# A METHOD FOR SPECTROPHOTOMETRIC DETERMINATION OF TIANEPTINE IN BULK AND CAPSULE DOSAGE FORM

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## *Abstract*

*Tianeptine, an atypical antidepressant drug, enhances the synaptic reuptake of serotonin, without affecting norepinephrine and dopamine uptake, while it lacks affinity for neurotransmitter receptors. We herein, report a new, simple, cost effective, sensitive and reproducible spectrophotometric method for the determination of the Tianeptine. Spectrophotometrical determination performed at 220 nm. The method was validated with respect to linearity, accuracy, precision and robustness. The method was found to be linear in a wide concentration range with good correlation coefficient (0.991). The suggested method was applied to the determination of the drug in capsules. No interference could be observed from the additives in the capsules. The percentage recovery was found to be with in limit. The developed method was successfully validated and applied to the determination of Tianeptine in bulk and capsule dosage form.*

***Keywords**: Tianeptine, sensitive, capsules.*

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## Introduction

Tianeptine is marketed for the treatment of major depression. This peculiar atypical antidepressant has drawn much attention, challenging traditional monoaminergic hypotheses of depression [1]. Structurally tianeptine can be viewed as a modified tricyclic antidepressant. Tianeptine exists as two isomers, of which the *l* isomer seems to be the therapeutically active form [2]. Tianeptine enhances serotonin uptake [3-5] (i.e. opposite to the action of other antidepressants such as the serotonin reuptake inhibitors), without significant activity at any receptors or other monoamine transporters. Furthermore tianeptine has been shown to be clinically effective, also in severe depression, in elderly and during alcohol withdrawal, and to possess anxiolytic properties, while it lacks common side effects of most antidepressants, notably sedative effects or sleep disruption, anti cholinergic effects, sexual dysfunction or adverse cardiovascular effects [6-10]. The present study focused on to develop a rapid, efficient and reproducible method for the analysis of Tianeptine in bulk and capsule dosage form.

## Material and Method

### Apparatus

A UV-visible double beam spectrophotometer (Model 1601; Shimadzu, Japan) with 1 cm matched quartz cells and UV probe software version 2.10 was used for the spectrophotometric method.

### Materials and reagents

All chemicals and materials were of analytical grade and were purchased from Merck (Mumbai, India). All solutions were freshly prepared in double distilled water. A pure sample of Tianeptine was purchased from Vivan Life Science Pvt. Ltd., Thane, India.

**Preparation of standard stock solutions**

A stock solution of drug having a concentration of 1 mg/mL (i.e.1000 µg/mL) was prepared by dissolving in methanol. Aliquots of the stock solution were further diluted in distilled water and were scanned in the wavelength at 220 nm.

**Standard plot**

The calibration graph was obtained by plotting the absorbance values of the drug against corresponding concentration values and compliance with Beer Lambert's law was assessed.

**Analysis of capsule formulation**

The contents of twenty capsules were mixed and weighed accurately. Powder equivalent to specification transferred into a 100 mL volumetric flask, dissolved in water and sonicated for 5 min., the volume was made up with water, shaken well for 5 min. and then filtered, further absorbance value noted in triplicate at 220 nm against reagent blank.

## Results and Discussion

The method was validated with respect to linearity, accuracy and precision **Table 1**. The regression plots compliance with Beer Lambert's law (linearity) for wide concentration range with a correlation coefficient ($r^2$) of 0.991. Precision were investigated by analyzing different concentrations of drug in three independent replicates on the same day (intra-day precision) and on three consecutive days (inter-day precision). The data is represented as relative standard deviation (RSD) and results have been shown in **Table 1**. Low relative standard deviation (RSD) values for intra-day and inter-day analysis indicate good precision of the method. Robustness was examined by evaluating the small variations in different experimental conditions such as heating temperatures (±2°C), working wavelengths, volume and concentration of reagents. Three replicate determinations at six different concentration levels of the drugs were carried out. The within-day RSD values were found to be with in limit indicating that the proposed method has reasonable robustness **(Table 1)**. The stability of the final sample solutions was examined by their absorbance values and responses were found to be stable for at least 6 hours at room temperature. Analysis of formulation (capsules) carried out by the proposed method and revealed that there is close agreement between the results obtained by the proposed methods and the specified claim. The accuracy of the method signifies the closeness of the measured value to the true value for the sample. To determine the accuracy of the proposed method, different levels of drug concentrations were prepared from independent stock solutions and analyzed. Method involved the addition of different concentrations of pure drug to a known pre analyzed dilution of the pure drug as well as formulation sample and the total concentration was determined using the proposed method. Recovery values lies with in specified limit **(Table 2)**.

**Table 1. Result of validation parameter**

| | | |
|---|---|---|
| **Absorption max.** | 220nm | |
| **Accuracy** | 100.11 ± 1.12 | |
| **Precision** | Intra-day = 0.61<br>Inter-day = 0.6 | |
| **Robustness** | Less than 1% | |
| **% Purity** | 99.7% | |
| **Precision** | RSD (%) | |
| | Within day, n = 3 | Between day, n = 3 |
| | 0.47 | 0.004 |

**Table 2. Results of recovery studies**

| Initial Conc. (mg/mL) | Amount of drug added | Amount recovered | RSD (%) |
|---|---|---|---|
| 1 | 50 | 49.5 | 0.17 |
| 1 | 100 | 99.5 | 0.28 |
| 1 | 200 | 199.1 | 0.43 |

## Conclusion

The method proposed is simple, rapid, inexpensive and sensitive for the determination of Tianeptine in bulk as well as in capsule form. There is no requirement of any sophisticated apparatus as in chromatographic methods. Omission of an extraction step with organic solvents is an added advantage. The method has been validated in terms of its sensitivity, simplicity, reproducibility, precision, accuracy and stability; suggesting its suitability for the routine analysis of Tianeptine in pure form as well as pharmaceutical formulations without interference from excipients.

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