Available online at www.scholarsresearchlibrary.com

Scholars Research Library

Der Pharmacia Lettre, 2016, 8 (7):21-26
(http://scholarsresearchlibrary.com/archive.html)

ISSN 0975-5071
USA CODEN: DPLEB4

Development of UV spectrophotometry and HPTLC techniques for Tiapride in formulation

B. Chitra* and T. K. Ravi

Department of Pharmaceutical Analysis, College of Pharmacy, SRIPMS, Coimbatore, Tamil Nadu, India

---

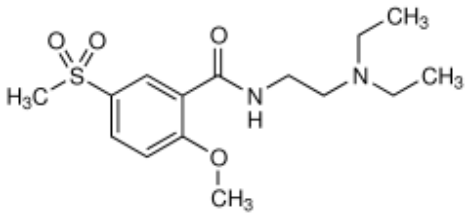
ABSTRACT

Simple, accurate and precise UV spectrophotometric and chromatographic methods have been developed and validated for the determination of tiapride in its pharmaceutical formulation. The two analytical methods UV spectroscopy and HPTLC were developed and validated according to the experimental conditions of the study. The UV spectroscopic analysis was performed using methanol as solvent and detection was done at 235 nm. The HPTLC method was performed using Pre-coated silica gel G60 F_{254} plate using the mobile phase chloroform, methanol and ammonia in the ratio of 9:1:0.1 v/v/v followed by analysis at 240nm.Linearity was found over the concentration range of 3- 18 µg/ml for UV method and 10 – 50 ng/spot for HPTLC method with correlation coefficient 0.9996 and 0.9992 respectively. Repeatability, Intraday and Interday studies shows % RSD less than 2, which indicates that the developed methods are precise. When compared to reported methods these methods are more sensitive and cost effective. They were successfully employed for the determination of tablets containing tiapride hydrochloride.

Key words: Tiapride, RP-HPLC, HPTLC, method development and validation.

INTRODUCTION

Tiapride hydrochloride is used as an atypical neuroleptic agent. Tiapride is a selective dopamine D_2 receptor antagonist, which selectively blocks dopamine D_2 and D_3 receptor and exhibits the pharmacological activity in the brain. It is widely used in the management of schizophrenia and behavioral disorders. It is used to treat a variety of neurological and psychiatric disorders including dyskinesia, alcohol withdrawal syndrome, negative symptoms of psychosis, agitation and aggression in the elderly. In addition to its antipsychotic action, substituted benzamides present antiemetic, antidyskinetic and antihypertensive action. Chemically it is N-[2-(diethylamino)ethyl]-2-methoxy-5-methylsulfonylbenzamide [1].



The literature survey revealed there are few analytical methods reported for the determination of tiapride hydrochloride [2-6] This paper proposes two new analytical methods viz UV spectroscopy and high performance thin layer chromatography which are simple, sensitive, reliable and cost effective for the determination of tiapride hydrochloride in tablet formulation.

MATERIALS AND METHODS

Chemicals and reagents:
The sample of tiapride hydrochloride was received from Rajesh chemicals limited, Mumbai, India with certificate of analysis. Methanol, chloroform and other solvents were supplied by S.D. Fine chemicals Ltd India and Qualigens fine chemicals Ltd, Mumbai, India. Tiapride hydrochloride tablet dosage forms were purchased from the local market.

Instrumentation and analytical conditions:
The UV spectroscopic analysis was performed on Jasco V – 630 UV/Vis Spectrophotometer and a pair of 1cm quartz cuvette was used to measure the absorbance of the solutions. The solvent used in this method was methanol and the λ_{max} was 235 nm.

The HPTLC method was performed using CAMAG TLC scanner, Linomat V sample applicator connected to a nitrogen cylinder, a twin trough chamber with WINCATS software. Pre-coated silica gel G60 F_{254} plate was used as stationary phase. The mobile phase selected for the study comprises chloroform, methanol and ammonia in the ratio of 9:1:0.1 v/v/v. The optimized chamber saturation time was 15 minutes. The wavelength at which the spots were analyzed was 240 nm.

