INTERNATIONAL RESEARCH JOURNAL OF PHARMACY
www.irjponline.com
ISSN 2230 – 8407

Research Article

DEVELOPMENT OF SPECTROPHOTOMETRIC METHOD FOR THE ESTIMATION OF BACLOFEN DRUG

Marwa S. Falih, Ruba F. Abbas *, Arwa M. Hussain, Wejdan M. Hammed, Dhifaf A. Abdul abass, Asma A. Maryoosh, Marwa A. Abed
Department of Chemistry, College of Science, Al-Mustansiryiah University, Baghdad, Iraq
*Corresponding Author Email: rubaf1983@uomustansiriyah.edu.iq

Article Received on: 23/10/18 Approved for publication: 12/11/18

DOI: 10.7897/2230-8407.0911254

ABSTRACT

Accurate, direct and inexpensive spectrophotometric methods have been used for simultaneous estimation of Baclofen in bulk and tablet dosage form. The proposed methods were applied in the wide concentration ranges of (50–450 mg/L). The detection limits were (0.451) for AUC1 and (0.520) for AUC2. The limit of quantitation was found to be (1.366) for AUC1 and (1.576) for AUC2. The results were analyzed statistically by using recovery and relative standard deviation studies.

Keywords: Baclofen, Area under curve, First and Second derivative Spectrophotometric.

INTRODUCTION

Baclofen(BAL) it is 4-amino-3-p-chlorophenyl butyric acid[1,2]. The first clinical employment of selective γ- aminobutyric acid has been widely used for the symptomatic relief of muscular spasm and multiple sclerosis caused by spinal or cerebral injury since its introduction in 1967[3,4,5]. Many methods have been reported for the estimation of BAL in pharmaceutical These methods such as HPLC[6,7], flow-injection chemiluminescence[8], Capillary electrophoresis[9], potentiometric membrane electrodes[10], and spectrophotometric UV[11]. Derivative spectrophotometry is a good technique that used for estimation drugs without any preliminary separation step or uses expensive reagent[12-15]. This paper considers simple, low-cost and rapid methods for the simultaneous estimation of the baclofen drug in pure and tablets forms.

MATERIALS AND METHODS

Equipment

The absorbance measurements were carried out in a model UV-1800 Shimadzu spectrophotometer equipped with a (1.0 cm) quartz cell.

Preparation of standard solution

Stock solution(1000mg/L)

Standard pure of Baclofen SDI - Samara-Iraq ($C_{10}H_{12}ClNO_2$) molecular weight (213.67gm/mol) was prepared by dissolving (0.25 g) of Baclofen in distilled water and then transferred to 250 ml volumetric flask.

Standard solutions

Different volumes of Baclofen stock solution (1000mg/L) ranging from (1 to 9 mL) were transferred into a series of (20 mL) volumetric flasks and completed to the mark with the same solvent to obtain a range of concentrations from (50 to 450 mg/L).

Preparation of the market tablet

Baclofen Tablets from (Lioresal) each tablet contains (10mg) were grounded into a powder, (1000 mg/L) from this tablet powder was prepared by dissolving (0.25 gm) from this powder and then transferred to (250 mL) volumetric flask. the concentration (75, 325 mg/L) from market tablets were prepared by taking (1.5, 6.5 mL) from Baclofen tablet powder in (20 mL) volumetric flask and complete the volume to the mark by distilled water.

Procedure

The standards solution of Baclofen (50 – 450 mg/L) were scanned in the range of (200 – 400 nm). The first derivative ($\frac{dA}{d\lambda}$) and the second derivative ($\frac{d^2A}{d\lambda^2}$) were calculated by the origin pro (2016) program. the AUC between a wavelength range (221-233nm) was considered for the analysis of the first derivative spectrum. While, the AUC between a wavelength range (215-225nm) was used for the analysis of the second derivative spectrum. UV-Visible spectrophotometer with the computer software program were selected two wavelengths (221 to 233 nm) for the first derivative and selected two wavelengths (215 to 225 nm) for the second derivative and then these ranges of the wavelength were used to estimation Ares under curves for baclofen drug.

