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UV Spectrophotometric Method Development and Validation for 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, economical, precise, sensitive, linear, accurate, rapid UV Spectrophotometric method that has been developed for the estimation of Nitrofurantoin in bulk and pharmaceutical formulation as per ICH guidelines. **Method:** Spiked Nitrofurantoin arrangement was checked over UV-visible extends for its wavelength of greatest absorbance. **Results**: The wavelength of most extreme absorbance for Nitrofurantoin was found to be 360.0 nm. The regression coefficient over the concentration of 10-50µg/ml was found to be 0.9982. The LOD and LOQ of Nitrofurantoin were found to be 0.030376 And 1.012745 respectively. The method was successfully applied to Nitrofurantoin in the marketed formulation and results were in good agreement with label claims. **Conclusion:** Depending on the results, the given method can successfully apply Nitrofurantoin in Tablet formulation.

INTRODUCTION:

Nitrofurantoin, an oral antibiotic, is employed to treat or prevent specific urinary tract infections. It works by halting bacterial growth. While it is effective for bladder infections, it is not considered efficient for kidney infections. Nitrofurantoin is taken orally, and its mode of action involves inhibiting the growth of bacteria. Therefore, it is commonly prescribed to combat bladder infections, but healthcare professionals advise against its use for kidney infections due to its limited effectiveness in that particular context.

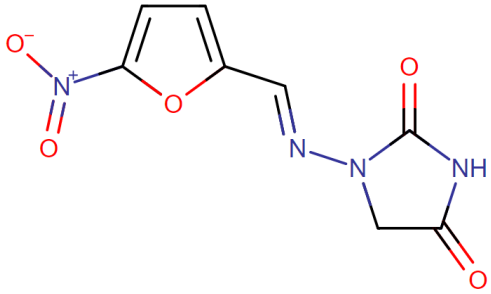

Fig.1: Chemical structure of Nitrofurantoin

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 have been reported so far for determining Nitrofurantoin in pharmaceutical formulations and bulk drugs. On the literature survey, it was found that rapid HPLC method for determination of Nitrofurantoin, Analysis of Nitrofurantoin using HPLC in tablet dosage form, UV spectrophotometric method have been reported for the determination of Nitrofurantoin. Still any area under the curve method not reported for the determination of Nitrofurantoin. Hence, the investigation of new analytical methods is in need for the quantitative estimation of Nitrofurantoin.

MATERIALS AND METHOD:

Materials:

Nitrofurantoin API was obtained as a gift sample from Sun Pharma Pvt. Ltd. Panoli, Gujrat, India. Tablets of Susten SR200 were purchased from the local market; each tablet was labeled to contain 200 mg. All chemicals and reagents used were of analytical grade.

Instruments:

A Double-beam UV Visible Spectrophotometer (Systronic-2201) was used for the detection of absorbance, a Sonicator (Microclean-1103), and a Weighing Balance (SHIMADZU AY220) was used for experimental purposes.

Chemical and Reagent:

0.1 N HCL, distilled water, and Whatman filter paper were used.

METHOD DEVELOPMENT:

Selection of solvent:

Solubility of Nitrofurantoin was performed in 0.1N HCL and UV spectra of the drug were recorded. 0.1N HCL was selected as a solvent as the drug is soluble in 0.1N HCL. The maximum absorbance of the drug was recorded in 0.1 N HCL as a solvent.

Determination of Wavelength:

A UV-VIS Spectrophotometric scanning in the range of 200-400nm was carried out to select the wavelength (λ_{max}) for the detection of nitrofurantoin. The drug showed maximum absorbance at 360nm wavelength. Hence, the λ_{max} of nitrofurantoin was selected as 360nm.

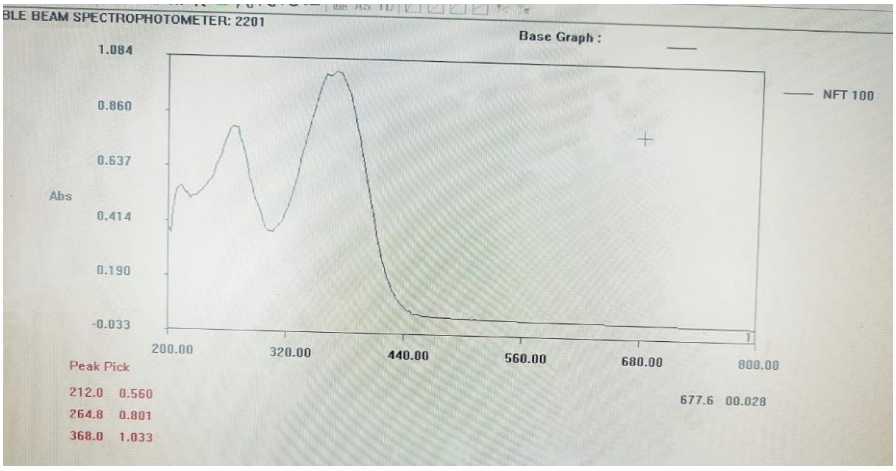

Fig.2: UV-visible spectra of Nitrofurantoin.

