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Analytical Validation and Simultaneous Estimation of Cefixime and Ornidazole by RP-HPLC Method

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ABSTRACT

Suitability, linearity, Precision, Accuracy method perform as the Analytical validation and simultaneous estimate consisting of the Cefixime and Ornidazole. The retention time & % RSD of Cefixime and Ornidazole find up to be 5.4 ± 0.2 min, 3.2 ±0.4 min, and 0.60% and 0.65%. The % RSD Obtained for Cefixime and Ornidazole were 0.60% and 0.65%. LOD, LOQ & Assay encounter ultimate integrity will be acquired from the Cefixime and Ornidazole were 0.80 ppm, 0.81 ppm, 2.25 ppm & 2.22 ppm, and 101.04% and 100.41% respectively.

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INTRODUCTION

The current written report used to be interested in an attempt to develop as well as validating a simple, accurate, precise, and economical RP-HPLC approach to the simultaneous estimate of Cefixime and Ornidazole [1]. Cefixime is utilized in the overall treatment of nonimmune diseases including gonorrhea, otitis, throat infection, chronic bronchitis, etc. Ornidazole is an antimicrobial agent utilized in the treatment of unresisting protozoa diseases. The brochure study exhibits there will be methods since the estimate of Cefixime and Ornidazole together or surrendered or with other medicine victimization UV, HPLC [2]. HPLC approach is a lot of photosensitive in comparison to UV, however, the RP-HPLC approach revealed have been with an admixture of 3 solvents as mobile phase. There's an object to originate the RP-HPLC approach for the simultaneous estimate of Cefixime and Ornidazole using 2 solvent that is more cost-effective [3].

MATERIALS AND METHODS

The Cefixime and Ornidazole had been acquired freely given samples from Chandra labs (Hyderabad, India). Acetonitrile, ammonium acetate, glacial acetic acid, tetrahydrofuran, potassium dehydrogenate phosphate buffer, Orthophosphoric acid, Triethylamine have been procured from S.D. Fine Chemicals Ltd, Mumbai. Methanol & water (HPLC grade) used to be acquired from Merck specialities private limited, Mumbai.

Methodology

Linearity

Linearity solutions will be prepared as Stock solutions of Cefixime and Ornidazole go down excited 6 abundant volumetric flasks and diluted to 10ml in addition to diluents along with the drugs [4].

