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SPECTROPHOTOMETRIC ESTIMATION OF NITROFURANTOIN AND ITS APPLICATION IN PHARMACEUTICALS PREPARATION

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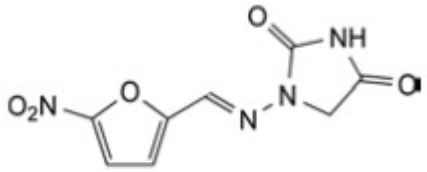
ABSTRACT : Nitrofurantoin is a nitro furan-derivative antibacterial agent. A new, very simple and economical method has been developed,for.estimation of Nitrofurantoin in pharmaceutical preparations form has been developed. The method is depend on the direct reaction between sodium hydroxide and nitrofurantoin to yield yellow-orange product)with maximum absorption at 390 nm (Beer's law) was obeyed with concentration range of 0.2-2.8µg/ml and molar absorptivity 2.546×10^4 l/mol.cm. The present method successfully applied for assay of nitrofurantoin in pure form and dosage formulations.

Key words : Nitrofurantoin, pharmaceutical preparations, sodium hydroxide.

INTRODUCTION

Nitrofurantoinis 1-(5-Nitrofurfurylideneamino) imidazolidine-2,4-dione) has the chemical formula $C_8H_6N_4O_5$ with a molecular weight of 238.2 g/mole (Fig. 1) used in veterinary and human medicine. Nitrofurantoina yellow odourless or almost odourless, crystalline powder or crystals. Very slightly soluble in water and in alcohol, Nitrofurantoin is bactericidal *in vitro* to most Gram positive and Gram-negative urinary-tract pathogens (Sweetman, 2009) (BMJ Publishing Group Ltd and Royal Pharmaceutical Society, 2015) (Konar *et al*, 2014).

Very few methods are used for the analytical of nitrofurantoin such as UV spectrophotometric methods (Karajgi *et al*, 2018; Tubino *et al*, 2011; Karajgi *et al*, 2018),visible spectrophotometric methods (Hadi and Mouayed, 2016), liquid chromatography, liquid chromatography tandem mass spectrometry (Patel *et al*, 2013), HPLC method (Wilasinee *et al*, 2015) and Voltammetric method (Krejèová *et al*, 2015). This method very simple spectrophotometric assay of nitrofurantoin in pure form and pharmaceutical formulations.



$C_8H_6N_4O_5$= 238.2

Fig. 1: Chemical Structure of Nitrofurantoin.

MATERIALS AND METHODS

Instrumentation

A spectra scan 50 UV-visible spectrophotometer, with 1.0 cm, quartz, cells was used [UVS-2700, Labomed, INC], USA.

Materials

Standard materials and pharmaceutical preparations (Pharmaceutical grade Nitrofurantoin (and) tablets 100 mg were kindly supplied, as a gift, sample from state drug company, (SDI)) Samara, Iraq, oral suspension 25mg/5ml and capsules 50mg manufactured by Bio Active T, United Kingdom provide from local market.

Nitrofurantoin.stock solution:100 µg/ml

Dissolving 0.010 g of Nitrofurantoin in 100 ml of 1N NaOH in a calibrated flask.

Nitrofurantoin standard solution : 10µg/ml (4.198×10^{-5}M) was preparedbydiluting 10ml (of the stock solution) to 100 ml by 1N NaOH in a calibrated flask.

Sodium hydroxide (1N)

Recommended procedure

Suitable aliquots of Nitrofurantoin standard; solution (5-70 µg) were diluted up to the mark, with D.W. to get final volume 25 ml. The absorbance's were measured at 390 nm against blank.

Sample preparation for analysis of tablet

For the purpose of obtaining a homogeneous component (10) tablets of Nitrofurantoin were weighed and grounded, then, the powder equivalent to 10mg of was accurately weigheds and transferred, into a 100 ml calibrated flask, 60 ml of 1N NaOH was added, and the solution was shake for 10 mins. Then the volume was made up to the mark with1N NaOH solution. 10ml of this solution was diluted to a 100ml with 1N NaOH solution in a calibrated flask. Different volume of above solution was treated as mentioned under recommended procedure.

