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Various analytical methods for the determination of clarithromycin- A review

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Abstract

Clarithromycin has a broad spectrum of antibacterial properties. It is considered safe and necessary in any health system according to the World Health Organization's Essential Medicines List. Therefore, it is important to develop simple and low-cost analytical methods for these compounds in order to obtain a better quality control. This paper reviews a number of analytical papers that identify clarithromycin in commercial preparations and biological samples, and these include chromatography, ion selective electrodes and spectrophotometric.
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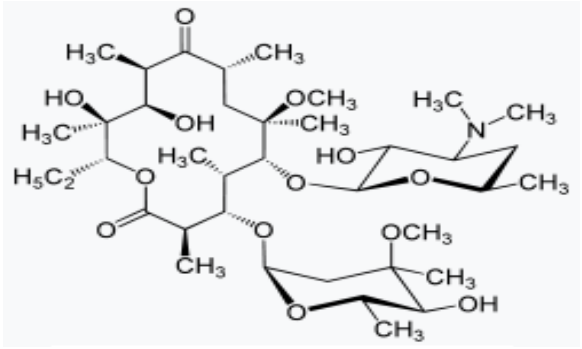
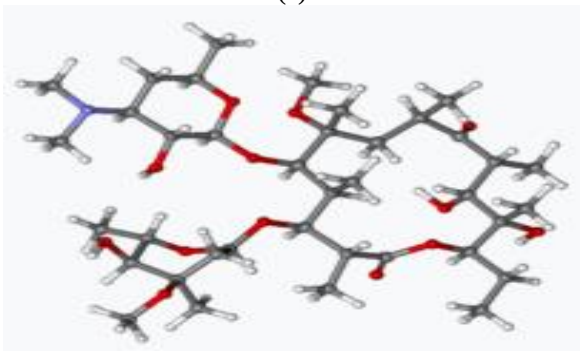
Keywords: Clarithromycin, ISE, HPLC, Spectrophotometric

1. Introduction

Clarithromycin is a type of medicine available as a generic medicine and is beneficial in treating some bacterial infections such as Helicobacter pylori, and pneumonia and it is also used as a penicillin substitute for cycloid bacteria.(1) It is an antibiotic that has good stability in stomach acid and its pharmacological profile is more suitable than erythromycin for semisynthetic macrolide.(2) Clarithromycin's chemical structure, as shown in figure 1, has the empirical formula ($C_{38}H_{69}NO_{13}$). It is almost crystalline, white powder with a molecular weight 748 g/mole, soluble in acetone, slightly dissolved in methanol, meanwhile insoluble in water.(3) To define and study clarithromycin, various analytical methods were used, and studied: limit of detection, concentration range, recovery, life time, type of column, mobile phase, slope, retention time and the range of PH for clarithromycin. The results were listed in Tables 1, 2, and 3.



(a)



(b)

Figure 1: (a) 2D chemical structures of clarithromycin, (b) 3D chemical structures of clarithromycin

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Table 1: HPLC for determination of clarithromycin

