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A Validated Rp-Hplc Method for Estimation of Ciprofloxacin and Tinidazole in Tablet Dosage Form

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ABSTRACT

For the estimation of ciprofloxacin and tinidazole in combination tablet dose form, a straightforward, specific, accurate, and exact Reverse Phase High Performance Liquid Chromatography (RP-HPLC) approach was created and validated. Using an Inertsil C18 (250X4.6mm) column and mobile phase phosphate buffers (pH 6.8): acetonitrile (82:18) v/v, the separation was performed at a flow rate of 1.0 ml/min. At 316 nm, detection was done. Ciprofloxacin and tinidazole were shown to have retention times of 5.6 and 9.82 minutes, respectively. The linearity, accuracy, and precision of the procedure were confirmed. The linearity of ciprofloxacin and tinidazole was found to be between 27.5 and 82.5µg/ml for ciprofloxacin and between 33µg/ml and 66µg/ml for tinidazole, with a correlation coefficient of 0.9999 for both medications. Ciprofloxacin and tinidazole were reported to have mean recovery rates of 99.7 and 100.4, respectively. Tinidazole and ciprofloxacin in combination tablet dose form may be routinely analyzed using the described approach

Key Words: Ciprofloxacin hydrochloride, tinidazole, RP-HPLC, precision, linearity, and specificity.

INTRODUCTION

Ciprofloxacin, also known as 1-cyclopropyl-6-fluoro-4-oxo-7-(piperazin-1-yl)-quinoline-3-carboxylic acid, is a broad-spectrum antimicrobial medication that is used as an anti-infective agent and is included in class 4 of the biopharmaceutics categorization of medications used to treat a range of infections. 1–3 Class 2 of the biopharmaceutics categorization of pharmaceuticals includes the prodrug 1-[2-(ethanesulfonyl)ethyl]-2-methyl-5-nitro-1H-imidazole, which is employed as an antiprotozoal agent. 4-6 No pharmacopoeia recognizes the combination of ciprofloxacin and tinidazole as a recognized medication. A There is a medication called Drug X that contains 600 mg of tinidazole and 500 mg of ciprofloxacin. Few chromatographic and spectrophotometric techniques have been documented for the detection of ciprofloxacin7 and tinidazole in individual8 and combined dose forms, according to a review of the literature. 9–14 However, no HPLC method for the assay development of tinidazole and ciprofloxacin in combination dose form has been published. The current study outlines a straightforward, accurate, and exact HPLC procedure for creating ciprofloxacin and tinidazole tablets.

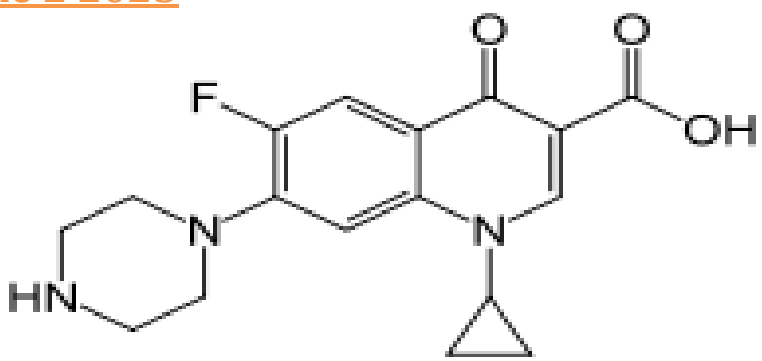

Figure – 1: Structure of Ciprofloxacin

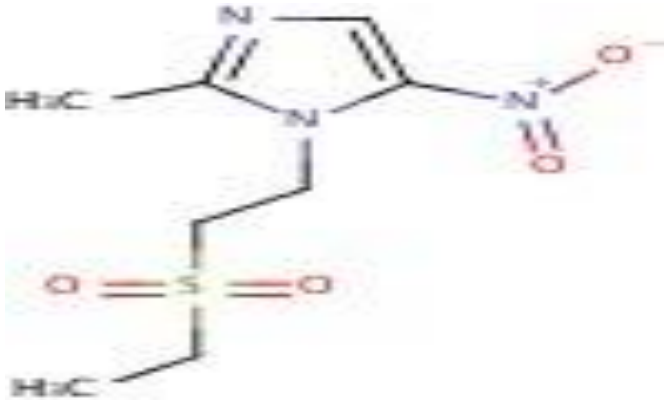

Figure – 2: Structure of Tinidazole

MATERIALS AND METHODS

Gift samples of the medications ciprofloxacin hydrochloride and tinidazole were acquired from Gracure Pharmaceuticals Pvt. Ltd. in Bhiwadi, Rajasthan.