Procedures for pharmaceutical preparations (capsules)

The content of tenfurantil capsules were weighed and equivalent of 10mg of Nitrofurantoin was accurately weighed and transferred into a 100 ml calibrated flask, 60 ml of 1N NaOH was added and the solution was shake for 10 min. Then the volume was made up to the mark with 1N NaOH solution. 10ml of this solution was diluted to a 100ml with 1N NaOH solutionin a calibrated flask. Different volume of this solution was treated as described under recommended procedure.

Procedures for pharmaceutical preparations (suspensions)

The contents of five bottles of furantil suspensions were mixed well and 2ml of suspension contain 10mg of Nitrofurantoin) suspensions was diluted to 100 ml with 1N NaOH solution. 10ml of this solution was diluted to a 100ml with 1N NaOH solution in a calibrated flask. Different volume of this solution was treated as mentioned under recommended procedure.

RESULTS AND DISCUSSION

Spectrophotometric methods development for the assay of drugs has been increased considerably in recent) years, because of, their importance, in pharmaceutical analysis (Ahmad and Hajum, 2012). Sodium hydroxide was investigated and used for determination of some pharmaceutical substances (Rahman and Al-Qazzaz, 2019; Dhumal *et al*, 2015; Narendra and Naresh, 2010). A new method has been developed for the spectrophotometric determination of Nitrofurantoin by sodium hydroxide. The method,was based on the formation of a yellow colored product. The suggested reaction is as shown in Fig. 1.

The product having (maximum absorption) at 390 nm against the reagent blank as shown in Fig. 2.

(Beer's law is obeyed over the conc. range) 2 - 20µg/ml. Linear regression equation: Y = 0.1069X+0.1736 (r = 0.998, n = 8). Where, (Y) is the, absorbance and (X) is the (concentration) in µg/ml as shown in Fig. 3. The apparent molar absorptivity was 2.546×10^4 l/mol.cm, and (Sandell sensitivity) 9.355×10^{-3}µg/cm^2.

Accuracy and precision

The accuracy and precision of the pure drug solution were studied, for three different levels, percentage relative standard deviation was calculated and the results shown in Table 1. Acceptance criteria: % RSD should not be more than 2.0.

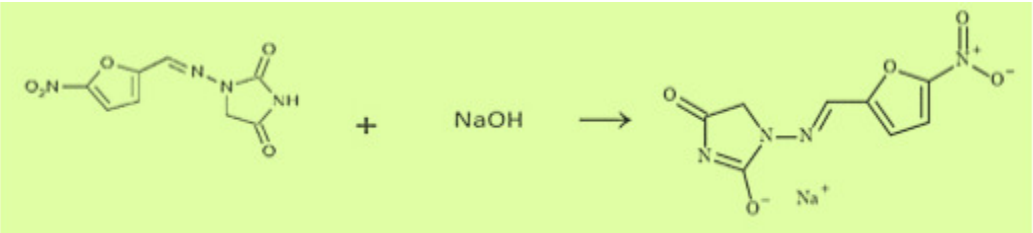


Fig. 1 :

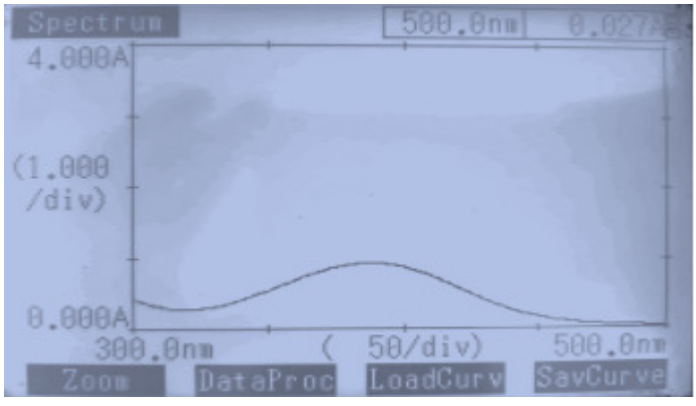


Fig. 2 : Spectra absorption of 2µg/ml of Nitrofurantoin against blank.

