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SIMULTANEOUS REVERSE PHASE HPLC ESTIMATION OF OFLOXACIN AND SATRANIDAZOLE IN TABLET DOSAGE FORM

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ABSTRACT: A simple, selective, rapid and precise reverse phase HPLC method has been developed for the simultaneous estimation of Ofloxacin and Satranidazole in tablets. The analyte was resolved by using a mobile phase 0.05 M phosphate buffer and acetonitrile in the ratio of 65:35 v/v at a flow rate of 1.0 ml/min on an isocratic HPLC system at a wavelength of 320 nm. The linearity was obtained in the concentration range of 5-40 µg/ml for Ofloxacin and Satranidazole, respectively. The proposed procedures were successfully applied for the simultaneous determination of both drugs in commercial tablet preparation. The results of the analysis have been validated statistically and by recovery studies.
Keywords: Ofloxacin; Satranidazole; reverse phase-HPLC.

INTRODUCTION

Ofloxacin (OF) is a fluoroquinolone derivative. Chemically, it is (±)-9-fluoro-2, 3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido-[1,2,3-de]-1,4-benzoxazine-6-carboxylic acid.[1] It is mainly used as antibacterial for the treatment of urinary tract infection and sexually transmitted diseases. Satranidazole (ST) is a novel nitroimidazole derivative. Chemically, it is 1-methylsulfonyl-3-(1-methyl-5-nitro-2-imidazolyl)-2-imidazolidinone[2]. It is used as antiprotozoal and antibacterial agent in the treatment of amoebiasis. Ofloxacin is official in USP and BP whereas Satranidazole is not official in any pharmacopoeia. Both the drugs are marketed as combined dose tablet formulation and the ratio is 200:300 mg OF: ST. Literature survey revealed that a number of methods have been reported for estimation of Ofloxacin individually or in combination[3-7] with other drugs and Satranidazole is estimated only individually[8-10]. However, there are some spectrophotometric methods[11-12] reported for the simultaneous estimation of Ofloxacin and Satranidazole in a combined dosage formulation. Present work describes a simple, accurate, reproducible and rapid methods for simultaneous estimation of OF and ST in tablet formulation.

EXPERIMENTAL

Instrument A Lachrom HPLC system consisting of L-7100 (Merck Hitachi) pump, L-7400 (Merck Hitachi) UV-VIS detector, a Kromasil-100-5C18 RP column (4.6mm i.d. x 25 cm) and 20 µl Rheodyne injector was used.

Materials Standard gift sample of Ofloxacin and Satranidazole were provided by Alkem Laboratories Limited, Baddi. Combined dose Ofloxacin and Satranidazole tablets (SATROGYL-O, 200 mg Ofloxacin and 300 mg Satranidazole; manufacture by Alkem Laboratories Limited, Baddi), were purchased from local market. Potassium dihydrogen orthophosphate of AR grade, HPLC grade acetonitrile and methanol were used (Universal Laboratories Pvt. Ltd., Mumbai). Double distilled water prepared by all glass distillation apparatus was used.

Mobile phase A mixture of 0.05 M phosphate buffer and acetonitrile (each, ultrasonicated for 5 min. and filtered through a 0.4µ membrane filter) in the ratio 65:35 v/v was used.

Stock solution: Standard stock solutions of OF (100 µg/ml) and ST (100 µg/ml) were prepared and used for the analysis.

Optimized Chromatographic conditions

Chromatograph - A Lachrom HPLC system
Mobile phase - 0.05 M phosphate buffer: acetonitrile (65:35 v/v)
Column - Kromasil C_{18} RP column, (4.6mm i.d. x 25 cm, 5µ)
Flow rate - 1.0 ml/min
Detection - UV set at 320 nm
Injection volume - 20 µl

Retention time:
Ofloxacin - 2.63 min.
Satranidazole - 5.94 min.
Run –time - 8 min.

Preparation of calibration curves

Appropriate dilution of the standard stock solution were done to get mixed standards of 5, 10, 15, 20, 25, 30, 35 and 40 µg/ml of OF and ST, respectively: injected into the column and the chromatogram was obtained. A graph was plotted as concentration of drugs v/s response (peak area) and it was found to be linear for both the drugs.