Preparation of stock solutions and working standard solutions:
UV method:
Tiapride hydrochloride (10 mg) was accurately weighed and dissolved in methanol and the final volume was adjusted to 10ml with methanol to prepare 1000 µg/ml stock solution of the drug. The working standard solutions of concentration ranging from 3 µg/ml to 18 µg/ml were prepared from the stock solution and scanned in the UV region 200 to 400 nm and the absorbance was measured at 235 nm. The UV spectrum of tiapride hydrochloride is shown in figure 1.

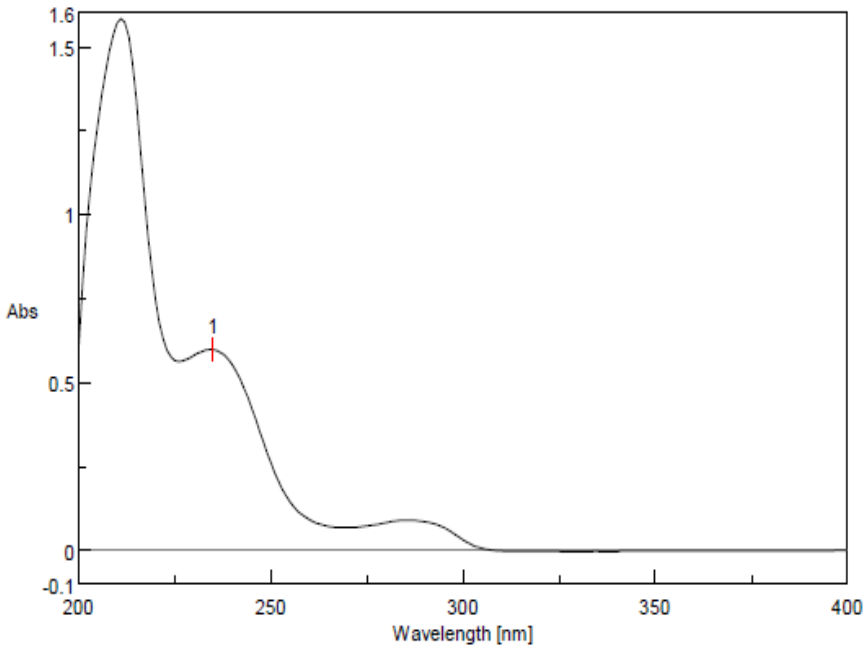


Figure. 1. UV absorbance spectra of Tiapride Hydrochloride

HPTLC method:
Tiapride hydrochloride (10 mg) was accurately weighed and dissolved in ethanol and the final volume was adjusted to 10ml with ethanol to prepare 1000 µg/ml stock solution of the drug. A 100 µg/ml of solution was prepared from the stock solution. From this stock solution 10 µl to 50 µl were spotted on HPTLC plate. A typical densitogram of tiapride hydrochloride is shown in figure 2.

