IRJSE International Research Journal of Science & Engineering
Int. Res. J. of Science & Engineering, 2018; Special Issue A3 :96-100
ISSN: 2322-0015
SJIF Impact Factor 4.11
UGC Approved Journal No. 63628
RESEARCH ARTICLE **OPEN ACCESS**

Estimation of Frusemide in bulk and tablet formulation by UV spectrophotometric Area under Curve method

Phalle Supriya, Patel SG, Dhobale SM

Department of Quality Assurance technique, Vishal Institute of Pharmaceutical Education and research, Ale, Tal - Junner , Pune (MH)412411
Email.ID: supriyashahane29@mail.com |9970108655

Manuscript Details
Available online on http://www.irjse.in
ISSN: 2322-0015

Editor: Dr. Arvind Chavhan

Cite this article as:
Phalle Supriya, Patel SG, Dhobale SM. Estimation of Frusemide in bulk and tablet formulation by UV spectrophotometric Area under Curve method, *Int. Res. Journal of Science & Engineering,* January 2018; Special Issue A3 : 96 - 100.

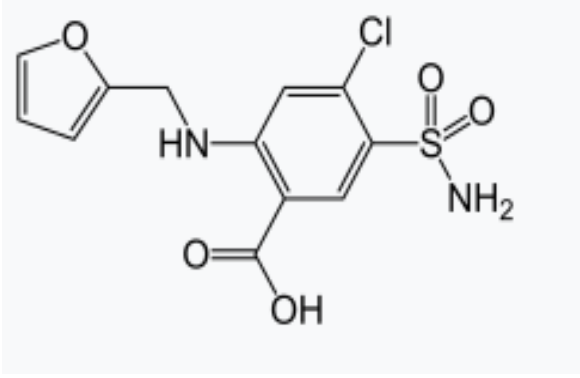
ABSTRACT

The present work was to develop simple UV spectrophotometric method for simultaneous estimation of frusemide in bulk and tablet dosage form and validate as per ICH guidelines. In which two methods, method A is absorption maxima method in that **λmax** was found to be **277 nm.** Method B is Area under curve (AUC). Furosemide is the most commonly used high potency loop diuretics use in clinical practices. A least time consuming efficient and simple UV spectrophotometric method for the assay of frusemide has been developed. Comparison of assay of brands of frusemide (Lasix 20mg) has also been made available in medical store. The assay is based on the ultraviolet UV absorbance maxima at about 277nm wavelength of frusemide using ethanol as solvent. A sample of drug was dissolved in methanol to produce a solution containing frusemide. Similarly, a sample of ground tablet was dissolved in ethanol and various dilutions were made. The absorbance of sample preparation was measured at 277nm against the solvent blank and the assay was determined by comparing with the absorbance of available brand. The developed methods were validated for linearity, precision, accuracy, LOD and LOQ as per ICH guidelines. Both the methods were found to be linear within the conc. Range of 5-25µg/ml for frusemide. The present methods were found to be simple, linear, precise, accurate and sensitive and can be used for routine quality control analysis for the estimation of frusemide in bulk and tablet dosage form.

Keywords- Frusemide, Area under Curve, ICH guidelines.

INTRODUCTION

Frusemide (Fu) chemical name is 5-(aminosulfonyl)-4-chloro-2-[(2-furanyl methyl)aminobenzoic acid]. It has the following generic names: Frusemide, Fursemide , Aisemide, Beronald, Desdimin, Lasilix and others. The empirical formula is C12H11ClN2O5S corresponds to molecular weight of 330.77. Frusemide is white to slightly yellow, odourless, almost tasteless crystalline powder, slightly soluble in water, chloroform and ether soluble in acetone, methanol,ethanol, dimethyl formamide [1] and in solutions of alkali hydroxides [2]. It melting point is 206°C; the pH of the aqueous solution is in the range 8.9 to 9.3. The UV spectrum of frusemide (0.01 mg/ml) in 0.1N NaOH was scanned from 190 to 400 nm using DMS 90 Varian spectrophotometer. It exhibited two maxima at 226 and 277 nm. Several methods have been reported for the determination of the components of this important drug (frusemide). Titrimetric methods [3-7], potentiometric methods [8, 9],Ultraviolet methods, Colorimetric methods. Because of cost-effective and minimal maintenance, UV spectrophotometry is always preferred at small scale industries. Literature survey reveals that so far many UV spectrophotometric methods have been reported for the estimation of Furosemide in alone or in combination with other drugs [9]. But out of them only few methods included single estimation of frusemide. Therefore the main objective of the proposed methods were to develop simple, new and economic UV spectrophotometric methods for the estimation of frusemide in bulk and tablet dosage form and validate as per ICH guidelines



