Future Journal of Pharmaceutical Sciences xxx (2017) 1–5

HOSTED BY

Contents lists available at ScienceDirect

Future Journal of Pharmaceutical Sciences

journal homepage: http://www.journals.elsevier.com/future-journal-of-pharmaceutical-sciences/

Simultaneous equation and area under the curve spectrophotometric methods for estimation of cefaclor in presence of its acid induced degradation product; A comparative study

Khalid A.M. Attia, Nasr M. Elabasawy, Ebrahim Abolmagd*

Pharmaceutical Analytical Chemistry Department, Faculty of Pharmacy, Al-Azhar University, 11751, Nasr City, Cairo, Egypt

ARTICLE INFO

Article history:
Received 15 July 2016
Received in revised form
9 April 2017
Accepted 7 June 2017
Available online xxx

Keywords:
Cefaclor
Simultaneous equation
Area under the curve

ABSTRACT

Two simple spectrophotometric methods were developed and validated for determination of cefaclor in presence of its acid induced degradation product; namely simultaneous equation method using two wavelengths 265 and 235 nm **Method (A)** and Area under the curve method using two wavelength ranges (230–240) nm and (260–270) nm **Method (B)**. The accuracy, precision and linearity ranges of the proposed methods were determined. The methods were validated and the specificity was assessed by analyzing synthetic mixtures containing the drug and its degradate. The two methods were applied for the determination of the cited drug in its pharmaceutical preparation and the obtained results were statistically compared with those of a reported method. The comparison showed that there is no significant difference between the proposed methods and the reported method regarding both accuracy and precision.

1. Introduction

Cefaclor (7R)-3-Chloro-7-(α-D-phenylglycylamino)-3-cephem-4-carboxylic acid monohydrate Fig. 1 is penicillinase-resistant antibiotic with significant activity against gram positive, gram negative bacteria and some beta - lactamase producing strains of *H. influenza* [1,2] Literature survey reveals that spectrophotometric methods [3–19], spectrofluorimetric methods [8,20,21], electrochemical methods [22,23], TLC method [24], HPLC methods [18,25–38] were also described for its analysis.

The scientific novelty of the present work is that the methods used are simple, rapid, selective, less expensive and less time consuming compared with other published LC, TLC and HPLC methods, furthermore these methods could determine the intact drug without any interference from its degradation product.

2. Experimental

2.1. Instruments

- SHIMADZU UV-1800 PC dual beam UV–visible spectrophotometer (Kyoto/Japan).
- Hot plate, Torrey pines scientific, USA.
- pH meter 3510 (Jenway,U.S.A.).

2.2. Soft wares

- UV-Probe personal spectroscopy software version 2.1. (SHIMADZU).
- The *t*-test and F-test were performed using Microsoft_ Excel.

2.3. Chemicals and reagents

All chemicals and reagents used throughout the work were of analytical grade and the water used throughout the procedure was freshly double distilled.

* Corresponding author.
E-mail address: Eb.Abolmagd@yahoo.com (E. Abolmagd).
Peer review under responsibility of Future University.

http://dx.doi.org/10.1016/j.fjps.2017.06.001

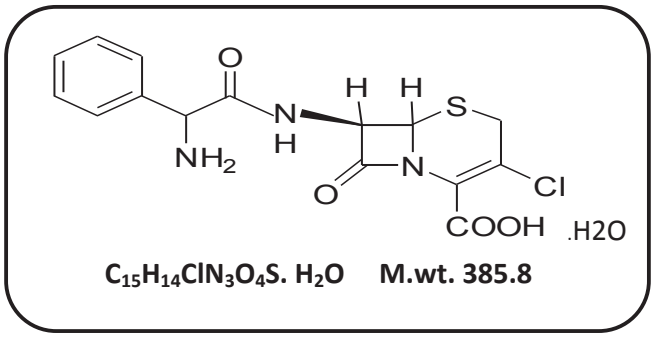

Fig. 1. Chemical structure of Cefaclor.

- Cefaclor powder was kindly supplied by PHARCO Pharmaceutical Company, Alexandria, Egypt.
- Pharmaceutical preparation: **Cefaclor®** 500 mg capsules (Batch no. 00104613), manufactured by Pharco Pharmaceutical Company. It is labeled to contain 500 mg of Cefaclor per capsule and purchased from local pharmacies.
- Hydrochloric acid (Al-gomhuria Company, Egypt) prepared as 1 N aqueous solution.
- Sodium hydroxide (Al-gomhuria Company, Egypt) prepared as 3 N aqueous solution.
- Methanol (Sigma–Aldrich, USA).

2.4. Standard solutions

2.4.1. Standard solution of cefaclor

A standard solution of cefaclor (100 μg/ml) was prepared by dissolving 10 mg of cefaclor in 50 ml of water and complete to 100 ml with water.