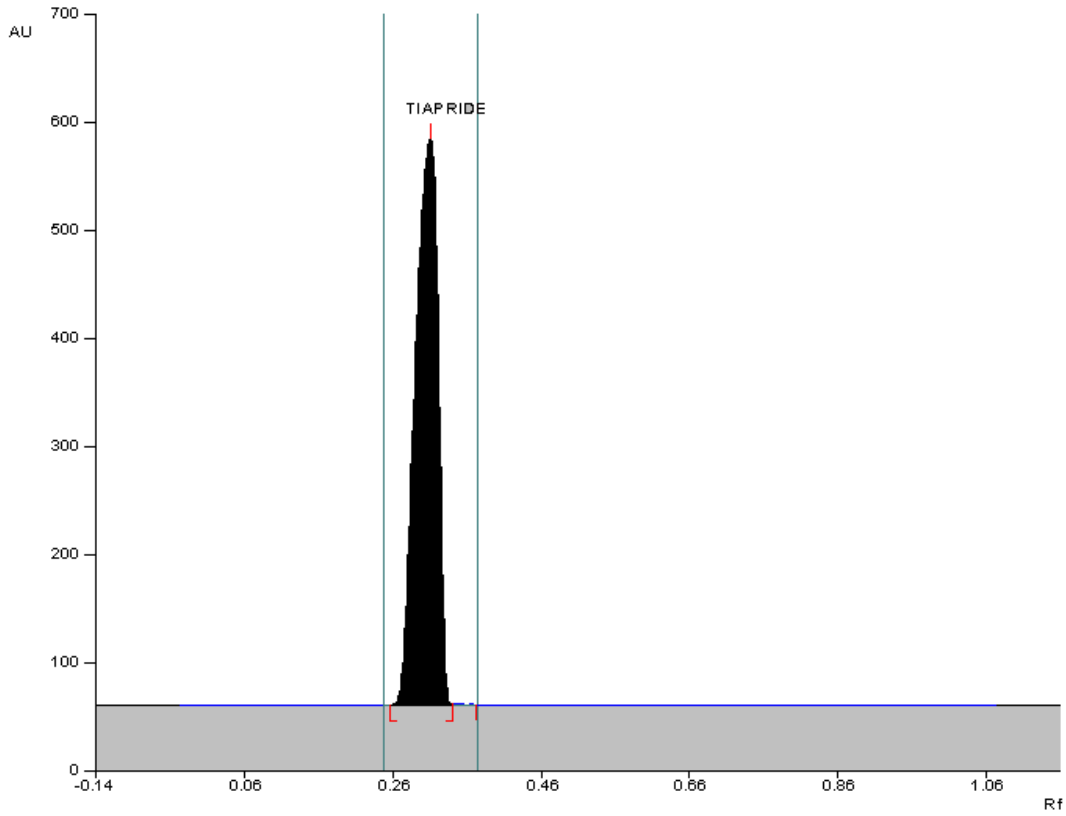


Figure.2.Densitogram of Tiapride Hydrochloride

Analytical method validation:
The developed methods were validated as per ICH Q2R1 guidelines [8]. The Parameters validated were linearity, accuracy, precision and repeatability.

Linearity:
Six different concentrations of the drug were prepared and checked for linearity in UV spectroscopic method. Tiapride hydrochloride showed good linearity in the concentration range of 3-18 µg/ml and the calibration curve was plotted between absorbance and different concentration of the drug. Calibration graph for HPTLC was obtained by plotting concentration vs peak area of drug ranging from 10 µg -50 µg/ spot. The calibration data and standard curves for tiapride hydrochloride are shown in table 1 and figure 3 and 4.

Table 1: Calibration data for UV and HPTLC

Parameters	UV	HPTLC
Linearity range	3 – 18 µg/ml	10 -50 ng/ml
Correlation coefficient (r)	0.9996	0.9992