Chemical structure of Frusemide

METHODOLOGY

1. Chemicals-

Frusemide was supplied by Sanofi Aventis, Andhari Mumbai, India. Tablet of frusemide 20mg (Lasix) was procured from local pharmacy. Ethanol S.D. Fine Chemicals, Mumbai, India) was used. All chemicals and reagents were of analytical reagent (AR) grade.

2. Instrumentation

A Shimadzu (Kyoto, Japan) model UV-1800 double beam UV-Visible spectrophotometer attached with computer operated software UV probe 2.33 with spectral width of 2 nm, wavelength accuracy of 0.5 nm and pair of 1 cm matched quartz cells was used to measure absorbance of the resulting solutions. Analytical balance, Mettler Toledo (Model JL1503- C).

3. Method

3.1 UV-Spectroscopy Methods

A) Absorbance Maxima Method:

UV-Visible spectroscopy refers to absorption or reflection spectroscopy in the ultra visible spectral region. It means it utilizes the light of visible and adjacent near-UV and near-infrared (NIR) ranges. The absorption or reflectance in the visible range directly affects the perceived colour of the chemical involved. In this range of electromagnetic spectrum, a molecule undergoes electronic transition, absorption measures transition from the ground state to the excited state.[11]

B) Area under curve method

The AUC (area under curve) method is applicable where there is no sharp peak or when broad spectra are obtained. It involves the calculation of integrated value of absorbance with respect to the wavelength between the two selected wavelengths λ1 and λ2. Area calculation processing item calculates the area bound by the curve and the horizontal axis. The horizontal axis is selected by entering the wavelength range over which area has to be calculated. This wavelength range is selected on the basis of repeated observation so as to get the linearity between area under curve and concentration. The above mentioned spectrums were used to calculate AUC. Thus, the calibration curve can be constructed by plotting concentration versus AUC.[15]

4 Experimental Work

a) To check the solubility of Frusemide-

10 mg of frusemide was weighed and solubility of this sample was checked in double distilled water, methanol, ethanol, 1N NaOH, acetonitrile 0.1N HCL. The drug was found to be soluble in ethanol was selected.[16]

b) To identify the λmax of frusemide-

10 mg of the pure drug was accurately weighed and dissolved in 10ml ethanol and the volume was made up to 10 ml with ethanol to give a standard stock solution of 1000µg/ml. Further 2.5ml of 1000ppm solution was withdrawn and was diluted to 25 ml of volumetric flask and 100ppm solution is prepared. Suitable dilutions were made with distilled water to get standard solutions of concentration: 5, 10, 15, 20, 25µg/ml.

C) Sample preparation for analysis of Tablet formulation

Twenty tablets (Frusemide) each tablet containing 20mg of frusemide weighed, average weight calculated and triturated to fine powder and then weighed equivalent to 25mg of frusemide transferred to 25ml of volumetric flask containing proposed diluent, then sonicated for 15 minutes and filtered through whatman filter paper no. 42 to form 1000µg/ml frusemide stock solution of and final volume made up to mark with diluent. From this, 2.5 ml of aliquot transferred in 25 ml of volumetric flask containing diluent to form 100µg/ml of erythromycin stearate stock solution and further dilution of 5, 10, 15, 20, 25ppm and scanned in the range of 200-400nm against ethanol as blank at 215nm and then drug content of solution was calculated by using standard calibration curve.[17]

