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Research Article

UV SPECTROPHOTOMETRIC AREA UNDER CURVE METHOD FOR THE DETERMINATION OF NITROFURANTOIN IN TABLET FORMULATIONS

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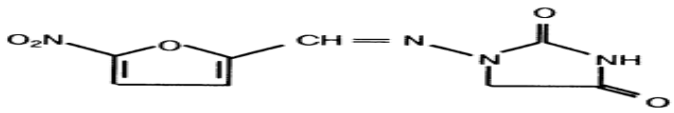
ABSTRACT

Objective: A simple, precise and economical procedure has been developed for the estimation of Nitrofurantoin in bulk drug and pharmaceutical dosage form using UV- spectrophotometer Shimadzu model UV 1800. **Method:** Area under curve method was employed for estimation of Nitrofurantoin using analytical grade acetone as solvent. **Results:** Nitrofurantoin obeys Beer's law in concentration range 20-40 µg/ml for the area between 330nm to 400nm.The recovery studies ascertained accuracy of proposed method and result validated according to ICH guideline. The result of analysis has been validated statistically by recovery studies. **Conclusion:** This method was successfully carried out for the estimation of Nitrofurantoin in tablet dosage form without the interference of common excipients.

INTRODUCTION

Nitrofurantoin is an antibiotic applicable for the care for bladder infections. It is not efficient for kidney infections. It is taken by oral cavity. This medication is used to treat or prevent certain urinary tract infections. This medication is an antibiotic that works by stopping the growth of bacteria (Internet).

Chemical structure



Nitrofurantoin is chemically 2, 4-Imidazolidinedione, I-f ((5-nitro-2-furanyl) methyl-ene) amino l-Synonyms: 1-((5-Nitrofurfurylidene) amino) imidazolidine-2, 4-dione; 1-((5 nitrofurfurylidene) amino) hydantoin (Internet).

Only very few analytical methods are reported so far for the determination of Nitrofurantoin in pharmaceutical formulations and bulk drugs. On literature survey, it was found that rapid HPLC method for determination of Nitrofurantoin (Hollifield and Conklin, 1970), Analysis of Nitrofurantoin using HPLC in tablet dosage form (Galliano Diaz *et. al*, 1997), UV spectrophotometric method (Tubinol *et. al*, 2011) have been reported for determination of Nitrofurantoin. Still any area under curve method not reported for the determination of Nitrofurantoin. Hence, investigation of new analytical methods is in need for the quantitative estimation of Nitrofurantoin.

MATERIALS AND METHODS

Materials

Shimadzu 1800 spectronic model UV Spectrophotometer with 1cm matched quartz cells was used as the instrument for data collection and analysis. Acetone was used as the solvent. Tablet brands were obtained from the local market for assay and recovery studies.

Method

Preparation of standard stock solution

Standard stock solution of Nitrofurantoin was prepared by dissolving accurately weighed quantity of Nitrofurantoin (25mg) in 100ml of acetone with sonication and transferred it to 25ml of volumetric flask. Volume was made up to the mark

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with acetone for obtaining standard stock solution of 100µg/ml concentration.

Determination of Area under curve

The standard solution of Nitrofurantoin (20µg/ml) was scanned in the wavelength range of 330nm to 400nm and the absorption maximum was found to be 360nm. Therefore, area between 355nm to 365nm was selected. (Figure 1)

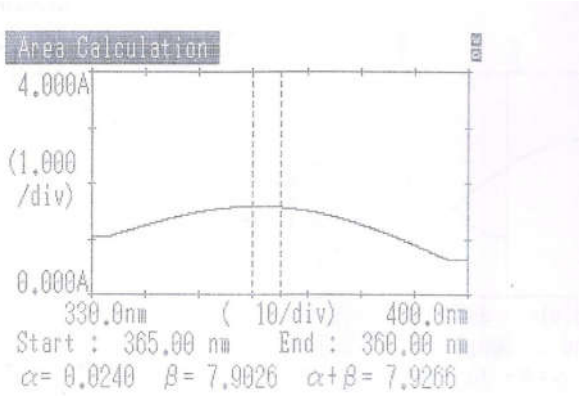

Figure 1 Area under curve of Nitrofurantoin between 360nm-365nm

Stability of Drug in Selected Solvent

The stability of drug in selected solvent was determined by measuring the absorbance of the drug solution (20µg/ml) at different time intervals. After every 5 minutes of interval the absorbance was measured the solution was found to be stable. (Table 1)