Preparation of Standard stock solution:

Accurately weighed 10 mg of Nitrofurantoin was transferred into a 10 ml volumetric flask; dissolved in 0.1 N HCL and volume was made up to the mark with 0.1 N HCL

(Concentration 1000µg/ml). Further, 1ml of Nitrofurantoin stock solution was pipetted out and transferred to a 10ml volumetric flask and diluted up to the mark with 0.1N HCL (conc.100µg/ml).

Preparation of Sample Stock Solution:

20 Tablets were weighted and triturated in a mortar pestle. Powder equivalent to 10 mg of nitrofurantoin was weighed and transferred into the 10 ml of volumetric flask. Add 5 ml of 0.1 N HCL sonicate for 10 minutes and dilute up to the mark with 0.1 N HCL. Further, 1 ml of nitrofurantoin sample stock solution was pipetted out and transferred to a 10 ml of volumetric flask and diluted up to the mark with 0.1N HCL (conc.100µg/ml).

METHOD VALIDATION:

The developed method was validated as per ICH guidelines. The parameters assessed were linearity, range, accuracy, precision (repeatability and reproducibility) and sensitivity.

RESULT AND DISCUSSION:

Linearity and Range:

Linearity is defined as the ability of the analytical procedure to obtain test results, which is directly proportional to the concentration of the analyte in the sample. Five different concentrations of Nitrofurantoin solutions were prepared by diluting 1ml, 2ml, 3ml, 4ml, 5ml to 10ml with 0.1N HCL to obtain the concentrations in the range of 10-50 µg/ml. These series of dilutions were analyzed at 360nm to assess the linearity.

Table 1: Calibration data of nitrofurantoin

Sr.No	Concentration (µg/ml)	Absorbance
1	10	0.135
2	20	0.245
3	30	0.353
4	40	0.451
5	50	0.540

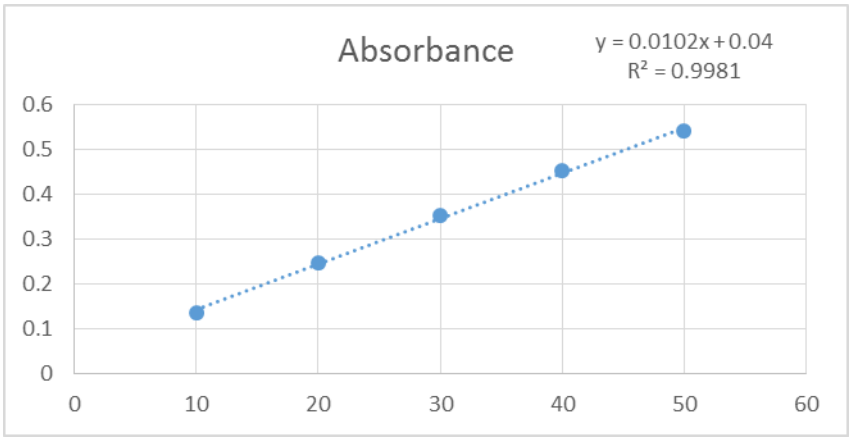

Fig.3: Calibration curve of Nitrofurantoin

The nitrofurantoin follows the Beer's Lambert Law in the linearity range of 10-50µg/ml. The regression coefficient R^2 value is 0.9981 with the equation y = 0.0102x + 0.04. The R^2 value is in the limit so the linearity parameter is validated.

Accuracy:

Accuracy is defined as, an analytical procedure that expresses the closeness of an agreement between the value that is accepted and either as a true conventional value. The accuracy was determined by calculating % recovery at three concentration levels 80, 100, and 120% of nitrofurantoin. It was carried out by following the standard addition method. A known amount of standard nitrofurantoin solution (API) was spiked to the tablet solution. The % recovery was calculated. %Recovery= observed value/true value×100

Table 2: Result of accuracy

%Level	Amt spiked (µg/ml)	Amt recovered (µg/ml)	% recovery
80	8	7.88	98.5
100	10	9.54	95.4
120	12	11.61	96.7

% Recovery of nitrofurantoin is better than 95.4-98.5% which is within the limit hence the method is accurate.

Precision:

Precision is to define the closeness of agreement between a samples of measurements obtained from multiple sampling of the same homogenous sampling in specific conditions. The precision of the analytical method was studied by performing repeatability studies by estimating responses of the working standard solution of 30µg/ml concentration for intra-day and inter-day. The results were reported in terms of percentage relative standard deviation (%RSD).