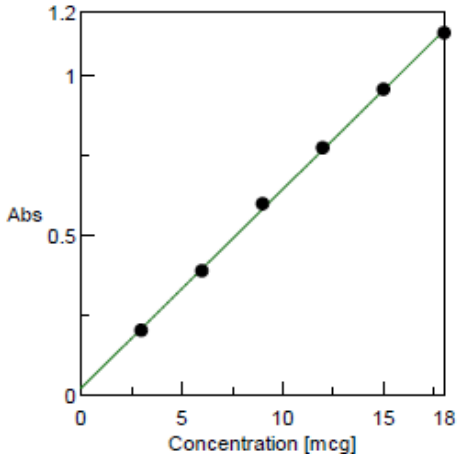


Figure.3: Standard graph of Tiapride hydrochloride obtained by UV

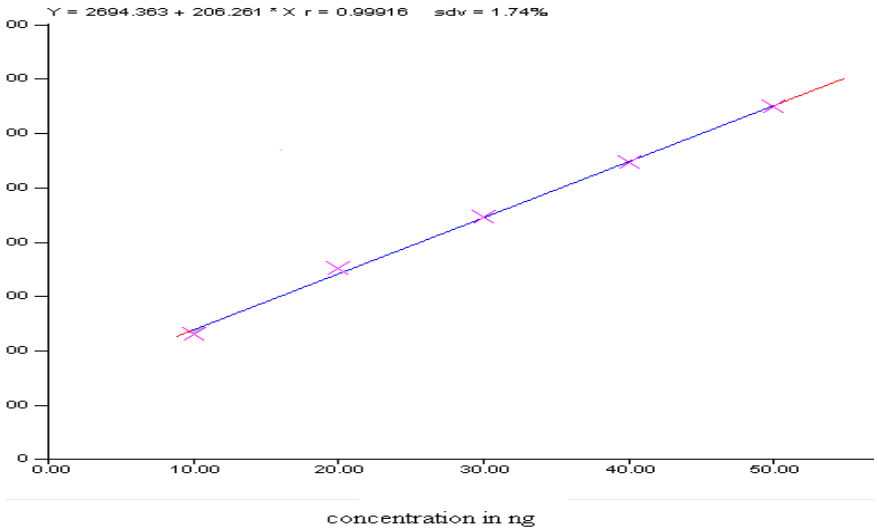


Figure.4: Standard graph of Tiapride hydrochloride obtained by HPTLC

Precision: Precision of the method was carried out by intra and inter day precision studies. Intraday precision was found by analyzing three concentrations of standard tiapride hydrochloride in the linearity range for three times on the same day. Inter- day precision was carried out on three different days using three replicates. Results were calculated and expressed in terms of % RSD. The results are tabulated in table no: 3 and 4 for the two methods developed.

Table 2 : Intraday and Interday precision for UV spectroscopic method

Concentration (µg/ml)	Absorbance		% RSD	
	Intraday	Interday	Intraday	Interday
9	0.5970	0.5968	0.33	0.20
	0.5963	0.5956		
	0.5932	0.5943		
12	0.7719	0.7736	0.17	0.13
	0.7745	0.7723		
	0.7726	0.7742		

Table 3 : Intraday and Interday precision for HPTLC method

Concentration (ng/spot)	Peak area		% RSD	
	Intraday	Interday	Intraday	Interday
20	7027.2	7023.1	0.10	0.23
	7036.5	7054.3		
	7042.4	7049.6		
30	8907.9	8915.8	0.07	0.13
	8921.2	8939.5		
	8918.6	8926.7		

REPEATABILITY:
Repeatability of measurement of absorbance in UV was carried out using six replicates of same drug concentration. Absorbance was measured six times and % RSD was calculated. Results are tabulated in table 4.

Repeatability of measurement of peak area in HPTLC was carried out using six replicates of same spot. These were analyzed by spotting 10 ng of standard drug solution on a precoated silica gel plate, followed by development of plate and recording the peak area after each scanning (6 times) without adjusting the position of plate and % RSD was calculated. The results are tabulated in table 5.

Table 4: Repeatability of measurement for UV spectroscopic method

Concentration (µg/ml)	Absorbance	% RSD
9	0.5970	0.44
	0.5936	
	0.5982	
	0.5957	
	0.5969	
	0.5910	

Table 5 : Repeatability of measurement for HPTLC method

Concentration (ng/spot)	Peak area	% RSD
10	4599.2	0.56
	4576.5	
	4585.7	
	4524.3	
	4558.5	
	4563.8	

Analysis of tablet formulation:
Twenty tablets of tiapride hydrochloride each containing 25mg/ tablet were taken and average mean was calculated. They were pulverized to fine powder in a glass mortar and pestle. The quantity of powder equivalent to 10 mg was transformed accurately to 10 ml volumetric flask. It was dissolved by adding methanol (for UV) and ethanol (for HPTLC). After sonication, the volume was made upto 10 ml using respective solvent. They were further diluted and analyzed by the developed UV and HPTLC methods. The amount of tiapride hydrochloride present was calculated and presented in table 6.