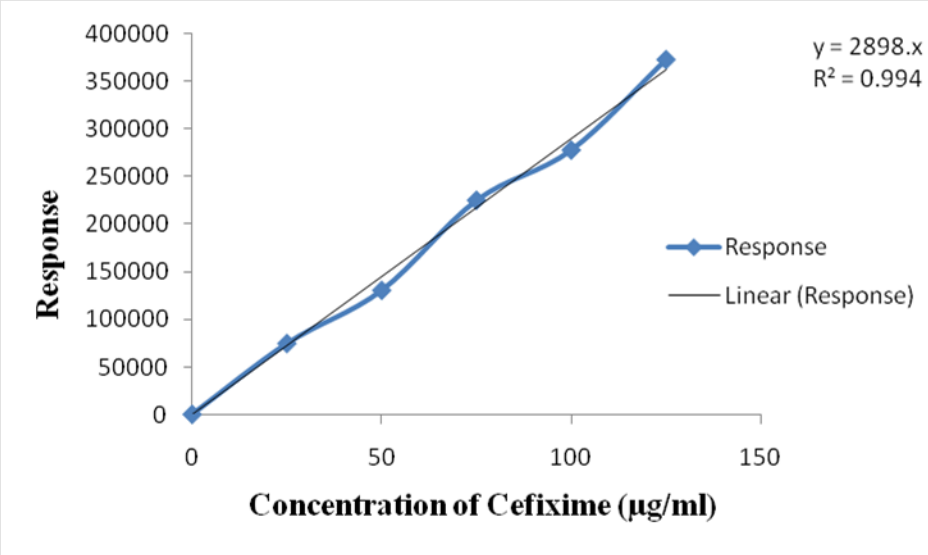

Figure 1: Calibration curve of Cefixime

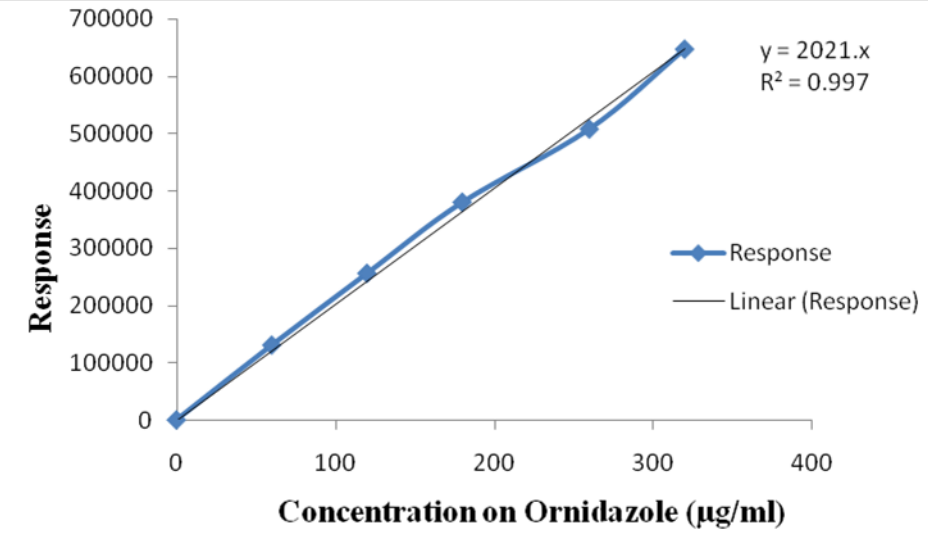

Figure 2: Calibration curve of Ornidazole

Table 1: System suitability studies of Drugs

Property	Cefixime	Ornidazole
Retention time (tR)	5.4 ± 0.2 min	3.2 ±0.4 min
Theoretical plates (N)	2921 ± 174.51	4832 ± 172.38
Tailing factor (T)	2.39 ± 0.226	2.42± 0.238

Table 2: Calibration data of Cefixime and Ornidazole method

S.No	Concentration Cefixime (μg/ml)	Response	Concentration Ornidazole (μg/ml)	Response
1	0	0	0	0
2	25	74516	60	130553
3	50	130300	120	255624
4	75	224982	180	379671
5	100	277837	260	507321
6	125	372858	320	646451