Method	results	Ref.
RP-HPLC	**Column:** A (5 μm) ODS Kromasil, 250×4.6 mm (C18 column). **Mobil Phase:** Contains a (0.05 M) phosphate buffer and (0.005 M) 1 sulphonic acid sodium salt mono-hydrate of (pH 3.2). For separati quantification, (50: 50 v/v) acetonitrile mixture was used. **Detector:** UV detector. **Conc. range:** 75–175 μg/mL. **LOD:** 5.230 μg/mL. **λ:** 205 nm. **t_R:** 2.21*min*	[4]
RP-HPLC	**Column:** In an isocratic mode, 5 µm particle size, 150 mm length×4.6 mm i.d (C18 column). **Mobil Phase:** composed of acetonitrile in a ratio of (55: 45, v/v).and 0.035 M potassium dihydrogen phosphate (pH 4.4 ±0.017) **Detector:** UV detector. **Conc range:** 320- 480 µg/ml. **LOD:** 0.04 µg/mL. **λ:** 210 nm. **t_R:** 4.100 ± 0.074 min.	[5]
RP-HPLC	**Column:** 250 x 4.6 mm, 5 µm, (C8 column). **Mobil Phase:** Consists of acetonitrile and dipotassium hydrogen orthophosphate buffer (0.1 M) of (pH 6.0) in a ratio of 50:50 (% v/v). **Detector:** UV detector. **Conc range:** 4.0–5000.0 µg/ml. **LOD:**4.0 (±6.6 %). **λ:** 210 nm.	[6]
Liquid Chromato-graphic	**Column:** Shim pack CLC-ODS column**.** **Mobil Phase:** a mixture of phosphate buffer (0.05 M) that contain a (17:83, v/v) methanol and (2 ml/l; pH 3.8) triethylamine. **Detector:** fluorescence detector. **Conc range:** 0.025-10 µg/ml. **λ:** 265nm.	[7]
HPLC	**Column:** Shodex Asahipak high-performance liquid chromatography (HPLC) column. **Mobil Phase:** it contain acetonitrile and phosphate buffer with the ratio of (pH 11 ± 0.05) of (60:40, v/v). **Detector:** the type is UV detector. **LOD:** from 214 to 228 µg/kg. **λ:** 210 nm.	[8]
RP-LC with Electrochemical Detection	**Column:** at 408 ºC, C8 column (5-mm (100 3 4.6 mm). **Mobil Phase:** Acetonitrile with (37:63, v/v) 0.045M H3PO4 and (pH 6.7). **Detector:** The electrochemical detector, L-ECD-6A, operates at (0.85 V) level, using a glass carbon electrode with a reference electrode (Ag/AgCl). **Conc range:** 0.05-5.0 mg/mL. **LOQ:** 0.05 mg/mL. **λ:** below 220 nm. **t_R:** 12.26 min.	[9]
HPLC	**Column:** C8 Lichrosorb TM analytical column, (150mm× 4.6 mm, 10µm). **Mobil Phase:** The mixture in ratio (33: 17: 50, v/v/v), (acetonitrile, methanol, phosphate buffer) at pH 3.5 **Detector:** UV detector. **Conc range:** 75-2000 µg mL^{-1}. **Coefficient of variation:** 0.862**.** **λ:** 210 nm. **t_R:** 5.44min.	[10]

RP-HPLC	**Column:** Waters Spheris orb 5 µm ODS2, 4.6x250 mm (C18 column). **Mobil Phase:** Pairing reagent (Acetonitrile/aqueous trifluoroacetic acid). **Detector:** SEDERE - ELS Detector (SEDEX MODEL 75). **Conc range:** 5-100 µg/mL. **LOD:** 1.6 mg/L. **t_R:** 4.7 min.	[11]
Pre-column derivatization with HPLC–UV method	**Column:** C_{18} column. **Mobil Phase:** (50 mM, pH 6.8, 0.7% triethylamine) potassium dihydrogen phosphate, (30:45:25, v/v/v), and methanol acetonitrile. **Detector:** UV detector. **Conc range:** 0.1–10 µg ml^{-1}. **LOD:** 30 ng ml^{-1}. **λ :** 275 nm.	[12]

Table 2: Ion –Selective Electrodes for Determination of clarithromycin

Type of Ion-pair for Electrodes	Results	Ref.
Clarithromycin phosphotun-gestate (CLR-PTA)	**Conc. Range:** 10^{-6} to10^{-2} mol/L. **Plasticizer:** dioctylphthalate (DOP). **Slope:** 58.8 mV/decade. **pH range:** 3-8. **Detection limit:** 2.5×10-6 mol. L^{-1}. **Correlation coefficient (r):**0.9999**.** **Life time:** 30 days.	[13]
Clarithromycin-tetraphenyl-borate ion pair complex	**Conc. Range:** 1×10^{-5}-1×10^{-3}, 1×10^{-5}-1×10^{-3}, 5×10^{-5}-1×10-3 and 1×10^{-5} -1×10^{-3} M) respectively. **Plasticizers:** Di-octyl phthalate (DOP); Di-butyl phosphate (DBP); Acetophenone (AP); Di-butyl phthalate (DBPH). **Slope:** 51.206, 53.930, 58.104 and 58.484 mV/decade). **Detection limit:** 8 $\times10^{-6}$, 6 $\times10^{-6}$, 2 $\times10^{-5}$ and 9 $\times10^{-6}$**.** **Life time:** 24,12,45 and 20 days.	[3]