RESULT AND DISCUSSION

Derivative spectrum and area under curve

Fig. (1a, 1b) show the first and second derivative spectrum for the baclofen drug.

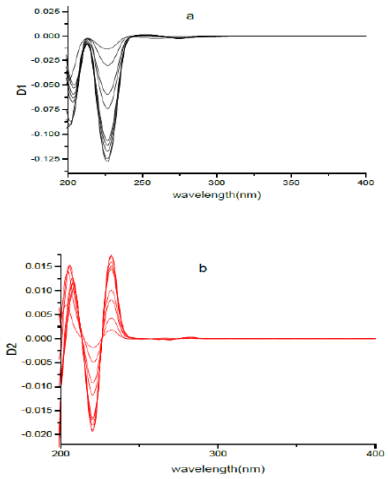

Figure 1: derivative spectrum of baclofen (50-450mg/L) a- first derivative and b-second derivative spectrophotometric

The AUC (area under curve) method include the calculation of the integrated value of absorbance with respect to the wavelength between two selected wavelengths λ1 and λ2. Area calculation processing item calculates the area bound by the curve and the horizontal axis. This wavelength range is selected from area under curve vs. concentration. The area under the curve for first and second derivative are depended on the following theoretical equations[16,17,18].

AUC1= $\int_{233}^{221} A1 d\lambda$

AUC2= $\int_{225}^{215} A2 d\lambda$

A1 and A2 = are the absorbance of baclofen for the first and second derivative, respectively.

$\int_{233}^{221} A1 d\lambda$ and $\int_{225}^{215} A2 d\lambda$= are the area under curve between 221-233 nm for first derivative and are the area under curve between 215- 225 nm for second derivative, respectively.

Fig. (2 and 3) shows the area under the curve of the first and second derivative spectrum for baclofen standard solutions. A calibration curve for these methods are plotted between area under curve against concentration. Finally, the validation data obtained from the calibration curve for baclofen recorded in table 1.

