICH recommendations where the approach is based on the signal-to-noise ratio. Chromatogram signals obtained with known low concentrations of analytes were compared with the signals of blank samples. A signal-to-noise ratio of 3:1 and 10:1 was considered for calculating LOD and LOQ respectively.

Table 4: LOD and LOQ for Piracetam

Name of the drug	LOD µg/ml	LOQ µg/ml
Piracetam	4.53 µg/ml	13.73 µg/ml

5. Robustness

The robustness of an analytical procedure describes its capability to remain unaffected by small and deliberate variation in the chromatographic conditions and is found to be unaffected by small variation ±0.1ml/min in wavelength results are shown in the table.

Table 5: Robustness for Piracetam

Wavelength (nm)	Absorbance
208	0.779
209	0.783
210	0.780

The absorbance values show only a small variation when the wavelength was deliberately changed by ±1 nm from the selected wavelength of 209 nm. The mean absorbance is approximately 0.783, indicating that the change in wavelength had no significant effect on the analytical response. Therefore, the proposed UV–Visible spectrophotometric method can be considered robust with respect to wavelength variation.

The analytical method for Piracetam was optimized to establish suitable experimental conditions that provide accurate, precise, sensitive, and reproducible results. Different analytical parameters such as wavelength, solvent/diluent, concentration range, and robustness were evaluated during method development. Based on the optimization studies, distilled water was selected as the suitable diluent and 209 nm was selected as the optimum detection wavelength for Piracetam. The optimized method showed good linearity over the range of 10–60 µg/mL with an R^2 value of 0.9993. The method also demonstrated satisfactory precision, accuracy, sensitivity, and robustness, confirming the suitability of the optimized conditions for quantitative estimation of Piracetam by UV–Visible spectrophotometry.

Table 6: Optimum Conditions of UV Spectroscopic Method of Piracetam

Parameter	Optimized condition for Piracetam
Analytical method	UV–Visible spectrophotometry
Detection wavelength [λ max (nm)]	209nm
Solvent/Diluent	Distilled water
Linear Range (µg/ml)	10-60
Correlation Coefficient (r^2)	0.9957
Limit of Detection (µg/ml)	4.53
Limit of Quantification (µg/ml)	13.73
Precision (%RSD)	0.885–1.204%
Accuracy (% recovery)	99.85–100.08%

Robustness	Robust at 208–210 nm
Blank	Distilled water

DISCUSSION:

The developed UV–Visible spectrophotometric method for the estimation of Piracetam was evaluated for linearity, precision, accuracy, robustness, and sensitivity. The method showed good linearity over the concentration range of 10–60 µg/mL at 209 nm, with a correlation coefficient (R^2) of 0.9957, indicating an excellent linear relationship between concentration and absorbance. The precision study showed low %RSD values ranging from 0.885–1.204% for intra-day and inter-day measurements, demonstrating good repeatability and reproducibility of the method. The accuracy study showed percentage recoveries of 99.85%, 100.08%, and 99.98% at 80%, 100%, and 120% levels, respectively. These results indicate that the method is accurate for the estimation of Piracetam. The robustness study performed at 208, 209, and 210 nm showed only minor variations in absorbance (0.779–0.780), indicating that the method was not significantly affected by small changes in wavelength. The reported LOD and LOQ were 4.53 µg/mL and 13.73 µg/mL, respectively, indicating adequate sensitivity for quantitative analysis within the validated range. Overall, the developed UV–Visible spectrophotometric method was found to be simple, accurate, precise, linear, sensitive, and robust, and can be used for the routine estimation of Piracetam in pharmaceutical dosage forms.

CONCLUSION:

In conclusion, Piracetam is an important nootropic drug that requires reliable and reproducible analytical methods for its quantitative estimation in pharmaceutical formulations. UV–Visible spectrophotometry provides a simple, rapid, economical, and easily accessible analytical technique for the determination of Piracetam based on its absorption characteristics. In the present study, the developed method demonstrated satisfactory analytical performance with good linearity, precision, accuracy, sensitivity, and robustness. The method showed a linear response over the selected concentration range and provided consistent absorbance measurements with good recovery of the drug. The low variation observed during precision and robustness studies further indicated the reliability and reproducibility of the method. Therefore, the developed UV–Visible spectrophotometric method can be considered a suitable and practical approach for the routine quantitative estimation and quality control of Piracetam in pharmaceutical dosage forms..

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