Table 6 : Analysis of formulation by UV and HPTLC methods

Trade name	Labeled claim mg/tablet	Calculated labeled claim mg/tablet		% label claim		% RSD*	
		UV	HPTLC	UV	HPTLC	UV	HPTLC
Tiaprex	10	9.813	9.921	98.13	99.21	0.53	0.47

** An average of 6 determinations*

Accuracy: Accuracy of the method was evaluated by standard addition technique. To the preanalyzed formulation standard tiapride hydrochloride was added at 50% and 100% levels. The mixture was reanalyzed by the two methods and % accuracy was calculated and shown in table 7

Table 7: Recovery study

Level	% Recovery		% RSD	
	UV	HPTLC	UV	HPTLC
50%	99.89	100.12	0.132	0.441
100%	98.93	100.45	0.314	0.215

RESULTS AND DISCUSSION

The two analytical methods UV spectroscopy and HPTLC were developed and validated according to the experimental conditions of the study. Linearity was found over the concentration range of 3- 18 µg/ml for UV method and 10 – 50 ng/spot for HPTLC method with respective correlation co efficient 0.9996 and 0.9992 respectively. Repeatability, Intraday and Interday studies shows % RSD less than 2, which indicates that the developed method is precise. The tiapride solution was found stable for 6 hrs in room temperature and 14 hrs in refrigeration. The drug on developed plates was stable for 8 hours. When compared to reported methods (2-6), these methods are more sensitive and cost effective. They were successfully employed for the quantitative determination of tablets containing tiapride hydrochloride and % label claim was satisfiable.

CONCLUSION

The developed UV and HPTLC analytical methods are simple, rapid, accurate and precise for the estimation of tiapride hydrochloride. As the method is simple and inexpensive they can be used in laboratories which lack sophisticated instruments like LC-MS/MS and GC-MS/MS which are costly and time consuming compared to UV and HPTLC methods and hence can be used for the routine analysis of tiapride in bulk and tablet dosage forms and quality control analysis.

Acknowledgements
The authors are thankful to S.N.R Sons charitable trust, Coimbatore for providing all the facilities to carry out the research work.

REFERENCES

[1] Nobilis M, Vybíralová Z, Szotáková B, Sládková K, Kuneš M, Svoboda Z. *J Chromatogr B Analyt Technol Biomed Life Sci*, **2011**, 879(32):3845-52.
[2] Nawal A. Alarfaj, Azza A. Mostafa, Zinah A. ALghamdi. *Asian Journal of Chemistry*, **2013**, 25(13) 7433-7436.
[3] Panchal Vihang U, K.S.Muralikrishna, Chauhan Prakash S, Dudhat Pradip R., Mistry Dhaval H, Desai Lay H, Shah Jemin R. *Indo American Journal of Pharmaceutical Research*,**2013**,2(12),1492-1502.
[4] Metwally FH, Abdelkawy M, Abdelwahab NS.*JAOAC Int*,**2007**,90(6),1554-65.
[5] Katarina Rankovića, Slavica Filipića,Danica Agbaba. *Journal of Liquid Chromatography & Related Technologies*, **2012**,35(10)
[6] Ya Moon, In Bok Paek , Hui-Hyun Kim, Hye Young Ji, Hye Won Lee, Hyoung-Geun Park ,Hye Suk Lee. *Arch Pharm Res*, **2004**, 27(9),901- 905.
[7] Zayed S. Anal Sci, **2011**, 27, 535-9.
[8] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH Guideline Q2 (R1): Validation of analytical procedures: text and methodology. Geneva, Switzerland; 19**9**4.
[9] United States Pharmacopeial Convention. General chapter 1225. Validation of compendial procedures.Rockville, United States Pharmacopeial Convention; **2009**.
[10] Boudreau SP, McElvain JS, Martin LD, *Pharmaceutical Technology* **2004**,28,54–66.