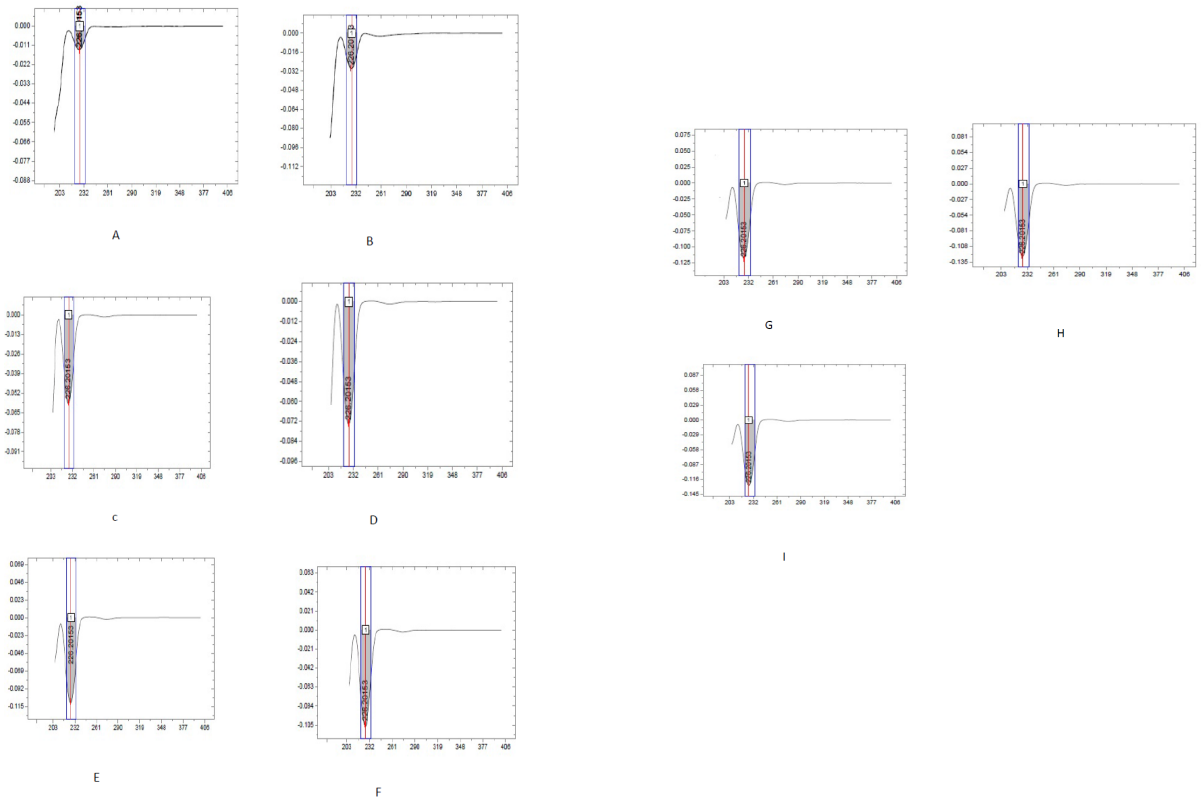

Figure 2: Area under curve for first derivative spectrophotometric of baclofen (A=50mg/L, B=100 mg/L, C=150 mg/L, D=200 mg/L, E=250 mg/L, F=300 mg/L, G=350 mg/l, H=400 mg/L, I=450 mg/L)