Table 3: Result of precision (Repeatability and Reproducibility)

Sr. no.	**Concentration**	**Intra-day readings**	**Inter-day readings**	
		Absorbance	**Absorbance (Day 1)**	**Absorbance (Day 2)**
1	(30 µg /ml)	0.342	0.343	0.343
2		0.343	0.343	0.342
3		0.342	0.343	0.342
4		0.344	0.342	0.343
5		0.343	0.344	0.343
6		0.342	0.341	0.344
	Mean	0.342667	0.342667	0.342167
	SD	0.000816	0.001033	0.001169
	%RSD	0.238277	0.301399	0.34166

The %RSD value for intra-day and inter-day precision is 0.238277& 0.34166 respectively. The % RSD values are less than 2% hence, the method is precise and valid.

Sensitivity:

Limit of Detection (LOD):

The limit of detection is defined as the lowest amount of analyte in a sample that can be detected. LOD is based on the standard deviation value from precision and slope of the regression coefficient. The formula for calculating LOD = 3.3*σ/S

Where, σ = Standard deviation, S = Slope of the regression coefficient.

LOD	0.378 µg/ml

The LOD for nitrofurantoin was found to be 0.378 µg/ml.

Limit of Quantification (LOQ):

The limit of quantification is defined as the lowest amount of analyte in the sample that can be quantified. LOQ is calculated by the formula; LOQ = 10*σ/S

Where, σ = Standard deviation, S = Slope of the regression coefficient.

LOQ	1.146 µg/ml

The LOQ for nitrofurantoin was found to be 1.146 µg/ml.

The method is sensitive as a small amount of nitrofurantoin is required to be detected and quantified. Hence, the sensitivity parameter is validated.

Assay:

Sample solution of concentration 10 µg/ml was analyzed at wavelength 360nm and the % purity was calculated.

Table 4: Result of Assay

Formulation	**Label claim**	**Absorbance**	**Amount obtained**	**% Purity**
Tablet Susten SR200	200 mg	0.140	196.06 mg	98.0

The percentage purity calculated by the regression equation was found to be 98.0%. The label claim of 200mg was recovered by 98.0% of nitrofurantoin in tablet dosage form.

Table 5: Optimization parameter of Nitrofurantoin

Parameter	**Method values**
Detection wavelength	360nm
Beers range	10-50 µg/ml
Correlation Coefficient	0.998
Regression coefficient	Y= 0.0102x + 0.04
Slope	0.0102
Intercept	0.04

CONCLUSION:

An analytical UV-visible spectrophotometric method was developed and validated for quantitative analysis of Nitrofurantoin in Tablet formulation. The presented method is simple, accurate, precise, easy, economical, and reproducible, and gives an acceptable recovery of the analyte. All the parameters were validated according to the Q2 R1 analytical guidelines as per ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use).

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REFERENCES:

1. Karajgi, S., & Mali, S. (Year). UV spectrophotometric area under curve method for the determination of nitrofurantoin in tablet formulations.
2. Hadi, H., & Mouayed, M. (Year). Determination of nitrofurantoin in pharmaceutical preparations using flow injection-spectrophotometry.
3. Kumar, M. S., & Shanmugapandiyan, P. (2017). "BIOANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF NITROFURANTOIN IN HUMAN PLASMA BY LC-MS/MS." International Journal of Pharmaceutical Sciences and Research, 8(10),
4. Abd-Alrassol, K. S., Sattar, M., & Mosa, M. N. (Year). "Spectrophotometric Determination of Nitrofurantoin in its Bulk and Pharmaceutical Formulations."
5. Tubino, M., Bianchessi, L. F., Palumbo, M., & Vila, M. M.D.C. (Year). "GREEN AND SIMPLE UV-VISIBLE DIFFUSE REFLECTANCE AND TRANSMITTANCE METHODS FOR THE DETERMINATION OF NITROFURANTOIN IN PHARMACEUTICAL PREPARATIONS."
6. Wijma, R. A., Huttner, A., Koch, B. C. P., Mouton, J. W., & Muller, A. E. (Year). "Review of the pharmacokinetic properties of nitrofurantoin and nitroxoline."
7. Sekhar, G. C., Satyanarayana, B., Suguna, P., & Narasimhulu, B. (Year). "Analysis of nitrofurantoin in bulk drug and pharmaceutical dosage forms by HPLC method." International Journal of Engineering Sciences & Research Technology,
8. Kumar, H., & Mallikarjuna, B. P. (Year). "Preparation of in-vitro evaluation of pro liposome of nitrofurantoin.".
9. Jain, P. S., Chaudhari, A. J., Patel, S. A., Patel, Z. N., Patel, D. T., Kumar, H., & Mallikarjuna, B. P. (Year). "Preparation of in-vitro evaluation of pro-liposome of nitrofurantoin."
10. Joshi, D., Singh, B., Rautela, A., Semwal, N. (2021). "Analytical Method Development and Validation of UV-Visible Spectrophotometric Method for the Estimation of Saxagliptin in Gastric Medium."