Application of the proposed method for the determination of OF and ST in tablets

Twenty tablets were weighed and average weight was calculated. The tablets were crushed to fine powder. Tablet powder equivalent to 50 mg of OF was transferred to 50.0 ml volumetric flask and volume made-up to the mark with the mobile phase and ultrasonicated for 5 minutes. The solution was then filtered through a membrane filter (0.2µm). From the filtrate, 5.0 ml solution was transferred to a 100.0 ml volumetric flask and diluted to the mark with same mobile phase. The solution was further diluted with mobile phase to obtain 15 µg/ml of OF and 22.5 µg/ml of ST. The resulting solutions were injected into the column and the responses were recorded and the concentration of both OF and ST were calculated.

Validation

The methods were validated with respect to linearity, accuracy, precision and selectivity.

Accuracy To ascertain the accuracy of the proposed methods, recovery studies were carried out by standard addition method at three different levels (80%, 100% & 120%). Percent recovery for OF and ST was found in the range of 98.40 % to 100.77 %.

Linearity The linearity of measurement was evaluated by analyzing different concentrations of the standard solution of OF and ST. Linearity range was found to be 5-40 µg/ml for OF and ST, respectively.

Precision The reproducibility of the proposed method was determined by performing tablet assay at different time intervals (morning, afternoon and evening) on same day (Intraday assay precision) and on three different days (Interday precision). Result of intraday and interday precision is expressed in % RSD. Percent RSD for Intraday assay precision was found to be 0.4381 (for OF) and 0.6155 (for ST) and Interday assay precision was found to be 0.3715 (for OF) and 0.6454 (for ST).

RESULTS AND CONCLUSION

The methods discussed in the present work provide a convenient and accurate way for simultaneous analysis of OF and ST. In the reverse phase HPLC method, wavelength selected for analysis was 320 nm and the retention time was 2.63 for OF and 5.94 for ST. The linearity for detector response was observed in the concentration range of 5-40 µg/ml for both OF and ST. Percent label claim for OF and ST in tablet analysis was found in the range of 98.24 % to 99.95 %. Standard deviation and coefficient of variance for six determinations of tablet sample was found to be less than ± 2.0 indicating the precision of the method. Accuracy of proposed method was ascertained by recovery studies and the results are expressed as % recovery. Percent recovery for OF and ST was found in the range of 98.40 % to 100.77 %; values of standard deviation and coefficient of variation were satisfactorily low indicating the accuracy of both the methods. Based on the results obtained, it is found that the proposed method is accurate, precise & reproducible and can be employed for routine quality control of Ofloxacin and Satranidazole in combined dose tablet formulation.

Table No. 1: Results of Linearity and System Suitability

Parameters	Ofloxacin (OF)	Satranidazole (ST)
Calibration range (µg/ml)	5-40	5-40
Slope (m)	491317	418296
Intercept (b)	243002	255917
Correlation coefficient (r)	0.9995	0.9991
Limit of detection(µg/ml)	0.057	0.037
Limit of quantitation(µg/ml)	0.172	0.113
Theoretical plates (N)	2144	10,937
Resolution between the peaks (R)	4.14	
HETP (h cm)	0.1167	0.0229
Retention time (t_R, min)	2.63	5.94

** y = mx + b, Where, y = peak response, m = slope, concentration (µg/ml), b = intercept.*

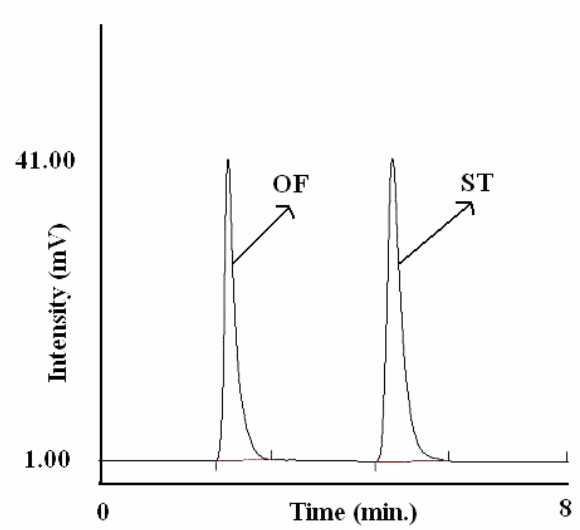

Fig.1 : Typical chromatogram of standard solution of OF and ST.

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