5. Analytical Method Development

1. Accuracy- It is closeness of the result obtained to the true value. It is often expressed as per cent age recovery by analyzing known added amounts of analyte. Also it can be determined by applying the procedure to quantitatively prepared samples.[18]

2. Precision- The precision of analytical procedure expresses closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the same homogenous sample under prescribed conditions. It may be considered at three levels: repeatability, intermediate precision and reproducibility. It is expressed as standard deviation or coefficient of variation.[19]

3. Linearity- The linearity of an analytical procedure is the interval between the upper and lower concentration of analyte in the sample for which it has been demonstrated that the analytical procedure is of precision, accuracy and linearity.
[20]

RESULTS AND DISCUSSION

Method A

A] Absorbance Maxima Method

Table 1-Calibration Data of frusemide absorbance maxima

CONC	5	10	15	20	25
Abs	0.523	0.886	1.321	1.695	2.046

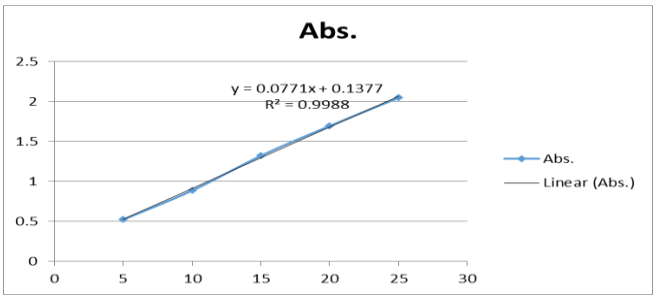


Fig no. 1 Calibration curve of frusemide

Table:

CONC	5	10	15	20	25
AUC	0.905	1.252	1.85	2.288	2.734

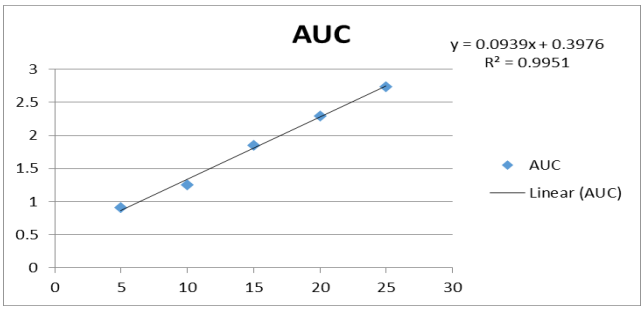


Table 2-Regression Analysis Data for Furosemide by Area under Curve Method

Parameter	AUC
Wavelength Range (nm)	243-277
Concentration Range (µg/ml)	5-25
Slope(m)	0.093
Intercept (c)	+0.397
Correlation Coefficient (r2)	0.995

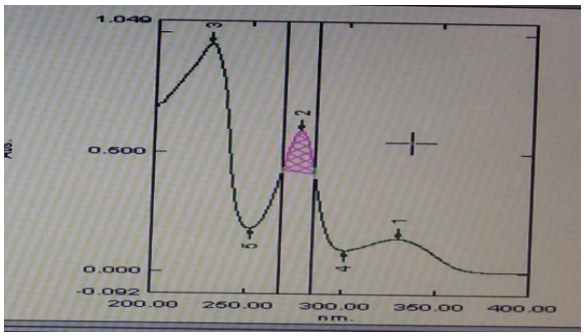


Fig.2 Area under curve of frusemide (10µg/ml)

Table 3: Results of Intra and Inter day precision

Parameter	± S.D.*	% RSD*
Inter day	0.7439	1.48
Inter day	0.8063	1.61

Table 4: Data of Recovery Studies

Level of Mean Recovery (%)	% Mean Recovery	SD*	% RSD*
50%	103.54	0.67	0.65
100%	101.83	0.1616	0.16
150%	102.90	1.1494	1.14

Table 5: Assay Results for the estimation of Furosemide in Pharmaceutical Formulation

Parameter	Label Claim (mg/tab)	Amount Found (mg/tab)	%Labeled Claim
AUC	20	19.84	99.2%

Table no.6. Validation data.

