

A SENSITIVE SPECTROPHOTOMETRIC DETERMINATION OF CENTBUCRIDINE HYDROCHLORIDE IN BULK DRUG & PHAMACEUTICAL FORMULATIONS

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ABSTRACT

A new, simple, sensitive Spectrophotometric method in ultraviolet region has been developed for the determination of Centbucridine hydrochloride in bulk and in dosage form. Centbucridine Hydrochloride shows maximum absorbance at 247 nm with apparent molar absorptivity of 1.0781×10^4 l/mol.cm. Beer's law was obeyed in the concentration range of 5 to 50 $\mu\text{g/ml}$. Results of analysis were validated statistically and by recovery studies. The developed method was found to be sensitive, accurate, precise and reproducible and can be used for the routine quality control analysis of Centbucridine.

INTRODUCTION

Centbucridine hydrochloride, chemically 4-N-Butylamino-1, 2, 3, 4-Tetrahydroacridine Hydrochloride, is a local anaesthetic agent with a quicker onset of action (Beri *et al.*, 1997; Biswas *et al.*, 2003). It is a new drug and is not official in any Pharmacopoeia. Surgeons all over the country had been experiencing the need of more effective and safer low dose local anesthetics. The currently available local anesthetic agents were not very quick in action and the duration of anesthetic effect was also not very long. This compound is not only safer and more effective than the currently available local anesthetic, lignocaine but also has features that give it better acceptability. This drug is a totally new chemical moiety and has no relation whatsoever with lignocaine. Centbucridine is superior to lignocaine in many aspects. Centbucridine has been found to possess several desirable properties. As compared to lignocaine, it is 4 to 5 times more potent, its onset of action is much quicker, and the duration of action is longer. Due to its vasoconstrictor activity, it does not require simultaneous administration of adrenaline. It does not affect the cardiovascular parameters due to its moderate antihistaminic activity and is not likely to show skin sensitivity. Moreover, it can be used in patients showing hypersensitivity to lignocaine (Baveja and Singh, 1986; Beckett and Stenlake, 2002). Literature survey revealed that there is no UV-Spectrophotometric method for

determination of Centbucridine from bulk as well as dosage form. The present investigation reports a simple UV-Spectrophotometric method for the analysis of Centbucridine hydrochloride in bulk as well as in injections.

MATERIALS AND METHODS

A Systronics UV-Visible spectrophotometer-2401 PC with 1cm matched quartz cells was used. Pure Centbucridine hydrochloride was obtained as a gift sample from Themis Medicare Ltd. Mumbai. The injection vials of different batches were purchased from the market (recent manufactured). Centbucridine hydrochloride (10 mg) was accurately weighed and dissolved in distilled water so as to give a stock solution of concentration of 100 $\mu\text{g/ml}$. Aliquots of stock solution were transferred into series of 10 ml volumetric flasks and volume was adjusted with distilled water to give final concentrations of 5,10,...50 $\mu\text{g/ml}$. The absorbance was measured at 247 nm against distilled water as a blank. We have taken a scan from 190 nm to 390 nm and we found maximum absorbance at 247nm. The repeated experimentation revealed the same wavelenth to be the best suitable one. It is also studied that the said wavelenth is not interfering to the analysis of said product because of any extraneous factors like solvent, analysis condition.

The proposed method was applied to the analysis of commercially available Centbucridine hydrochloride

injection. A volume equivalent to 10 mg of Centbucridine hydrochloride was transferred into 100 ml volumetric flask. A small volume of distilled water was added and shaken well to dissolve. It was made up to volume and the solution is filtered. The filtrate was further diluted with distilled water to 10 µg/ml concentrations and the absorbance measured at 247 nm against distilled water as a blank.

Recovery studies were carried out by adding a known quantity of pure drug (1mg/ml) to the pre-analyzed formulations and the proposed method was followed. From the amount of drug found, percentage recovery was calculated.

RESULTS AND DISCUSSION

The proposed method of determination of Centbucridine hydrochloride showed molar absorptivity of 1.0781×10^4 l/mol.cm. Linear regression of absorbance on concentration gave the equation $y = 0.0162 + 0.0521x$ with a correlation coefficient of 0.9988. Relative standard deviation of 0.006, 0.005 and 0.002 (for each batch) were observed for analysis of six replicate samples, indicating precision and reproducibility. Centbucridine hydrochloride exhibits maximum absorption at 247 nm and obeyed Beer's law in the concentration range of 5 to 50 µg/ml. The results of analysis and recovery studies are presented in Table 1. The percentage recovery value 99.9, 99.6 and 99.7 (for each batch) indicates that there is no interference from the excipients present in the formulation.

Table 1: Results of assay and recovery studies

Pharmaceutical formulations	Label claim (mg)	Amount found*		% Recovery*	Standard deviation(±)	Coefficient of variation
		mg	%			
Batch A	5	4.98	99.60	99.9	0.0601	0.0492
Batch B	5	5.01	100.20	99.6	0.0752	0.0661
Batch C	5	5.01	100.20	99.7	0.0271	0.8041

* Mean of six determinations

CONCLUSION

The developed method was found to be sensitive, accurate, precise and reproducible and can be used for the routine quality control analysis of Centbucridine hydrochloride in bulk drug and pharmaceutical formulations. This method is not reported yet & tried for the first time. The method may have an impact on Pharmacological or Pharmaco-kinetic studies.

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