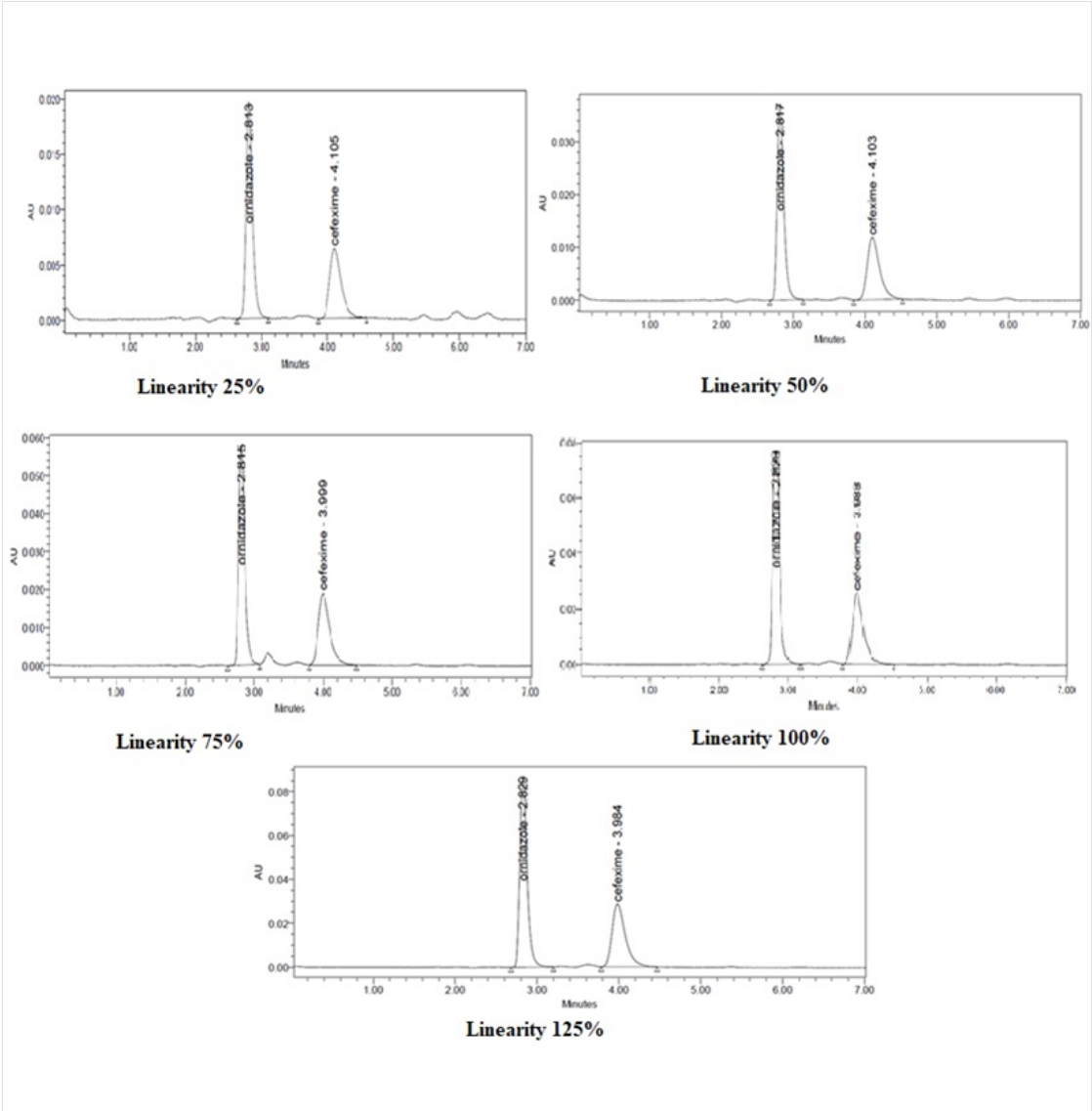

Figure 3: Chromatogram of Cefixime and Ornidazole Linearity method

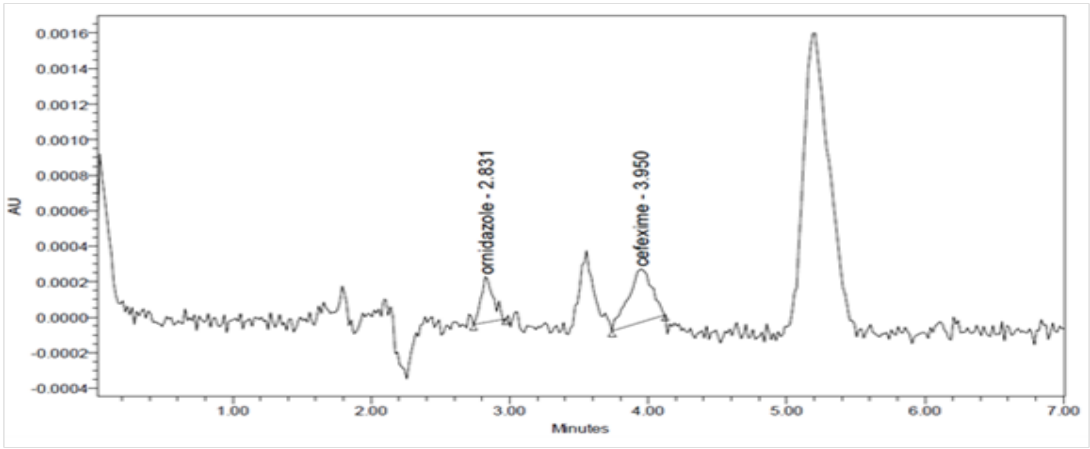

Figure 4: LOD Chromatogram of Cefixime and Ornidazole method

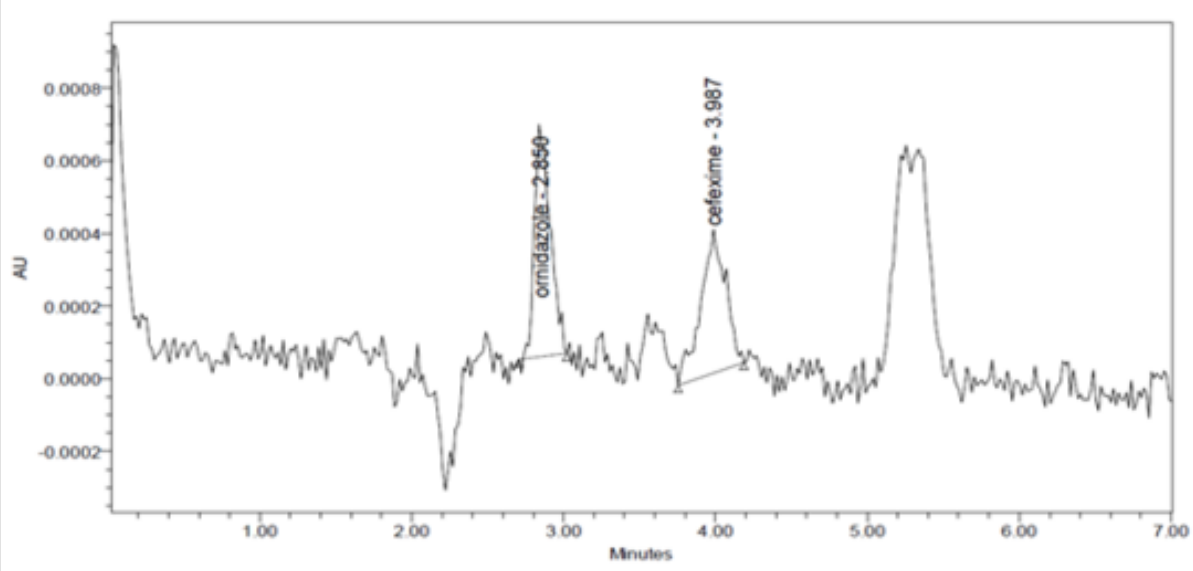

Figure 5: LOQ Chromatogram of Cefixime and Ornidazole method

