UV SPECTROPHOTOMETERIC METHOD DEVELOPMENT AND VALIDATIONFOR ESTIMATION OF NITROFURANTOIN IN BULK AND TABLET DOSAGE FORM

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ABSTRACT:
Objective: The objective of the present work is to develop a new, simple, sensitive and precise UV spectrophotometric method for Nitrofurantoin in bulk and pharmaceutical formulation as per ICH guidelines.
Method: The UV spectrophotometric method has been developed using by Dimethylformamide : Methanol as solvent to determine the Nitrofurantoin in bulk and pharmaceutical formulation. The λ_{max} of Nitrofurantoin in Dimethylformamide : Methanol was found to be 369.6 nm.
Results: The drug was proved linear in the concentration range of 2-10 µg/ml and regression coefficient was found to be 0.999. The LOD and LOQ of Nitrofurantoin was found to be 0.468821 and 1.420671 respectively. This method was successfully applied to Nitrofurantoin in marketed formulation and results were in good agreement with label claims.
Conclusion: Depending on the results, the given method can be successfully applied for assay of Nitrofurantoin in Tablet formulation.

KEYWORDS:

Nitrofurantoin, Validation, Specificity, LOD, LOQ

Introduction

Nitrofurantoin is an antibiotic drug applicable for the care for bladder infections. It is not efficient for kidney infections. Nitrofurantoin taken by oral cavity[1]. Nitrofurantoin is an antibiotic drug that fights bacteria in the human body. Nitrofurantoin is used to treat urinary tract infections(UTI). We should not take Nitrofurantoin if you have severe urination problems, kidney disease or a history of jaundice or liver problems caused by nitrofurantoin[2].
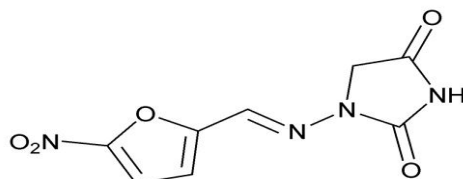

Fig 1. Chemical Structure of Nitrofurantoin

Molecular formula and weight of Nitrofurantoin is $C_8H_6N_4O_5$ and 238.16 g/mol respectively[1]. Nitrofurantoin is practically insoluble in water but soluble in Methanol, ethanol, acetone and ethyl acetate. Analytical methods are reported for determination of Nitrofurantoin by UV Visible spectroscopy[2-4]. The aim of this study is to give a new, simple, sensitive, precise and reproducible UV spectroscopic method was developed for Nitrofurantoin in Tablet formulation.

MATERIALS AND METHODS:
Materials:
Nitrofurantoin was obtained as gift sample from
Instruments**:**

Analytical balance (Shimadzu AY220), Sonicator (Microclean-1103), UV-Visible spectrophotometer (Systronic 2201).

Experimental:
Preparation of standard stock solution:
Accurately weighed 10 mg of Nitrofurantoin was transferred to a 10 ml volumetric flask; dissolved in Dimethylformamide : Methanol (70:30) and volume was made upto the mark with Dimethylformamide : Methanol (70:30). (Conc: 1000µg/ml)

Working Standard:
Add 0.1 ml of standard stock solution in 10 ml volumetric flask and add 5 ml of Dimethylformamide : Methanol (70:30), mix for 2 min and make up the volume upto 10 ml with Dimethylformamide : Methanol. (Conc: 10 µg/ml) Selection of analytical wavelength was done by scanning above solution in the range 200-400 nm

Procedure for plotting calibration curve:
For calibration curve, in a series of 10 ml volumetric flasks, 0.2, 0.4, 0.6, 0.8 and 1ml of standard stock solution of 100µg/ml was pipetted out separately and the volume was made upto the mark using Dimethylformamide : Methanol (70:30). The absorbance was measured at wavelength 369.6 nm against the blank solution.

A. Sample stock solution:
20 Tablet content were weighed and mix them in mortar and pestle. Powder weight equivalent to 10 mg Nitrofurantoin was weighed and transferred into the 10 ml volumetric flask and add 5 ml of Dimethylformamide : Methanol (70:30), sonicate for 10 minutes and make the volume to 10 ml with Dimethylformamide : Methanol. (Conc: 1000µg/ml)

B. Sample solution:
0.5 ml of above solution was then transferred into a 10 ml volumetric flask and 5 ml of Dimethylformamide : Methanol was added, sonicate for 10 minutes and make the volume upto 10 ml with the Dimethylformamide : Methanol and analysed at 369.6 nm. Then % purity of Nitrofurantoin was calculated. (Conc: 50 µg/ml)