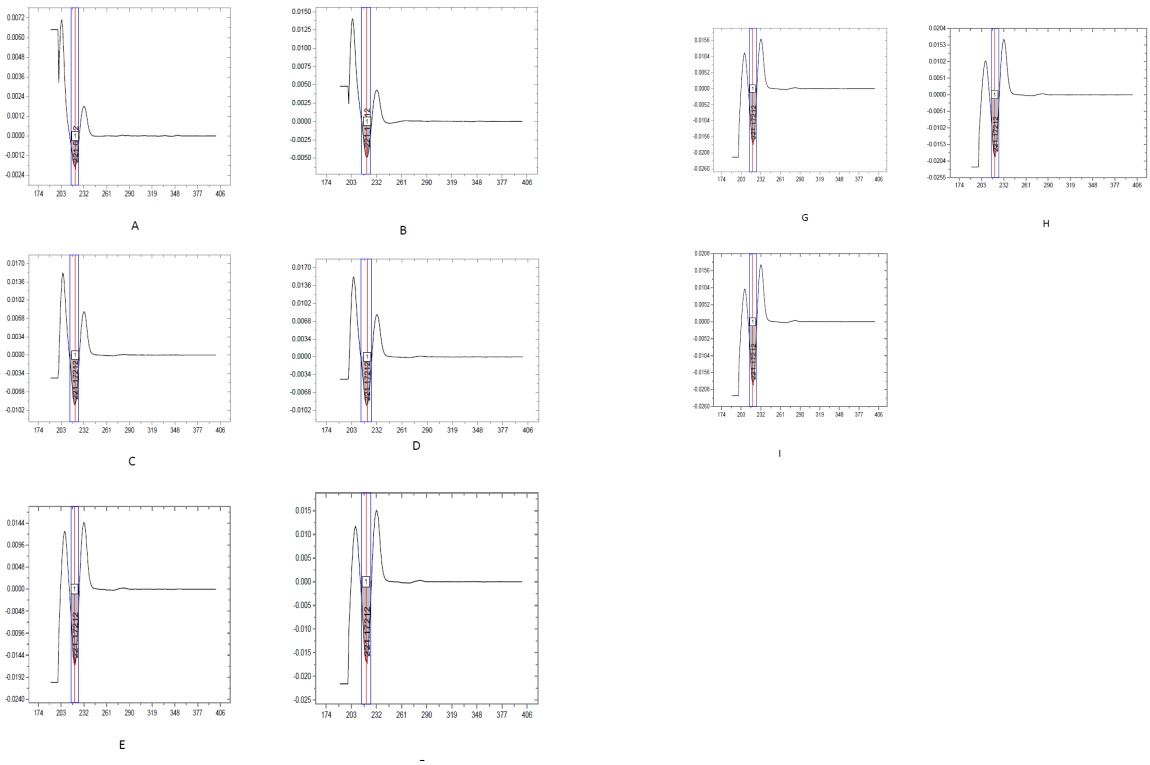

Figure 3: Area under curve for second derivative spectrophotometric of baclofen (A=50mg/L, B=100 mg/L, C=150 mg/L, D=200 mg/L, E=250 mg/L, F=300 mg/L, G=350 mg/L, H=400 mg/L, I=450 mg/L)

Table 1: Validation data obtain from the calibration curve for baclofen

Parameters	Methods	
	AUC1	AUC2
Wavelength (nm)	221-233	215-225
R^2	0.997	0.995
Linearity range (mg/L)	50-450	50-450
Equation for linearity	Y=-0.03x-0.056	Y=-0.026x-0.032
Slope, b	-0.03	-0.026
Intercept, a	-0.056	-0.032
LOD (mg/mL)	0.451	0.520
LQD (mg/mL)	1.366	1.576

AUC1=Area under curve for first derivative spectrophotometric, AUC2= Area under curve for second derivative spectrophotometric, LOD= limit of detection = 3.3×SD_b/S, LQD= limit of quantitation = 10×SD_b/S, SD_b=0.0041= is the standard deviation of the distilled water (distilled water as a blank) (n=3), S is the slop of the corresponding calibration curve.

Accuracy and precision

The accuracy and precision of the suggested methods were examined by analyzing three times of Baclofen using AUC for the first and second derivative spectrophotometric method for two different concentrations within the range of linearity for the drug.

The accuracy and the precision for the experiment were checked by relative error(E%), recovery (Rec%) and relative standard deviation (RSD%). The values of recovery a greater than 99.9211% and relative standard deviation values not exceed than 0.1261 were indicating a good Accuracy and precision, all results are listed in table 2.

Table 2: Accuracy for the AUC derivative spectrophotometric methods

Methods	Amount of baclofen (mg/L)		E*%	Rec*%	RSD*%
	Taken	found			
AUC1	175	174.862	-0.0788	99.9211	0.0583
	275	274.940	-0.0218	99.9781	0.1261
AUC2	175	174.952	-0.0274	99.9726	0.0753
	275	274.922	-0.0283	99.9716	0.1042

AUC1= Area under curve for first derivative spectrophotometric, AUC2= Area under curve for second derivative spectrophotometric, *Average of three time, E% = relative error ==$\frac{found-taken}{taken}$ ×100, Rec% =recovery and RSD%=relative standard deviation

Application

Area under curve method was successfully applied for the estimation of Baclofen in (Lioresal) market Tablets from, two different concentrations (75, 325 mg/L) from market tablet were measured According to the procedure, Fig.4 shows the first and second derivative spectrum for (75 and 325 mg/L) and Fig. (5 and 6) shows the area under curve of the first and second derivative spectrum for the same two concentrations (75, 325 mg/L). The results in (Table 3) are shown the high percentage

recoveries and low relative standard deviation suggested good accuracy and efficiency of this method for analysis of baclofen pharmaceutical market tablets form.

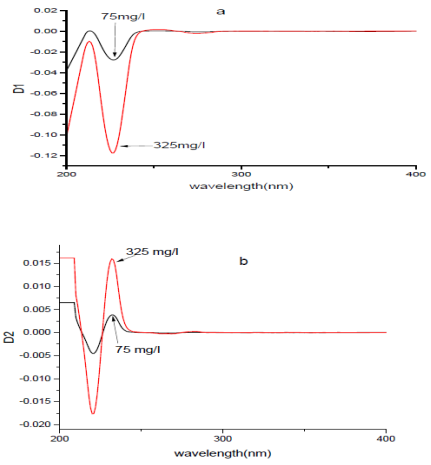

Figure 4: Derivative spectrum of baclofen (Lioresal) tablet drug at 75 and 325mg/l a-first derivative and b-second derivative spectrophotometric.