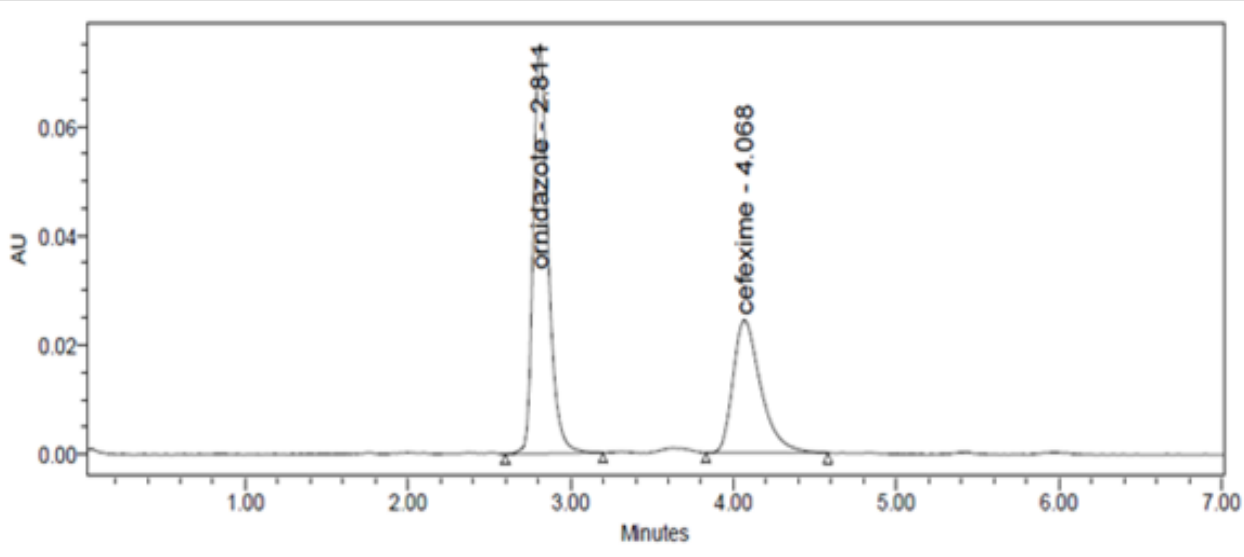

Figure 6: Assay of Tablet

Standard Preparation

Appropriately visually inspected along with transmitted 15mg of Cefixime and 30mg of Ornidazole operating requirements right into a 10ml transfer into a volumetric flask, add $3/4^{th}$ of diluents, sonicated for five mins final volume with diluents [5].