The following chemicals and reagents were acquired from Merck Co. in Mumbai and S.D. Fine Chemicals in Mumbai, respectively: orthophosphoric acid (analytical grade), acetonitrile (HPLC grade), methanol (HPLC grade), and water (HPLC grade). Every chemical and reagent utilized in the analysis was of analytical and HPLC quality. Conditions of the experiment: Waters e2695 high performance liquid chromatography, variable wavelength programmable PDA detector, and empower software were employed. The reverse phase Inertsil C18 column (250 x 4.6 mm) with a particle size of 5 µm was the chromatography column that was utilized. The mobile phase consisted of an 82:18 mixture of phosphate buffers (pH 6.8) and acetonitrile, which was filtered using a 0.45µ Millipore membrane filter. The mobile phase flow rate was kept constant at 1.0 milliliters per minute. At normal temperature, the detection was performed at 316 nm. A ciprofloxacin and tinidazole standard solution was made in diluent. After weighing and transferring a quantity of powder equal to roughly 50 mg of USP ciprofloxacin hydrochloride and 60 mg of tinidazole to a 100 ml volumetric flask with 60 ml of mobile phase, the mixture was sonicated. Using mobile phase, the volume was adjusted to the mark (100 ml). Whatmann filter paper was used to filter the contents. Additional dilutions were created to get 50µg/ml of ciprofloxacin and 60µg/ml of tinidazole. Twenty pills containing 600 mg of tinidazole and 500 mg of ciprofloxacin each were weighed and ground into powder. A 200 ml volumetric flask with 120 ml of mobile phase was filled with a weighted amount of powder equal to 250 mg of ciprofloxacin. For half an hour, the mixture was sonicated. Using the mobile phase, the volume was increased to 200

ml. Whatmann filter paper was used to filter the contents. To achieve a concentration of 50 µg/ml of Ciprofloxacin and 60 µg/ml of Tinidazole, additional dilutions were done. Chromatograms were recorded for up to 15 minutes after 20 microliters of the test and standard solutions were injected separately.

OUTCOMES AND CONVERSATION

The RP-HPLC method was used to test ciprofloxacin and tinidazole in a combination tablet dosage form. The goal of the current study was to create a straightforward, accurate, and exact HPLC method for estimating the dose forms of ciprofloxacin and tinidazole in combination tablets. To choose the column and mobile phase for the technique development, a number of trials are conducted. Following testing, the Inertsil C18 column (250 x 4.6 mm, 5µm) was utilized in this procedure, and the mobile phase consisted of buffer and acetonitrile in an 82:18 v/v ratio. Since both medications demonstrated good absorbance at 316 nm, this wavelength was chosen. A satisfactory resolution between ciprofloxacin and tinidazole was obtained using the mobile phase composition previously stated. Ciprofloxacin and tinidazole were shown to have retention times of 5.6 and 9.82 minutes, respectively.correspondingly. The injection volume was 20µl, and the run time was 15 minutes. Figures 3 and 4 depict a typical chromatogram of the standard and test solutions, respectively. Both medications had symmetrical peak shapes with asymmetry factors smaller than 2.0. The standard and test solutions' response factors were computed. The suggested approach was verified in accordance with ICH regulations. Six injections of each sample were made, and the retention period was recorded in each instance. The suggested approach (RSD) was shown to have a precision of 0.29% for repeatability and 0.27% for tinidazole, and 0.39% for ciprofloxacin and 0.33% for tinidazole for intermediate precision. The suggested method's high precision was demonstrated by its low RSD value. The response was determined to be linear in the range of 27.5 - 82.5µg/ml for ciprofloxacin and 33 - 66µg/ml for both drugs after linearity experiments were conducted three times at five different concentrations.