Table 1 Stability Data for Nitrofurantoin

Sr. No.	Time (min)	AUC
1	0	7.8263
2	05	7.8313
3	10	7.8420
4	15	7.8435

Linearity

From the standard stock solution of Nitrofurantoin, appropriate aliquots were pipette out into 25ml of volumetric flask and dilutions were made with acetone to produce working standard solution of Nitrofurantoin 20, 25, 30, 35 and 40µg/ml. The difference in Area under Curve of Nitrofurantoin was measured in the area from 355nm to 365nm. The calibration curve of the drug Nitrofurantoin was plotted. The concentration range over which the drug followed linearity was chosen as an analytical concentration range i.e. 20 to 40µg/ml for Nitrofurantoin. (Table 2 and Figures 2 to 7)

Table 2 Calibration data Table for Nitrofurantoin

Sr. No.	Concentration (µg/ml)	Area Under Curve
1	0	0
2	20	7.8313
3	25	9.9072
4	30	11.490
5	35	13.944
6	40	14.937

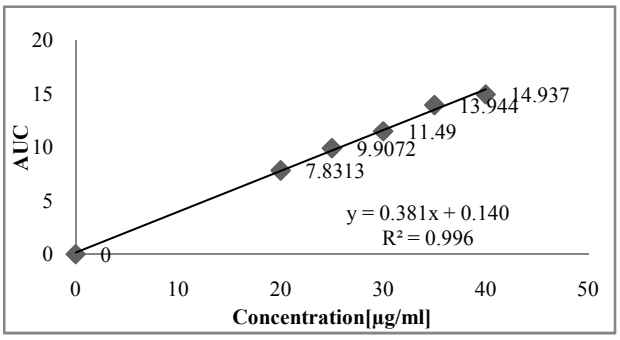

Figure 2 Calibration curve for Nitrofurantoin

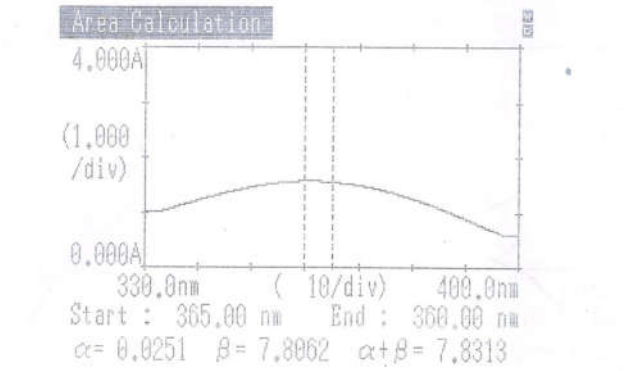

Figure 3 Area under curve of Nitrofurantoin 20µg/ml

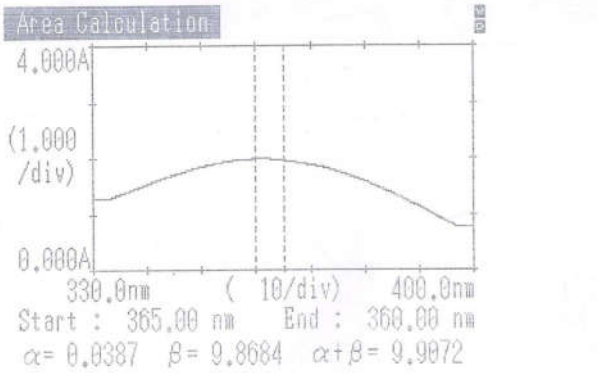

Figure 4 Area under curve of Nitrofurantoin 25µg/ml

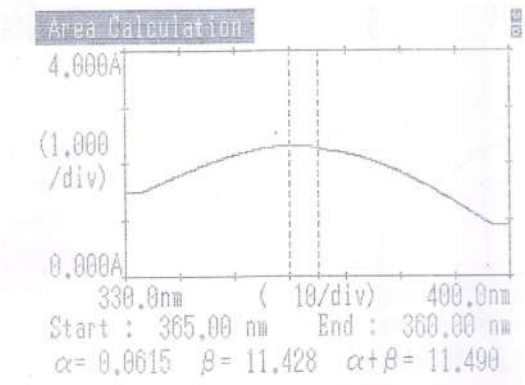

Figure 5 Area under curve of Nitrofurantoin 30µg/ml

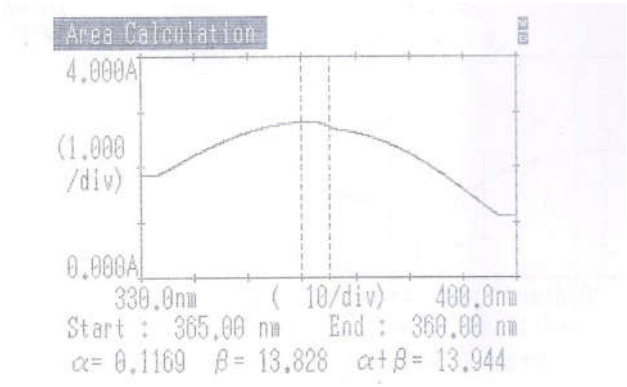

Figure 6 Area under curve of Nitrofurantoin 35µg/ml

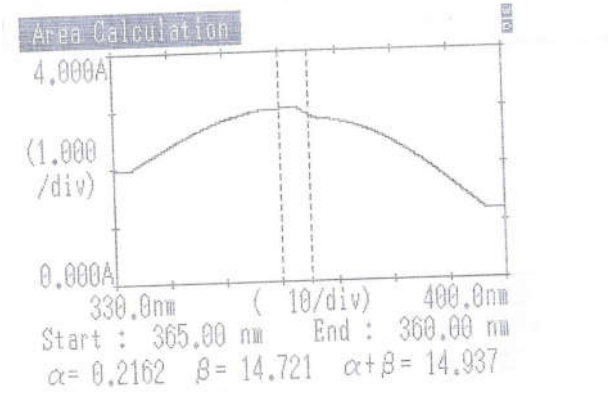

Figure 7 Area under curve of Nitrofurantoin 40µg/ml

Estimation of Drug from Dosage Form: (Tablet Assay Study) Brand name- NIFTAS 50

Standard