Sample Preparation

15 pills were weighed (equivalent to 600 milligrams of Cefixime and 1350mg of Ornidazole) used to be conveyed right into a 100mL volumetric flask, 75mL of diluent additional furthermore sonicated for 25 minutes [6]. Further, the volume retract diluents and screened.

Accuracy

Accuracy solutions will be prepared as Stock solutions of Cefixime and Ornidazole go down excited 6 abundant volumetric flasks and diluted to 10ml in addition to diluents along with the drugs [7].

Standard Preparation

Appropriately visually inspected along with transmitted 15mg of Cefixime and 30mg of Ornidazole operating requirements right into a 10ml transfer into a volumetric flask, add $3/4^{th}$ of diluents, sonicated for five mins final volume with diluents [8].

Method Validation

The developed method was validated for Suitability, Precision [9], Assay [10], LOD, and LOQ [11] as per the ICH guidelines.

Table 3: Repeatability results for drugs

S. No	Cefixime	Ornidazole
1	305211	507191
2	304821	503640
3	300582	498908
4	302957	495368
5	303650	496621
6	301165	494450
Mean	302878.6	494510.9
Std. Dev.	2058.5	3068.21
%RSD	0.70	0.66

*Average of six determinations

Table 4: Inter day precision results for Cefixime and Ornidazole

S. No	Cefixime	Ornidazole
1	307885	499644
2	307232	498109
3	306596	499877
4	308616	499919
5	307070	499117
6	304394	499009
Mean	306856.6	498847.5
Std. Dev.	1639.7	602.802
%RSD	0.60	0.65

Table 5: Accuracy results of Cefixime and Ornidazole

Sample	Amount added (μg/ml)	Amount Recovered (μg/ml)	Recovery (%)	% RSD
Cefixime	100	100.15	100.15	0.09
	150	162.50	113.77	0.30
Ornidazole	250	250.70	100.45	0.05
	375	385.70	110.17	0.80

Table 6: Assay of Tablet

S. No.	Cefixime (%)	Ornidazole (%)
1	110.65	109.07
2	108.79	110.32
3	106.30	108.32
4	105.10	107.65
5	106.40	108.89
AVG	107.44	108.85
STDEV	0.70	0.65
%RSD	0.69	0.65

RESULTS AND DISCUSSION

System Suitability

The entire suitability probabilities will be within just range and satisfactory given that according to ICH guidelines [Table 1].

Linearity

Six concentrations of Cefixime and Ornidazole will be prepared plus injected. The calibration curve & regression coefficient of the drugs as displayed Table 2 & Figures 1, 2 and 3.

Precision: Intraday precision (Repeatability)

The % RSD for combined drugs encounter impending 0.70% and 0.66% respectively Table 3.

Inter Day Precision

It used to be carried out with 24 hours time lag and also the percentage RSD procured as Cefixime and Ornidazole was 0.60% and 0.65% Table 4.

Accuracy

2 levels 100%, 150%, were injected during a triplicate way, and also the amount Recovered and % Recovery was displayed in Table 5.

Limit of Detection

The Cefixime and Ornidazole approach encounter to be 0.80 ppm, 0.81 ppm respectively [Figure 4].

Limit of Quantification

The Cefixime and Ornidazole find to be 2.25 ppm & 2.22 ppm respectively [Figure 5].

Assay

The typical percentage assay used to be calculated and found impending 101.04% plus 100.41% for Cefixime and Ornidazole respectively [Table 6 & Figure 6]

CONCLUSION

The analytical method validation consisting of Cefixime and Ornidazole in tablet dosage form by way of encounter impending RP-HPLC was found to be satisfactory and could use as routine pharmaceutical analysis. The process used to be validated as specified in ICH guidelines like system suitability, accuracy, precision, linearity, LOD & LOQ, and solution stability, therefore the RP-HPLC method can be employed as routine analysis of those drugs in pharmaceutical formulations.

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Conflict of Interest

The authors declare no Conflict of interest, financial or otherwise.

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