RESULTS AND DISCUSSION:
The absorption spectrum shows λ_{max} of Nitrofurantoin at 369.6 nm.The proposed method was validated according to ICH Q2 R1 guidelines for validation of analytical procedure.
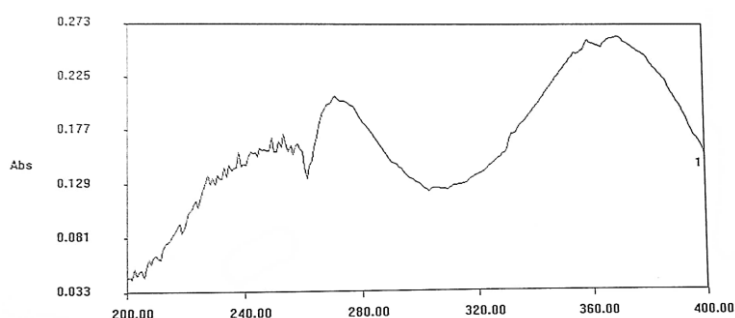

Figure 2. UV scan of Nitrofurantoin *Linearity:*[5]

Five different concentrations of Nitrofurantoin were prepared and analysed at wavelength 369.6 nm. The regression coefficient was found to be 0.999. The absorbance was found in limit i.e. 0-1. (table no 1)

Table 1

Sr.No	Conc (µg/ml)	Abs
1	2	0.046
2	4	0.09
3	6	0.132
4	8	0.176
5	10	0.222

y = 0.0219x + 0.0018
R^2 = 0.9998
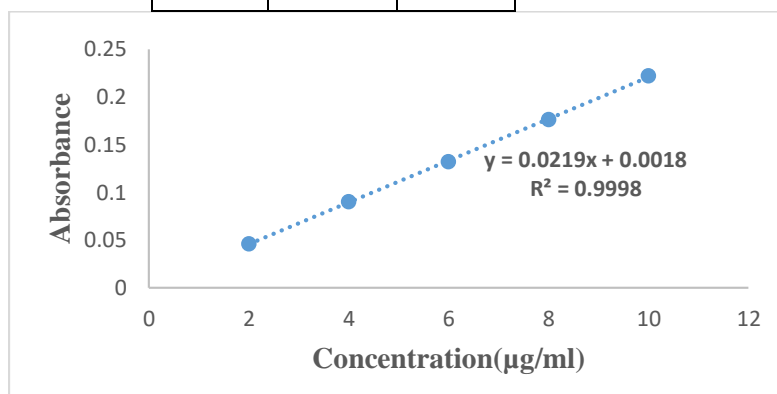
Fig 3. Linearity

Table no 2: Optimization parameters of Nitrofurantoin

Parameters	Method values
Maximum Wavelength	369.6
Beers law	2-10µg/ml
Correlation Coefficient	0.9998
Regression Equation	Y=0.0219x + 0.0018
Slope	0.0219
Intercept	0.0018

1. Accuracy:

The concentration 2,4,6µg/ml was taken as 50,100,150% and % recovery was found to be in range 99%-101%. Henceforward the parameter was found to be validated.

Table 3: Results of Accuracy

Name of Drug	Recovery Level in %	Concentration	Amount Recovered	% recovery with SD
Progesterone	50	2µg/ml	2.01	100.8±0.577
	100	4µg/ml	4.03	100.75±0.25
	150	6µg/ml	5.97	99.6±0.096

2. Range:

Range is an interval between highest and lowest concentration limit of the analyte i.e. 2-10 µg/ml.

3. Precision:

In precision intra-day and inter-day precision were performed at concentration (6µg/ml). The obtained results were found within limit i.e., less than 2%RSD.

Table 4: Results of Intra-day Precision

Sr. no.	Concentration	Absorbance
1	(6µg/ml)	0.132
2		0.13
3		0.128
4		0.132
5		0.133
6		0.132
	SD	**0.001835**
	%RSD	**1.398867**

Table 5: Results of Inter-day precision

Sr.no.	Concentration	Absorbance (Day1)	Absorbance (Day2)
1	(6µg/ml)	0.132	0.133
2		0.13	0.131
3		0.128	0.132
4		0.132	0.133
5		0.133	0.13
6		0.132	0.128
	SD	**0.001835**	**0.001941**
	%RSD	**1.398867**	**1.479637**

4. Limit of Detection (LOD):

It was calculated by ANOVA technique. The limit of detection was found to be 0.46882 µg/ml.

5. Limit of Quantification (LOQ):

The limit of quantification was found to be 1.42067 µg/ml.

6. Ruggedness:

The change in analyst with same concentration and environmental condition didn't affect the results.

Table 6: Results of Ruggedness

Concentration	Absorbance (Analyst1)	Absorbance (Analyst2)
10µg/ml	0.222	0.222
	0.221	0.221
	0.223	0.223
	0.220	0.220
	0.221	0.221
	0.224	0.224
Average	0.221833	0.2218
SD	0.001472	0.001472

Assay:

Sample solution of concentration 50 µg/ml was analysed at wavelength 369.6 nm and the % purity was calculated.

Table 7: Result of Assay

Formulation	Labeled Amount	Amount obtained	% purity
Niftas 100mg Tablets	1 mg	99.48	99.48%

CONCLUSION:

An analytical UV spectrophotometric method was developed & validated thoroughly for quantitative determination of Nitrofurantoin in Tablet Formulation. The presented method was found to be simple, precise, accurate, and reproducible gives an acceptable recovery of the analyte.

ACKNOWLEDGEMENT:.

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