From the standard stock solution of Nitrofurantoin, appropriate aliquots were pipette out into 25ml volumetric flask and dilutions were made with acetone to obtain working standard solution of Nitrofurantoin 20µg/ml. This concentration was scanned at area of 355nm to 365nm.

Sample

Ten tablets of brand Niftas- 50 containing 50 mg of Nitrofurantoin weighed, and finally powered with the help of mortar. Each film coated tablet contains 50 mg of Nitrofurantoin. A quantity of powder sample of equivalent to 50 mg of Nitrofurantoin was taken into volumetric flask. And dilution was made to get concentration of 20µg/ml respectively. These concentrations were scanned at area between 360nm to 355nm. (Table 3)

Table 3 Assay of Nitrofurantoin in Tablet Form

Brand Name	Label Claim (mg/tablet)	Amount Found (mg/tablet)	% Of Label Claim	Mean	SD	CV
	50	49.89	99.78			
	50	50.02	100.04			
	50	50.01	100.12	99.992	0.1285	0.00128
NIFTAS 50	50	49.99	99.98			
	50	50.02	100.04			

Accuracy (Recovery Study)

Recovery experiments are used for the study of accuracy method. This study was carried out by adding known amount bulk sample to the tablet and recovery was performed at three levels, 80, 100 and 120% of Nitrofurantoin standard concentration. Samples for recovery studies were prepared according to before mentioned procedure. 3 samples were prepared for each recovery level. The solutions of sample were analyzed and % recoveries were calculated by using fallowing formula.

$$\text{Recovery} = \frac{\text{Observed amount of compound in sample}}{\text{Amount of all compound present in sample}} \times 100$$

The recovery values are summarized in following table 4.