Tinidazole. A response factor versus concentration graph was used to plot the linearity of ciprofloxacin and tinidazole. Figures 4 and 5 display the correlation coefficient (r) values for ciprofloxacin and tinidazole, which were 0.9999 and 0.9999, respectively. Recovery experiments were used to calculate the method's accuracy at three different levels. Each level's drug recovery amount was computed. Each level's recovery percentage was computed. The recovery study data for tinidazole and ciprofloxacin are displayed in Table 1. Both ciprofloxacin and tinidazole had an average recovery of 99.80%. The formulation's sample recoveries matched the label claim quite well. A high recovery percentage demonstrated that the excipients employed in the formulations did not interfere with the process. Table 2 lists the ciprofloxacin and tinidazole system suitability characteristics. The study's findings show that the proposal technique is straightforward, exact, very accurate, and targeted.

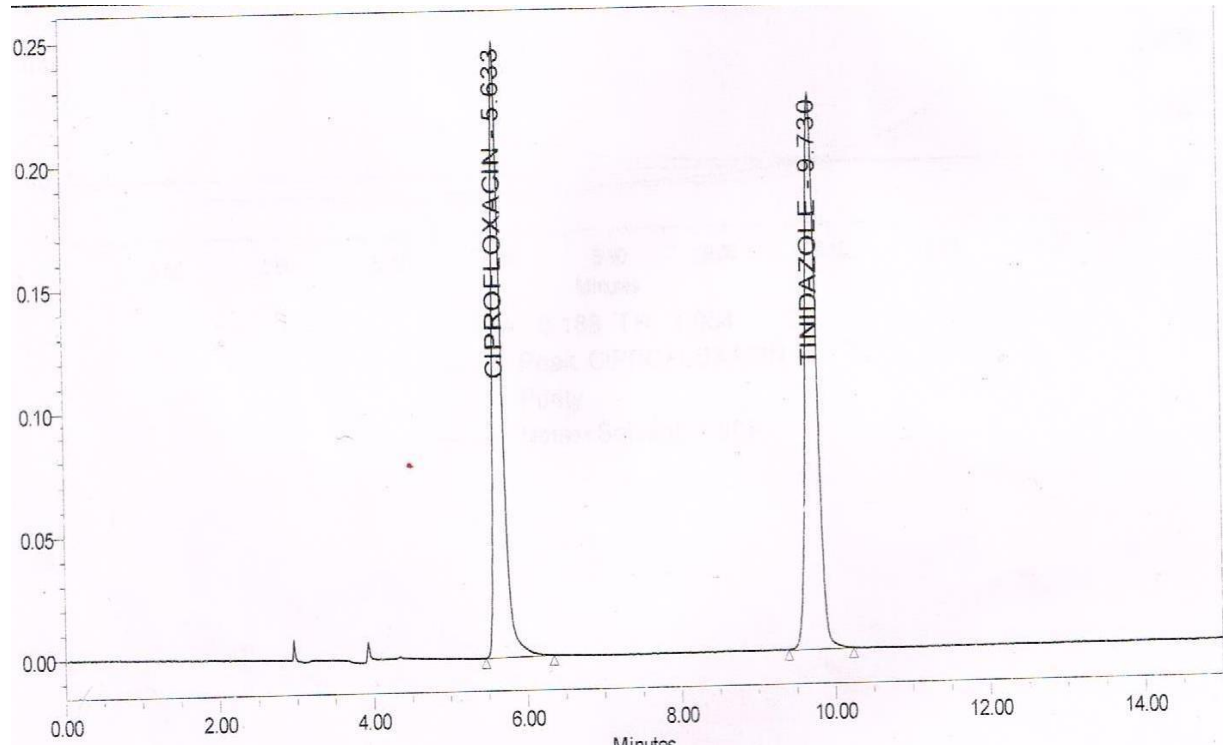

Fig. 3: Chromatogram of the standard drugs

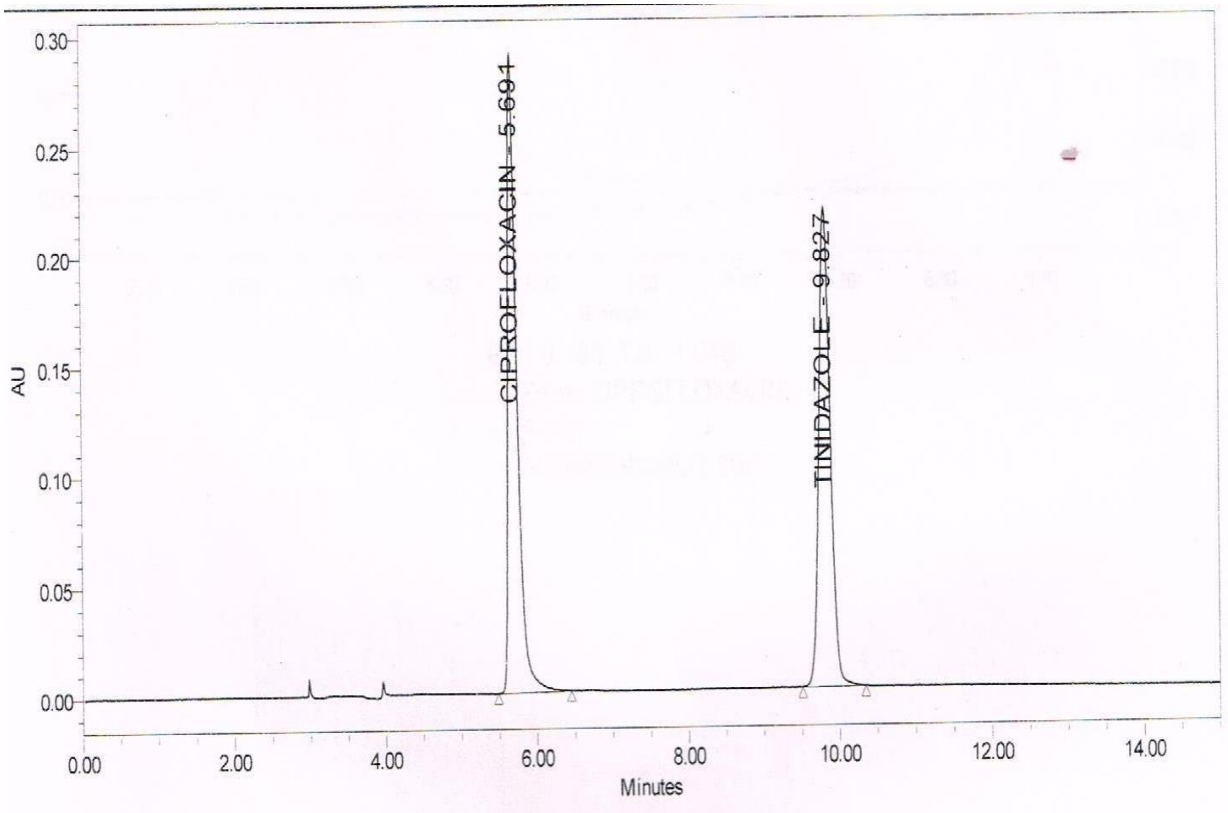

Fig. 4: Typical chromatogram of the sample solution

Typical chromatogram of the sample solution containing ciprofloxacin hydrochloride and tinidazole at the retention time of 5.6 and 9.82 min.