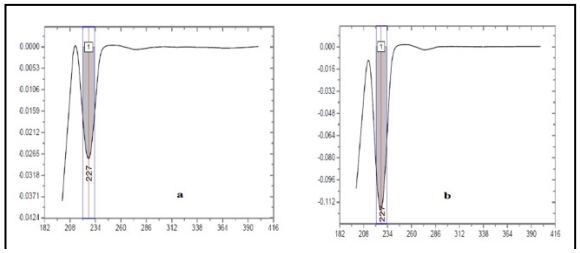

Figure 5: Area under curve for first derivative spectrophotometric of baclofen (Lioresal) tablet drug a=75mg/L and b= 325mg/L

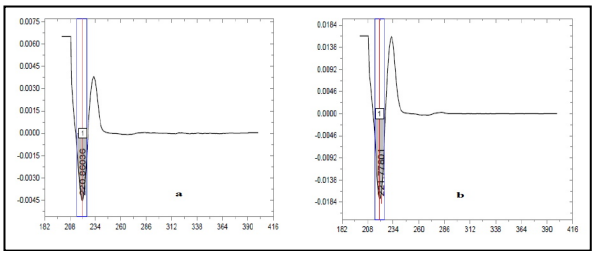

Figure 6: Area under curve for second derivative spectrophotometric of baclofen (Lioresal) tablet drug a=75mg/L and b= 325mg/L

Table 3: Application of baclofen drug tablet at (75 and 325 mg/L) for the AUC derivative spectrophotometric methods

Pharmaceutical sample	methods	Amount of baclofen (mg/L)		E*%	Rec*%	RSD*%
		Taken	found			
LIORESAL 10 mg Baclofen NOVARTIS	AUC1	75	74.731	-0.3585	99.6413	0.0513
		325	325.095	0.0292	100.0292	0.0737
	AUC2	75	75.164	0.2186	100.2186	0.0632
		325	325.120	0.0369	100.0369	0.1317

AUC1=Area under curve for first derivative spectrophotometric, AUC2= Area under curve for second derivative spectrophotometric, *Average of three time, E% =relative error ==$\frac{found-taken}{taken}$ ×100, Rec% =recovery and RSD%=relative standard deviation.

CONCLUSION

A fast, nontoxic and economical spectrophotometric methods for the estimation of baclofen drug were developed by using area under curve technique. Area under curve method can be calculated directly in a single sample without to need the solvent extraction or used toxic material. So, this method easily used for the assessment of baclofen in the pharmaceutical market Tablets format.