2.4.2. Standard solution of degradation product

100 mg of pure cefaclor powder was refluxed with 50 ml 1 N HCl for 4 h. After cooling, the solution was neutralized by 3 N NaOH, evaporated to dryness under vacuum, the residue was extracted three times with 25 ml methanol, filtered into 100 ml volumetric flask then the volume was adjusted by the same solvent to obtain a solution labeled to contain degradate derived from (1000 μg/ml) of cefaclor [18].

Transfer 10 ml of this solution to 100 ml volumetric flask and complete to the mark with water to make a solution labeled to contain degradate derived from (100 μg/ml) of cefaclor.

3. Procedure

3.1. Linearity and construction of calibration curves

Different aliquots of cefaclor standard solution (100 μg/ml) ranging from (40–220) μg were transferred to 10 ml volumetric flasks and completed to volume with water. The absorption spectra (from 200 to 400 nm) of these solutions were recorded using water as a blank.

3.1.1. Simultaneous equation method

The absorbance of each component at 235 nm and 265 nm were recorded and the absorptivity values were calculated. The absorbance and absorptivity values were used for calculating the concentration of cefaclor by using the following equations:

$$C_x = (A_2\ a_{y1} - A_1\ a_{y2})/a_{x2}\ a_{y1} - a_{x1}\ a_{y2} \quad (1)$$

$$C_y = (A_1\ a_{x2} - A_2\ a_{x1})/a_{x2}\ a_{y1} - a_{x1}\ a_{y2} \quad (2)$$

where,

Cx and Cy = the concentrations of x and y.
a_{x1} and a_{x2} = absorptivities of x at λ_1 (λ_{max} of x) and λ_2 (λ_{max} of y).
a_{y1} and a_{y2} = absorptivities of y at λ_1 (λ_{max} of x) and λ_2 (λ_{max} of y).
A_1 and A_2 = the absorbance of the diluted samples at λ_1 and λ_2.

3.1.2. Area under the curve method

The absorption spectra (from 200 to 400 nm) of these solutions were recorded using water as a blank. The area under the curve values for each component were recorded over the wavelength ranges of (230–240) nm and (260–270) nm and the calibration graphs were constructed. The area absorptivity values were calculated at each wavelength range for the two components then the concentration of cefaclor was calculated from the equations:

$$A_1 = a_{x1}\ C(x) + a_{y1}\ C(y)\ (\lambda_1 - \lambda_2)\ nm \quad (3)$$

$$A_2 = a_{x2}\ C(x) + a_{y2}\ C(y)\ (\lambda_3 - \lambda_4)\ nm \quad (4)$$

$$C_{(x)} = [A_2 \times a_{X2} - A_1 \times a_{y2}]/[a_{X2} \times a_{Y1} - a_{X1} \times a_{Y2}] \quad (5)$$

$$C_{(y)} = A_2 - a_{X2} \times C(x)/a_{Y2} \quad (6)$$

where,

a_{x1} and a_{x2} are absorptivities of x at (λ_1-λ_2) and (λ_3-λ_4) respectively.
a_{y1} and a_{y2} are absorptivities of y at (λ_1-λ_2) and (λ_3-λ_4) respectively.
A_1 and A_2 are AUC of mixed standard at (λ_1-λ_2) and (λ_3-λ_4) respectively.
$C_{(x)}$ and $C_{(y)}$ are the concentration of x & y, respectively.

3.2. Application to laboratory prepared mixtures

Accurate aliquots of cefaclor and its degradate were transferred from their working solutions into a series of 10 ml volumetric flasks to prepare mixtures containing different ratios of both. The volumes were completed with the water. The spectra of the prepared series from 200 to 400 nm were recorded and stored. The concentrations of cefaclor were calculated as described under linearity for each proposed method.

3.3. Application to pharmaceutical preparation

A content of ten capsules of Cefaclor® 500 capsules was mixed well and accurately weighed then an accurate portion equivalent to 10 mg was extracted by shaking with 50 ml of water for 15 min, then filtered into 100 ml volumetric flask and the volume was adjusted with the same solvent. Repeat the general procedure described under linearity using aliquots covering the working concentration range. Determine the drug concentrations from the equations described under linearity.

4. Results and discussion

The spectrophotometric methods have the advantages of being the most simple, fast and applicable in all laboratories, as most of the active compounds show absorbance in the UV region. But,

Please cite this article in press as: K.A.M. Attia, et al., Simultaneous equation and area under the curve spectrophotometric methods for estimation of cefaclor in presence of its acid induced degradation product; A comparative study, Future Journal of Pharmaceutical Sciences (2017), http://dx.doi.org/10.1016/j.fjps.2017.06.001