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Research article

ESTIMATION OF DIGOXIN IN ITS TABLET DOSAGE FORM

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ABSTRACT

Digoxin belongs to a class of medications called cardiac glycosides. It works by affecting certain minerals (sodium and potassium) inside heart cells. This reduces strain on the heart and helps it maintain a normal, steady, and strong heartbeat. It is also used to treat certain types of irregular heartbeat (such as chronic atrial fibrillation). This UV-spectrophotometric technique is quite simple, accurate, precise, reproducible, and sensitive. The UV method has been developed for quantification of digoxin in tablet formulation. The validation procedure confirms that this is an appropriate method for their quantification in the formulation. It is also used in routine quality control of the formulations containing this entire compound.

Keywords: Digoxin, Tablet form, Estimation.

INTRODUCTION

Digoxin belongs to a class of medications called cardiac glycosides. It works by affecting certain minerals (sodium and potassium) inside heart cells. This reduces strain on the heart and helps it maintain a normal, steady, and strong heartbeat. It is also used to treat certain types of irregular heartbeat (such as chronic atrial fibrillation). Treating heart failure may help maintain your ability to walk and exercise and may improve the strength of your heart. Treating an irregular heartbeat can also improve your ability to exercise [1]. Although some effects of digoxin may be noticed soon after taking, it can take up to 7-14 days or longer after drug initiation or a dosage change for the full effects to be seen. 500 to 750 mcg usually produces a detectable effect in 0.5 to 2 hours with a maximal effect in 2 to 6 hours. Additional doses of 125 to 375 mcg may be given at 6 to 8 hour intervals until clinical evidence of an adequate effect is noted. The usual amount of tablets that a 70 kg patient requires to achieve 8 to 12 mcg/kg peak body stores is 750 to 1250 mcg.

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METERIALS AND CHEMICALS

Digoxin was bought from sigma Aldrich ltd. All chemicals (distilled water, methanol) and reagents used were of analytical grade and purchased from Qualigens Fine Chemicals, Mumbai, India [2-3]. A Labindia UV–visible spectrophotometer (UV-T60-India) was used for all absorbance measurements with matched quartz cells.

METHODOLOGY

Preparation of standard stock solution

Accurately weighed 10 mg of digoxin was transferred to a 100 ml volumetric flask, dissolved in 20 ml distilled water by shaking manually for 10 min. The volume was adjusted with the same up to the mark to give the final strength, i.e. 100 µg/ml.

Estimation of wavelength maximum

Appropriate volume 0.5 ml of standard stock solution of digoxinwas transferred into a 10 ml volumetric flask, diluted to a mark with distilled water to give concentration of 5 µg/ml(and also 10, 15µg/ml). The resulting solution was scanned in the UV range (200–400 nm). In spectrum digoxin showed absorbance maximum at 283 nm [4-5].

Method Validation

The method was validated in terms of linearity, accuracy, precision, and ruggedness. Linearity study Different aliquots of digoxinin the range 0.5–3 ml were transferred into series of 10 ml volumetric flasks, and the volume was made up to the mark with distilled water to get concentrations 5, 10, 15, 20, 25, and 30 µg/ml, respectively. The solutions were scanned on a spectrophotometer in the UV range 200–400 nm. The spectrum was recorded at 287 nm. The calibration plot was constructed as concentration vs. absorbance [6-7].

Accuracy

To the pre analysed sample solutions, a known amount of standard stock solution was added at different levels, i.e. 50%, 100%, and 150%. The solutions were reanalyzed by the proposed method [8-9].

Precision

Precision of the method was studied as intraday and interday variations. Intraday precision was determined by analyzing the 10, 15 and 20 µg/ml of digoxin solutions for three times in the same day. Interday precision was determined by analyzing the 10, 15, and 20 µg/ml of digoxin solutions daily for 3 days over the period of week [11-14].

LOD AND LOQ

The sensitivity of measurements of digoxin by the use of the proposed method was estimated in terms of the limit of quantification (LOQ) and limit of detection (LOD). The LOQ and LOD were calculated using equation LOD = 3 × N/B and LOQ = 10 × N/B, where 'N' is standard deviation of the peak areas of the drugs (n = 3), taken as a measure of noise, and 'B' is the slope of the corresponding calibration curve [15-16].

Repeatability

Repeatability was determined by analyzing 20 µg/ml concentration of digoxin solution for six times.

Ruggedness

Ruggedness of the proposed method is determined for 20 µg/ml concentration of digoxin by analysis of aliquots from a homogenous slot by two analysts using same operational and environmental conditions [17].

RESULTS & DISCUSSION

Selection of wavelength for analysis of digoxin. During the development phase, the use of ethanol as the diluent resulted in preferable outcome in UV analysis. The pre-determined wavelength of maximum absorption (λmax) was 283 nm.

Table 1: solubility of drug in the solvents

S. No	Solvent	Amount (mcg/ml)
1	Pet ether	2.14
2	Chloroform	1.67
3	Methanol	0.99
4	Ethnaol	0.82
5	Acetone	0.73
6	Distilled water	0.51

Table 2: Estimation of accuracy and Recovery study

Parameter	Digoxin
Amount used	52mcg
Amount recovered	50.74mcg
Percentage recovered	99.87%
Label Claim	600mg
Estimated amount	499.12mg
Percentage of assay	99.1%

Table 3: Estimation of precision and other parameters

S. No	Parameters	values
1	max(nm)	283
2	linearity range	21-45µg/ml
3	regression equation	Y=0.0896X-0.0896
4	correlation coefficient	2.415
5	slope	0.0923
6	intercept	0.0867
7	Limit of detection(µg/ml)	0.9462

8	Limit of quantification(µg/ml)	7.8765
10	Intra day variations	0.9892±0.0720
11	Inter day variations	0.9508±0.0384

CONCLUSION

This UV-spectrophotometric technique is quite simple, accurate, precise, reproducible, and sensitive. The UV method has been developed for quantification of digoxin in tablet formulation. The validation procedure confirms that this is an appropriate method for their quantification in the formulation. It is also used in routine quality control of the formulations containing this entire compound.

CONFLICT OF INTEREST

Authors declare no conflict of interest.

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