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UV Spectrophotometric Method for Determination of Cinitapride in Pure and its Solid Dosage Form

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Abstract: A new, rapid, precise, accurate and sensitive analytical method was developed for the UV spectrophotometric assay of cinitapride (CTP)**.** The drug obeyed the Beer's law and showed good correlation. It showed absorption maxima at 260 nm in methanol. The linearity was observed between 5-40 μg mL^{-1}. The results of analysis were validated by recovery studies. The recovery was more than 99%. The proposed method is the only method available for spectrophotometric determination of the drug. It is simple, precise, sensitive and reproducible and can be used for the routine quality control testing of the marketed formulations.

Keywords: UV Spectrophotometry, Cinitapride and Tablet analysis.

Introduction

Cinitapride, chemically 4-amino-*N*-[3-(Cyclohexan-1-yl-methyl)-4-piperidinyl]-2-ethoxy-5-nitrobenzamide (Figure 1), is a substituted benzamide gastroenteric prokinetic agent acting via complex, but synergistic effects on serotonergic 5-HT2 (inhibition) and 5-HT4 (stimulation) receptor and dopaminergic D2 (inhibition) receptors in the neuronal synapses of the myenteric plexi[1-3]. A survey of literature revealed a polarographic method[4] and LC-MS/MS methods for its determination in plasma[4,5]. No spectrophotometric method has been reported so far. Hence an attempt was made to develop simple and economical spectrophotometric methods with greater precision, accuracy, and sensitivity for the analysis of CTP in tablets.

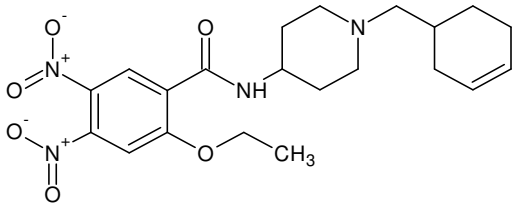

Figure 1. Chemical structure of cinitapride.

Experimental

The spectrophotometric measurements were carried out using An Elico UV/Visible double beam spectrophotometer SL-164 with 1 cm matched quartz cells.

Reagents

CTP was tested for purity by measuring its melting point and IR spectra and no impurities were found. Methanol used were of analytical grade.

Standard solutions

Standard stock solution of CTP (1000 μg mL^{-1}) was prepared in methanol. It was further diluted to obtain 5, 10, 20, 30 and 40 μg mL^{-1} with methanol. The absorbance was measured at 260 nm against methanol as blank. The calibration curve was plotted in the concentration range of 5 to 40 μg mL^{-1} of CTP in methanol.

Procedure for tablets

Twenty tablets were weighed accurately and triturated to fine powder. The powder equivalent to 10 mg CTP was weighed and transferred to 25 mL volumetric flask. To this 15 mL of methanol was added and sonicated for 15 minutes, then filtered through Whatman No. 42 filter paper. The residues were washed thoroughly with methanol and further diluted with methanol to 20 μg mL^{-1} concentration and the absorbance measured at 260 nm against methanol as a blank.

Results and Discussion

The UV spectrum of standard solutions of CPT in methanol was illustrated in Figure 2. The optical characteristics such as Beer's Law limit, molar absoptivity, Sandell's sensitivity, slope and intercept are summarized in Table 1. The assay and precision studies results for tablets containing CPT are shown in Table 2.

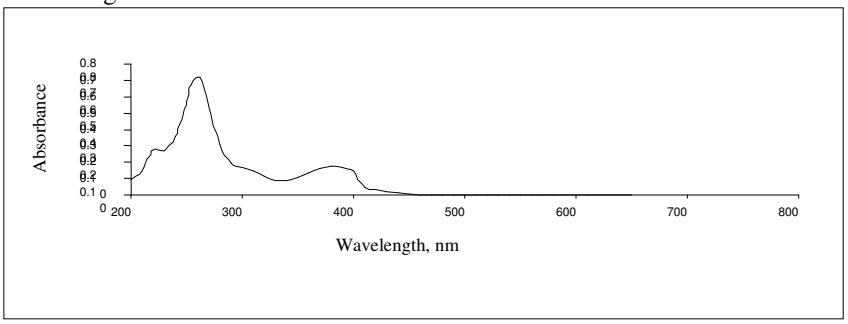

Figure 2. UV spectrum of cinitapride in methanol.

Table 1. Optical characteristics of proposed method.

Parameters		Values
λ_{max}, nm		260
Beer's law limit, μg mL^{-1}		5-40
Sandell's sensitivity, μg cm^{-2}/0.001 absorbance unit		2.5×10^{-5}
Molar absorptivity, L mol^{-1} cm^{-1}		1.7911×10^{4}
Regression equation (Y = a + bc)		
	Slope (b)	0.0239
	Intercept (a)	0.0082
Correlation coefficient (r^2)		0.9994

Validation

The assay of CPT was validated with respect to stability, linearity, precision and accuracy.

Stability

The standard stock solutions of CPT were stored, in two different conditions, at ±4 ^{0}C and at ambient temperature for one month. During this period, the solutions were analyzed with UV spectrophotometric method, the spectrum was compared with the spectrum of daily prepared standard solution, and no difference was obtained between them. It is decided that CPT is highly stable in the mentioned conditions.

Linearity and range

In developed UV method, calibration curve was linear in the range from 5 to 40 μg mL^{-1} of CPT.

Precision

Inter-day precision

This was done by analyzing formulation by same analyst for six days subsequently. The % RSD values are shown in Table 2.

Intra-day precision

This was done by analyzing formulation in same day for six times of individual preparation and observation. The % RSD and datas are shown in Table 2.

Table 2. Assay results and precision studies.

Sample	Labeled amount mg/ tab	Amount found in mg*	(%) label claim* ± S.D	Precision**		
				Repeatability	Inter-day	Intra-day
Cinitapride	1	1.006	100.54 ± 0.293	0.471	0.0349	0.0298

** Average of six determinations. **SD of five determinations.*

Accuracy

To ensure the accuracy and reproducibility of the results obtained, known amounts of pure drug was added to the previously analysed formulated samples and these samples were reanalyzed by the proposed method and also performed recovery experiments. The percentage recoveries thus obtained were given in Table 3.

Table 3. Recovery study.

Drug	Label Claim, mg/tab	Estimated Amount, mg/tab	Spike Level, %	Amount of drug added, mg	Amount of drug recovered, mg	Percentage recovery ± SD*
Cinitapride tablets	1	1.006	80	8.0	8.02	100.28±0.3374
			100	10.0	9.99	99.97±0.2967
			120	12.0	12.01	100.09±0.5428

**Mean of six determinations.*

Conclusions

The proposed method is found to be rapid, precise, accurate and sensitive. The statistical parameters and recovery study data clearly indicate the reproducibility and accuracy of this method. Analysis of the authentic sample containing CPT showed no interference from the common excipients. Hence, these methods could be considered for the determination of CPT in the quality control laboratories.

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