Spectrophotometric Method for the Estimation of Finasteride in Tablets

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A simple and sensitive method has been developed for the estimation of finasteride in tablet formulations. The method is based on the reaction of the drug with 0.2 % w/v 3-methyl-2-benzthiazolinone hydrazone (MBTH) reagent in presence of 7% w/v ferric chloride solution to yield a green colour, which has the characteristic light absorption in the visible region with an absorption maxima at 446 nm. The chromogen formed is stable for 45 min. Beer's law is obeyed in the concentration range of 2 to 10 µg/ml. The reproducibility of the method is 98.8%. The proposed method is precise, accurate and reproducible and is extended to the analysis of finasteride in the tablet formulations.

Finasteride[1,2] is chemically (5α,17β)-N-(1,1-dimethylethyl)-3-oxo-4-azaandrost-1ene-17-carboxamide. It is the first 5α-reductase inhibitor used in the treatment of benign prostatic hyperplasia (BPH)[3,4]. Finasteride is official only in Martindale Extra Pharmacopoeia[2]. A survey of literature reveals that finasteride is estimated in plasma by HPLC[5] and LC[6]. No spectrophotmetic methods are cited in the literature. The present work deals with the spectrophotometric determination of the drug in its dosage form using 3 (MBTH). The proposed method is simple, selective and sensitive.

A Systronics UV spectrophotometer 119 with I cm matched quartz cells was used for all absorbance measurements. All the chemicals used were of analytical grade. Aqueous solutions of MBTH (0.2% w/v) and ferric chloride (7% w/v) were prepared freshly. Finasteride was obtained from M/s. Cipla Ltd. Mumbai, as a gift sample.

About 100 mg of finasteride was accurately weighted and dissolved in 100 ml of methanol to give a concentration of 1000 µg/ml. The above solution was suitably diluted to a concentration of 10 µg/ml. Aliquots (0.2 to 2 ml) of the solution were taken in 10 ml volumetric flasks and 1 ml ferric cholirde solution was added, followed by 6 ml of MBTH reagent, and kept aside at room temperature for 10 minutes. The absorbances were measured at 446 nm against a reagent blank.

Twenty tablets of finasteride were accurately weighed and powdered. The amount of powder equivalent to 100 mg of finasteride was weighed accurately and dissolved in 50 ml of methanol and filtered through Whatmann filter paper no. 41. The filtrate was diluted to 100 ml with methanol. Further analysis was carried out by using the above procedure. The amount of finasteride present in sample solution was computed by using the following formula, $C_t = A_t \times$ Average weight of tablet/$A_{std} \times$ Weight of the powder taken. Where C_t is the concentration of sample solution C_{std} is the concentration of standard solution, A_{std} is the absorbance of standard solution and A_t the absorbance of test solution.

The recovery studies were carried out to ascertain the accuracy and precision of the method by adding a known amount of standard solution at three levels to previously analyzed sample solution and measuring the absorbance. The results are given in Table 1.

Secondary amines are known to undergo oxidation to give hydroxylamine which converts into a stable nitroxide. Hence the authors are of the opinion that a nitroxide type of compound is formed which gives a green colour complex with MBTH reagent.

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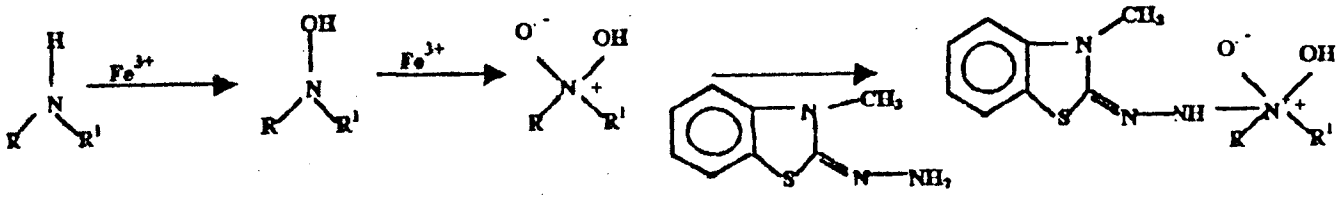
TABLE 1: ANALYSIS OF FINASTERIDE TABLETS.

Formulation	Labeled Amount (mg/tab)	Estimated Amount* (mg/tab)	Estimated Amount* Percentage (%)	Percentage Recovery
Brand 1	5	4.94	98.8±0.52	97.89±0.621
Brand 2	5	5.01	100.2±0.49	99.71±0.501

* Each reading is a mean ± SEM of six values.



$R = C_{19}H_{26}NO_2$

$R^1 = C_4H_9$

The coloured solution exhibited λ_{max} at 446 nm. The colour obeyed Beer's law in the concentration range of 2 to 10 µg/ml. The molar absorptivity is 1.4×10^5 l/mol/cm. The regression line was found to be y = 0.01995x + 0.2519, where x is the concentration of finasteride in µg/ml of dilution and y is absorbance at the respective absorption maxima. The low value of standard deviation and co-efficient of variation indicates that the proposed method is precise. The precentage recovery values of the two brands indicate that there is no interference of excipients in the formulation. The proposed method is simple, sensitive, accurate and reproducible and can be used for routine quality control analysis of finasteride in bulk and dosage forms.

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