REFERENCES

1. Kun Ya, Yu-J Z, Fu H Ch, Xue M L, Guang W K, Zhi L Su, Zhao Y L. Determination of Baclofen Residue in Muscle, Liver, Kidney and Fat of Swine by Liquid Chromatography-Tandem Mass Spectrometry. Food Anal. Methods. 2017; 10(12): 3866–3873
1. Paweł S, Agnieszka C, Grzegorz B, Grzegorz T. Application of high-resolution mass spectrometry to determination of baclofen in a case of fatal intoxication. Forensic Toxicol. 2016; 34 :268–276.
2. Laurence L, Antonio G, Ana RM, Bénédicte D, Bernard G, Xavier D. Liquid chromatography high resolution mass spectrometry for the determination of baclofen and its metabolites in plasma: Application to therapeutic drug monitoring. Biomedical Chromatography. 2017; 31(8):1-9
3. Laurence L, Antonio G, Ana R M, Bénédicte D, Bernard G, Xavier D. Baclofen-loaded solid lipid nanoparticles: Preparation, electrophysiological assessment of efficacy, pharmacokinetic and tissue distribution in rats after intra peritoneal administration. European Journal of Pharmaceutics and Biopharmaceutics. 2011; 79 (1) :135–141.
4. Seyed M F, Alireza S, Afshin Z, Khoddam A. Bioequivalence Studies of Two Formulations of Baclofen Tablet in Healthy Volunteers. Iranian Journal of Pharmaceutical Research. 2003; 2(3): 153-155.
5. Dukova OA, Krasnov EA, Efremov AA. Development of an HPLC Method for Determining Baclofen. Pharmaceutical Chemistry Journal. 2015; 48(10): 48-10.
6. Manisha S, Ravi B. HPLC enantio separation of racemic bupropion, baclofen and etodolac: modification of conventional ligand exchange approach by pre-column formation of chiral ligand exchange complexes. Biomed .Chromatogr. 2016; 30(11): 1728–173
7. Alireza K, Aliyeh H, Mortaza I, Sang WJ. A novel flow-injection chemiluminescence method for determination of baclofen using l-cysteine capped CdS quantum dots. Sensors and Actuators B. 2015; 215: 272–282.
8. Piotr K, Aleksandra C, Lucyna K, Ilona O, Pawet KZ, Henryk L. The bioequivalence study of baclofen and lioresal tablets using capillary electrophoresis. Biomed. Chromatogr. 2004; 18: 311–317.
9. Alexander AR, Raluca-Ioana SS. Determination of baclofen enantiomers in pharmaceutical formulations using maltodextrin-based enantio selective. potentiometric membrane electrodes. Il farmaco. 2004; 59: 993–997.
10. Ghadah F. Flow Injection Spectrophotometric Determination of Baclofen in Pharmaceutical Formulation Using Prussian Blue Reaction. Journal of Al-Nahrain University. 2017; 20 (1):17-24.
11. Maha A H, Ali M Y, Azza A M. Stability-indicating method for the determination of mosapride citrate in the presence of its degradation products according to ICH guidelines. Drug Test. Analysis. 2012; 4:104–115.

12. Maissa Y S, Amira M E, Mohamed G E, Mohamed K A. Spectrophotometric and spectrodensitometric methods for the determination of rivastigmine hydrogen tartrate in presence of itsdegradation product. Drug Test. Analysis. 2010; 2: 225–233.
13. Hassan M B, Fadel J M, Mohammed A. Determination of the exact zero cross-excitatory spectroscopy of binary mixtures of acetyl Manganese acetonate (II) and aluminum (III). Baghdad Journal of Science. 2013; 3(10): 866 – 882.
14. Hussain A A, khalf FA. Spectral estimation of metronidazole and metronidazole Benzoat using spectroscopy the first and second derivatives. Baghdad Journal of Science. 2017; 2(14): 320 – 327.
15. Ruba F A, Hend A A, Rawa M M, Dhifaf A A, Marwah A A. Estimation of the Folic Acid Using Zero Order, Area Under Curve and First Derivative Spectrophotometric Methods in Pure and Marketed Tablet Formulations. Journal of Al-Nahrain University. 2017; 20 (3): 34-41.
16. Ranjale A R, Jain H K, Gujar K N. Development and validation for uv spectrometric estimation of ambroxol hydrochlorde in blunk and tablet dosage form using area under curve method. International Research Journal of Pharmacy. 2014; 5(7): 580-583.
17. Dahivadkar M S, Jain H K, Gujar K N. Development and validation of uv spectrophotometric estimation of ebastine in bluk and tablet dosage form using area under curve method. International Research Journal of Pharmacy. 2013; 4(6): 201-204.

Cite this article as:

Marwa S. Falih *et al*. Development of spectrophotometric method for the estimation of Baclofen drug. Int. Res. J. Pharm. 2018;9(11):37-41 http://dx.doi.org/10.7897/2230-8407.0911254

Source of support: Nil, Conflict of interest: None Declared