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RP-HPLC Estimation of Haloperidol and Trihexyphenidyl in Tablets

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Abstract: A method for the determination of haloperidol (HP) and trihexyphenidyl (THP) in tablets has been developed using reverse phase high performance liquid chromatography. The elution was done using a mobile phase consisting of methanol and water (70:30 v/v) on RP-C_{18} (250 x 4.6 mm) analytical column with flow rate 1 ml/min with detection at 220 nm. The elution time was 2.99 min for HP and 5.01 min for THP. The method was found suitable for routine quantitative estimation of haloperidol and trihexyphenidyl in tablets.

Key words: Haloperidol, Trihexyphenidyl, RP-HPLC

Introduction

Haloperidol is 4-[4-(4-chlorophenyl)-4-hydroxy-1-piperidyl]-1-(4-fluorophenyl)-butan-1-one and is an anti-dyskinetic and anti-psychotic drug; trihexyphenidyl is 1-cyclohexyl-1-phenyl-3-(1-piperidyl)-1-propanol and is an anti-dyskinetic and anti-parkinson drug.[1] Literature survey revealed that HPLC[2, 3] methods have been reported for the estimation of haloperidol and trihexyphenidyl individually and with other drugs in pharmaceutical dosage forms. The present work describes a simple, isocratic RP-HPLC method for the determination of HP and THP in tablets. The developed method was validated using ICH guidelines for validation.[4]

Materials and Method

The drug samples, haloperidol and trihexyphenidyl were obtained as gift samples from Stadmed Pvt. Ltd., Kolkata. The solvents used were HPLC grade methanol and water from Merck Co, Mumbai.

Instrument: The liquid chromatographic system used was an isocratic HPLC (CHEMITO) system consisting of UV-1600 detector, pump (K-105) and C_{18} column (250 x 4.6 mm).

Preparation of mobile phase: The mobile phase used was a mixture of methanol and water in the ratio of 70:30 v/v and was filtered before use through membrane filter paper (0.4 µ). The elution was carried out at the flow rate of 1 ml/min. Detection was carried out at 220 nm at ambient temperature.

Preparation of solution: Standard stock solution of the drugs were prepared by dissolving 25 mg of HP and THP in mobile phase and volume was made up to 50 ml with the same solvent (500 µg/ml).

Preparation of working solution: Working standard solutions were prepared by diluting 2.5 ml of the standard stock solutions to 50 ml with mobile phase (25 µg/ml).

Standard calibration curve: Various dilutions were prepared by taking 2.5-12.5 µg/ml (HP) and 1.0-5.0 µg/ml (THP) solutions. Twenty microliters of the solution from the flasks was injected. Calibration curve was constructed by plotting peak areas against the corresponding drug concentrations.

Estimation of drug in commercial tablet formulation: For the estimation of drugs from commercial formulation, twenty tablets, each containing 5 mg of HP and 2 mg of THP, were weighed and finely powdered. Accurately weighed tablet powder (20 mg) was suspended in the mobile phase and shaken for 15 min. The volume was made up to 50 ml with mobile phase and filtered through Whatman filter paper. Aliquot portion of this solution was diluted to produce 5 µg/ml (HP) and 2 µg/ml (THP) and filtered through membrane filter paper (0.4 µ). Equal volumes of 20 µl of standard and sample solutions were injected separately after the equilibrium of stationary phase and area under the curve noted. Amount of the drugs in the tablet formulation were calculated.

Results and Discussion

In RP-HPLC method for estimation of HP and THP, mobile phase used was methanol and water in the ratio (70:30 v/v) at flow rate of 1 ml/min. The detector response was recorded at 220 nm. The retention time was found to be 2.99 min (HP) and 5.01 min (THP) [Fig. 1 and 2]. Linearity for HP and THP was in the range of 2.5-12.5 µg/ml and 1.0-5.0 µg/ml, respectively. To study the accuracy, reproducibility and precision of the proposed method, recovery experiments were carried out. A fixed amount of the preanalyzed sample was taken and standard drug was added at three different concentration levels. The recovery values were in the range of 99-100 %.

Conclusion

The present study proposed an RP-HPLC method to determine HP and THP from tablet dosage form. The values of percent recovery and standard deviation indicate that the method is accurate, reproducible and precise.

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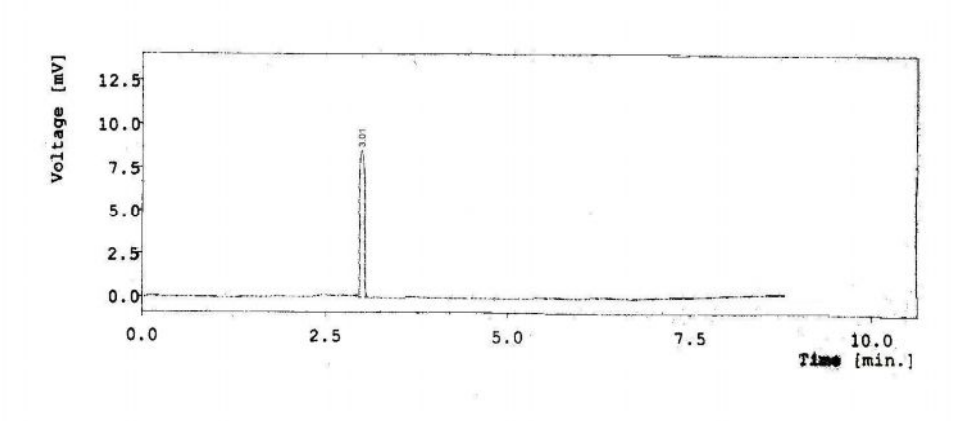

Fig.1: Chromatogram of Haloperidol. Retention time is 2.99 min.

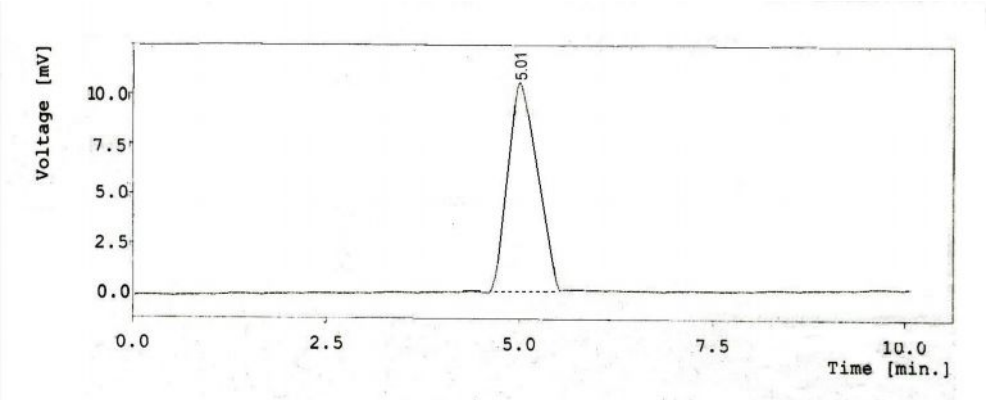

Fig.2: Chromatogram of Trihexyphenidyl. Retention time is 5.01 min.

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