Quantitative Determination of Clindamycin and Clindamycin Phosphate by the Method of Iodometry using Peroxomonosulfate

M.Ye. Blazheyevskiy[†], D. Alfred-Ugbenbo*[‡], V.V. Diadchenko[§], V.P. Moroz[†], O.S. Kryskiv[†]

[†] Department of General Chemistry, National university of pharmacy, 61168, Kharkiv, Ukraine;
[‡] Department of Pharmaceutical and Medicinal Chemistry, Faculty of Pharmaceutical Sciences, Bayelsa Medical University P.M.B. 178 Imgbi Rd, Yenagoa, Bayelsa State, Nigeria; *e-mail: audeghinmotei@gmail.com
[§] Military Institute of Armored Forces of NTU "KhPI", 62472, Ukraine

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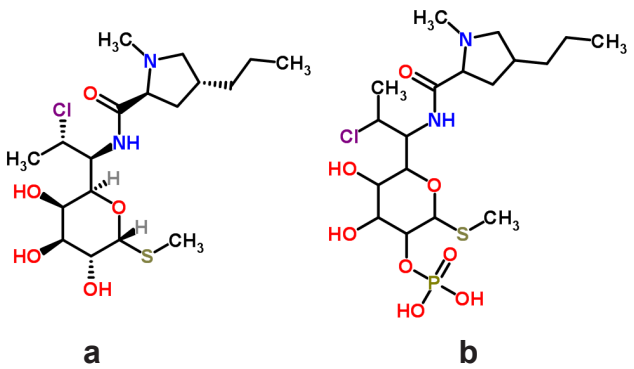
The pH-dependent kinetics and mechanism of the oxidation reaction of clindamycin hydrochloride (CLN) with potassium hydrogen peroxomonosulfate ($KHSO_5$) at 20°C was studied in order to develop a novel assay method. It has been established that the reaction kinetics obey the general laws of specific acid-base catalysis. Stoichiometrically, $KHSO_5$ was found to react with CLN in an alkaline medium (pH 8.0–9.0), at a 3:1 mole ratio, to form the corresponding sulfone-N-oxide. Methods for the oxidimetric determination of CLN and Clindamycin phosphate (CLN-P) were developed using KHSO5 as an analytical reagent: a known excess of the reagent is added and after a specified time its residual amount is determined by iodometry. The developed method was successfully used to determine clindamycin in dosage forms such as capsules and injection. RSD does not exceed 1.7%.

Keywords: clindamycin hydrochloride, clindamycin phosphate, iodometry, oxidimetric titration, oxone, potassium hydrogen peroxomonosulfate, assay

Introduction

Clindamycin (CLN, *syn*. Cleocin, Aclinda, Basocin, Tidact etc) (Fig. 1) is a semisynthetic antibiotic of the lincosamide group, a derivative of lincomycin, synthesized from it by replacing the 7(R)-hydroxyl group with chlorine. This drug exceeds lincomycin in all positive respects, including absorption into the gastrointestinal tract, antibacterial activity, and antimicrobial spectrum [1, 2]. Being both bacteriostatic and bactericidal, CLN has been reported to have significant activity against nonenterococcal gram-positive organisms and numerous anaerobes, including B. fragilis. It is available as capsules and pediatric powders of water-soluble salts [3–5].



a **b**

Fig. 1. Chemical structures of clindamycin (a) and clindamycin phosphate (b).

There are several analytical techniques available to determine CLN and clindamycin phosphate (CLN-P) in different matrices. Among these, HPLC-UV is recommended by the State Pharmacopoeia of Ukraine, European Pharmacopoeia and the USP [6–8]. HPLC is accurate and specific, making it the most commonly used method [9-14]. Other techniques such as liquid chromatography-mass spectrometry [15–17], miceller chromatography [18], chemiluminescence [19, 20], electrochemiluminescence [21], potentiometry [22], capillary electrophoresis [23], chemometrics [24], spectrophotometry [25], conductometry [26], flow injection spectrophotometric analysis [27], kinetic spectrophotometry [28], and voltammetry [29] are also used. But some of these techniques are time consuming, require extraction with organic solvents, and have complex designs that require expensive equipment or specific detectors.

Clindamycin hydrochloride has been titrated with 0.5 potassium hydroxide using potentiometry. The point at which $\Delta E/\Delta V$ was greatest was considered the endpoint [30]. A direct titrimetric assay based on the oxidation of the drug by *N*-bromosuccinimide in acidic medium has been reported [31]. While most of the methods described above were complex and required expensive equipment, literature reviewed so far reveals no reports of a sensitive and efficient analytical method for the titrimetric determination for CLN or CLN-P analyses using peroxomonosulfate.

Despite these contributions, literature surveys have revealed a gap: no reports exist on titrimetric methods employing peroxomonosulfate for the selective determination of CLN or CLN-P.

Given this analytical void, our study focuses on the development of a rapid, sensitive, and cost-effective