Sr.no	Parameter	AUC Method
1	Linearity	5-25
2	Regression Equation	Y=0.093x+0.397
3	Correlation coefficient	R^2=0.995
4	Precision	
4.1	Inter day	0.7439
4.2	Intra day	0.8063

CONCLUSION

Simple UV spectrophotometric methods have been developed and validated for the determination of furosemide in bulk and tablet dosage form. The results of the validation parameters show that the UV spectrophotometric methods were found to be accurate, precise and sensitive. Because of cost-effective and minimal maintenance, the present UV spectrophotometric methods can be preferred at small scale industries and successfully applied and suggested for the quantitative analysis of furosemide in pharmaceutical formulations for QC, where economy and time are essential and to assure therapeutic efficacy.

REFERENCES

1. Merck index, Maryadele J.O. Neil Edu. In: 13 Ed, Merck Research Lab NJ, USA. 2001: 868.
2. Bays HE, Moore PB, Drehobl MA et al. Effectiveness and tolerability of simvastatin in patients with primary hypercholesterolemia pooled analysis of two phase II studies. Cli. Ther 2001; 23 (8): 1209-1230.
3. Arayne MS, Sultana N, Hussain F, & Ali SA. Validated spectrophotometric method for quantitative determination of Simvastatin in pharmaceutical formulations and human serum. *Journal of Analytical Chemistry*, 2007; 62(6): 536-541.
4. Jain N, Jain R, Swami H, Pandey S, & Jain DK. Spectrophotometric Method for simultaneous estimation of Simvastatin and Ezetimibe in bulk drug and its combined dosage form. *Internat. J. Pharmacy Pharm. Sci,* 2009; 1(1): 170-175.
5. Rajput, SJ, & Raj HA. Simultaneous Spectrophotometric estimation of Ezetimibe and Simvastatin in tablet dosage forms. *Indian Journal of Pharmaceutical Sciences,* 2007; 69(6): 759.
6. Mane VB, Babar S, & Kulkarni N. Development of UV Spectrophotometric method for the simultaneous estimation of Simvastatin and Ezetimibe in tablet dosage form by Simultaneous Equation and Absorbance Ratio Method. Development, 2011; 3(3): 1459-1466.

7. *International Journal of Advances in Pharmaceutics 5* (6) 2016 170.
8. Balaji, S, & Sunitha A. Development and validation of Spectrophotometric method for simultaneous determination of Simvastatin and Ezetimibe in tablet formulations. *Pak. J. Pharm. Sci,* 2010; 23(4): 375-378.
9. Bhatia, NM, Deshmukh DD, Kokil SU, & Bhatia, MS. Simultaneous Spectrophotometric estimation of Simvastatin and Ezetimibe in tablet formulation. *J. Chem*, 2009; 6(2): 541-544.
10. Michael E, Swartz Ira S. Krull, Analytical method development and validation, Marcel Dekker, Inc., 1997; 17: 25-2.
11. Christian GD, Analytical chemistry, sixth edition, John Wiley and Sons, 2003; 1-2,604- 620.
12. Skoog, Holler, Nieman, Principles of Instrumental Analysis, fifth edition, Thomson Asia Pvt. Ltd., Singapore, 2004; 300-325.
13. Beckett AH, Stenlake, JB, Practical Pharmaceutical Chemistry, 4th edition, CBS Publishers and Distributors, New Delhi, 2002; 2: 275-295.
14. Samaa, JR, Kalakuntlab RR, Rao VSN, & Reddannaa, P. Simultaneous estimation of Simvastatin and Ezetimibe in pharmaceutical formulations by RP-HPLC method. *J. Pharm. Sci.* Res, 2010; 2(2): 82-89.
15. Hefnawy M, Al-Omar M, & Julkhuf S. Rapid and sensitive simultaneous determination of ezetimibe and simvastatin.