Calibration curve of Ciprofloxacin and Tinidazole

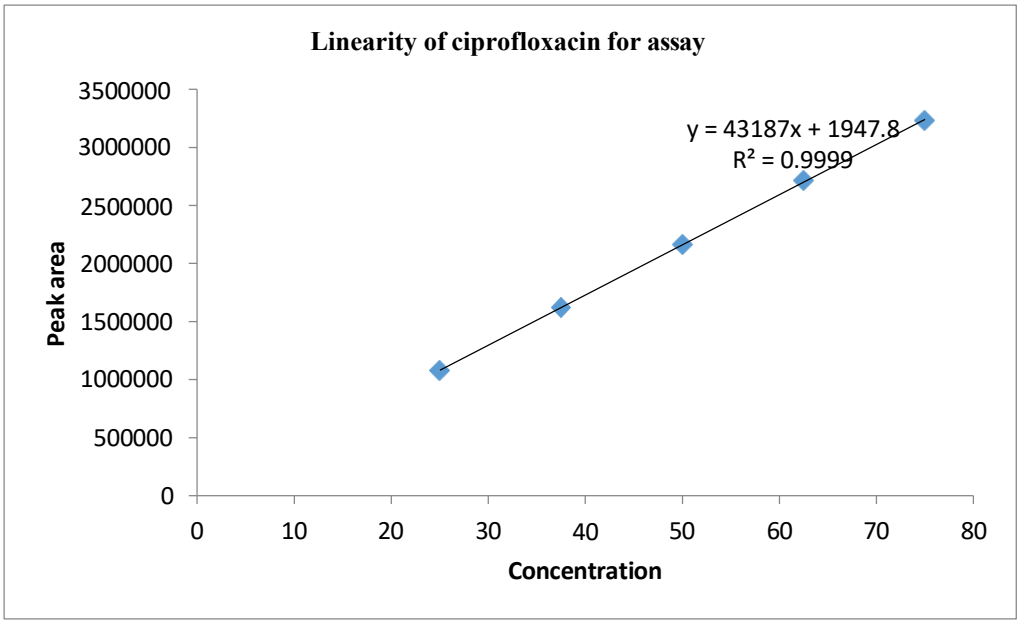

Figure 5: Calibration curve of ciprofloxacin

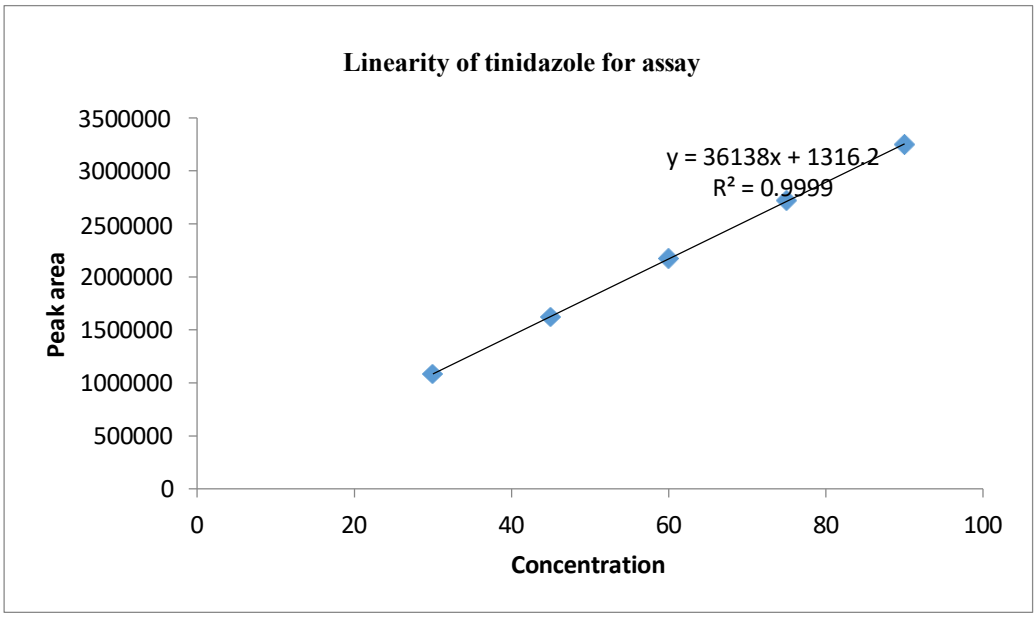

Figure 6: Calibration curve of tinidazole

Table 1: Result of Recovery Study

DRUG	AMOUNT ADDED	AMOUNT RECOVERED	RECOVERY (%)	AVERAGE RECOVERY (%)
CIPROFLOXACIN	126.2	125.6	99.52	99.80
	251.2	250.4	99.68	
	372.4	373.2	100.21	
TINIDAZOLE	150.38	149.98	99.73	99.80
	299.54	298.82	99.75	
	448.64	448.38	99.94	

Table 2: Result of System Suitability Parameter

Parameters	Ciprofloxacin	Tinidazole
Tailing factor	1.36	1.05
Theoretical plates	9841	15816
Calibration range	27.5 - 82.5µg/ml	33- 66µg/ml

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