Table 4 Result for accuracy parameters of Nitrofurantoin (Brand NIFTAS 50)

Label % recovery	Amount present (mg/tablet)	Amount Of Standard added (mg/tablet)	Amount Recovered (mg/tablet)	Total % recovery	%mean recovery	SD	CV
80	50	40	39.89	99.72			
80	50	40	40.02	100.05	99.93	0.1824	0.0018
80	50	40	40.01	100.02			
100	50	50	49.88	99.76			
100	50	50	50.01	100.02	99.94	0.1562	0.0015
100	50	50	50.02	100.04			
120	50	60	59.89	99.81			
120	50	60	60.02	100.03	99.95	0.1216	0.0012
120	50	60	60.01	100.01			

Precision

The precision (inter–day) was carried out by using four independent sample of Nitrofurantoin. The intermediate precision (inter-day precision) of the method was evaluated using four different analysts in the same laboratory. (Table 5)

Table 5 Determination of Precision of Nitrofurantoin

Sample Number	Assay of Nitrofurantoin as % of Labelled amount(inter – day precision)			
	Analyst 1	Analyst 2	Analyst 3	Analyst 4
1	99.97	100.23	98.99	100.03
2	98.99	100.04	99.95	100.12
3	99.99	99.87	99.99	99.85
4	99.98	100.12	99.96	99.99
Mean	99.73	100.06	99.72	99.99
SD	0.4950	0.1515	0.4886	0.1123
CV	0.0049	0.0015	0.0048	0.0011

RESULTS AND DISCUSSION

The standard solutions of Nitrofurantoin in Acetone (20µg/ml each) subjected to scanning under area between 330nm to 400nm. For area under curve method using Shimadzu 1800 spectronic UV-Visible spectrophotometer. The calibration curve of Nitrofurantoin was found to be linear at conc. range 20 to 40µg/ml at area between 360nm to 355nm. Therefore, it was clear that Nitrofurantoin can be determined in the presence of acetone with no intervention of any irrelevant substance in pharmaceutical products. With the intention of determining the practicability of the developed technique for the assessment of commercially available brands (NIFTAS 50) of medicinal formulations, the technique was initially attempted on bulk drugs in their synthetic mixture sample as well as concentrations were estimated. Then the technique was

subjected to the assay of in marketed dosage forms and satisfactory results were attained within the appropriate limits as per the content of the label claim for Nitrofurantoin. The newly developed method was validated as per the international guidelines and parameters. The novel method for the quantitative investigation of Nitrofurantoin was subjected to different validation parameters like specificity and selectivity in presence of formulation additives and excipients, studied for Linearity and range at different levels of concentrations and calibration standards where the determination range was optimized, accuracy was proved by recovery studies at different concentration levels, precision was established through inter-day precision studies, where the samples were subjected to changed conditions other than optimized parameters.

CONCLUSION

From the above experimental studies, it can be concluded that Area under curve method by UV spectrophotometry instrument developed for estimation of Nitrofurantoin. The proposed methods for the selected drugs were found to be precise and accurate. The most important features of spectrophotometric methods are their rapidity & simplicity. Results of validation parameters demonstrate that these performed analytical procedures are suitable for its intended purpose and meet the criteria defined in ICHQ2A/B guidelines. The method is an excellent alternative to HPLC methods for routine analysis and accurate and better than the zero order UV spectrophotometric method.

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