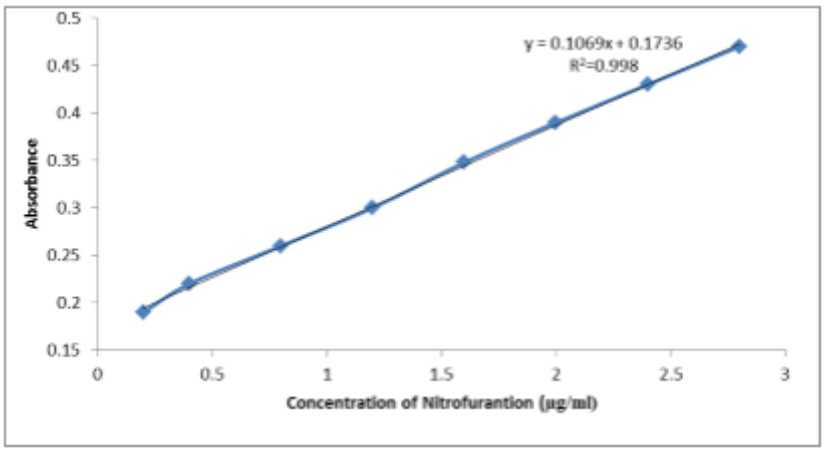


Fig. 3 : Calibration curve of Nitrofurantoin.

Table 1 : Spectral and statistical data for the determination of nitrofurantoin.

Parameters	Value
ë max (nm)	390
Molar absorptivity, (l.mol^{-1}.cm^{-1})	2.546x10^4
Beer's law limits, (î g.ml^{-1})	0.2-2.8
'Sandell's sensitivity' (ng\cm^2)	9.355
Correlation coefficient (r)	0.998
Regression equation (y= a + bx)	Y=0.1069X+0.1736
Intercept (a)Slope (b)	0.17360.1069
Recovery (%)	100 ±0.75
Relative standard deviation (%)	< 1.9

Table 2 : Determination of 2µg/ml of Nitrofurantoin in the presence of excipients.

Substances interfering	Amount added(mg)	Amount Found*(µg)	Recovery (%)
Corn starch	40	2.016	100.8
Microcrystalline cellulose	20	1.99	99.5
Mannitol	1000	2.01	100.5
Talc	1000	2.015	100.75
Propylene glycol	1000	2.016	100.8
Lactose	30	1.996	99.8
Magnesium stearate	40	2.018	100.9
Polyethylene glycol	20	2.015	100.75

*Average of 6 determinations.

Table 3 : Assay of Nitrofurantoin in dosage form.

Dosage forms	Label (mg)	Found *(mg)	Recovery (%)
Tablet: (SDI)	100mg/tab	99.95	99.95
Furantil suspension (Bio Active T)	each 5ml contain 25mg	25.06 mg/5ml	100.24
Furantil Capsules (Bio Active T)	50mg/cap	50.01	100.02

*Mean of ten determinations.

Interference studies

To assess the possible applications of the present procedure. The effect of interference substances with Nitrofurantoin in pharmaceutical preparations were studied. The results as shown in Table 2.

Analytical application

The method was applied to tablets, oral suspensions and capsules the results of the assay and the label claim shown in Table 3.

CONCLUSION

The proposed analytical method. A new very simple and economical method has been developed for estimation of Nitrofurantoin and applied for routine quality control analysis of Nitrofurantoin in pure form and different dosage forms.

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