Table 3: Spectrophotometric methods for determination of clarithromycin

Methods	results	Ref.
Derivative Spectrophoto-metric	**Sample:** Clarithromycin. **Conc range:** 5.0 to 60 µg mL^{-1}. **Slope:** 0.00625. **r^2:** 0.9998. **LOD:** 1.055 µg/mL**.** **λ_{max}:** 268 nm**.**	[14]
UV Spectrophoto-metric	**Sample:** terbinafine hydrochloride and clarithromycin (TRB, CAM). **Conc. range:** a TRB: 0.5-3.0 ml, 50µg.ml^{-1}; CAM: 0.5-3.0 ml, 100 µg.ml^{-1}. **Slope:** (3.013 × 10^{-2}, 1.829 × 10-2). **r^2:** (0.9999, 0.9999). **LOD:** (1.299 × 10^{-1}, 0.2737). **λ_{max}:** 350 nm.	[15]
U.V. spectroscopy	**Sample:** Clarithromycin. **Conc range:** *2-40 µg/ml.* **Slope:** 0.63 at pH=1.2. **r^2:** *0.9808*. **LOD:** 1.242 µg/ml. **λ_{max}:** *353 nm.*	[16]
Spectrophoto-metric	**Sample:** Clarithromycin. **Conc range:** 10-70µg.ml^{-1}. **Slope:** 0.0089. **r^2:** 0.9999**, λ_{max}:** 600nm.	[16]
UV Spectrophoto-metric	**Sample:** Clarithromycin. **Conc.:** 100 ppm in 100 ml. **λ_{max}:** 210nm **.**	[17]

UV Spectrophoto-metric	**Sample:** clarithromycin. **Conc. range:** 20-120µg/mL. **Slope:** 0.012. **r ^{2}:** 0.9997. **λ_{max}:** 760.5 nm.	[18-19]
Spectrophoto-metric	**Sample (1):** (Clarithromycin and bromothymol blue (BTB)). **Sample (2):** (Clarithromycin and bromocresol purple (BCP)). **Conc range:** BTB 0.5-25.0 µg/ml and BCP 1.0-25.0 µg /ml, **Slope:** 0.0232and 0.0322 for BTB and BCP respectively. **r ^{2}:** 0. 9998 and 0. 9997 for BTB and BCP. **LOD:** 0.36 µg/ml and 0.24 µg/ml, for BTB and BCP. **λ_{max}:** 416 nm and 418 nm for BTB and BCP.	[19]
Visible Spectrophoto-metric	**Sample (1):** (clarithromycin, HCl, acetone). **Conc. range:** 50-500 µg/mL. **λ_{max}:** 485nm. **Sample (2, 3):** (clarithromycin, bromocresol green, bromopbnol blue). **Conc. range:** 0-60 µg/mL. **λ_{max}:** 414nm.	[20]
UV visible spectrophoto-meter	**Sample:** Clarithromycin **Conc range:** 10-50µg/ml**.** **r^2:** 0.990 **λ_{max}:** 416 nm	[17]

2. Conclusions

In Table 1, 2, and 3 diverse theoretical studies of three analytical methods for calculating clarithromycin were included. It turns out from the study that, the best way to calculate clarithromycin in pharmaceutical preparations is (HPLC) high-performance liquid chromatography method. This method gave a wide range of concentration that was specified in ng/ml and µg/ml, as well as low detection limit plus the most commonly used solvents are acetonitrile and methanol. Nonetheless, spectrophotometric and ion selective electrodes, can be described as easy to use methods and applications for calculating clarithromycin in pharmaceutical samples in addition to their low coast in quality control analysis compounds in pharmaceutical preparations.

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