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## НАПРЯМ 3. ФАРМАЦЕВТИЧНІ НАУКИ

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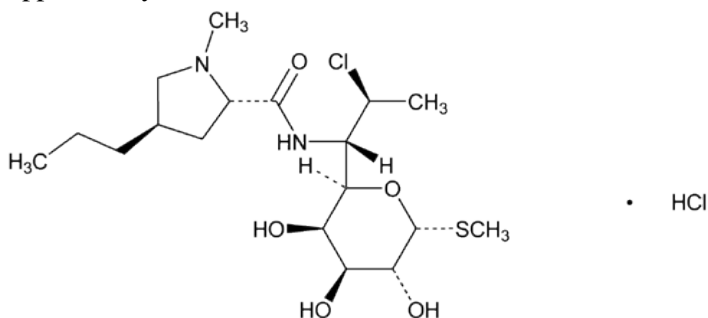
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### TITRIMETRIC MICRO-DETERMINATION OF CLINDAMYCIN HYDROCHLORIDE USING OXONE

Clindamycin Hydrochloride (CLI) is the hydrated hydrochloride salt of Clindamycin, a substance produced by the chlorination of Lincomycin, with inversion of chirality (Fig. 1) [1]. CLI is a lincosamide antibacterial drug with a primary bacteriostatic action against gram-positive aerobes and a wide range of anaerobic bacteria. It gives its action by binding to bacterial ribosome and inhibits the early stages of protein synthesis [2].

CLI is official in both the British Pharmacopoeia (BP) and the United States Pharmacopoeia (USP). HPLC method has been used in the USP35- NF30 for determination of clindamycin but no simple

method is reported [3]. The literature survey revealed that are many analytical methods for analyzing clindamycin in various pharmaceutical compositions, as well as in biological samples. High-performance liquid chromatography (HPLC) is the most commonly used [4-7], micellar chromatography [8], potentiometry [9], chemiluminescence method [10, 11], voltammetry [12] and indirect spectrophotometric determination that dependent on color forming [13]. The CLI structure is not conjugated and therefore exhibits very poor UV absorption (see Fig. 1). Determination of CLI by the spectrophotometric method requires preliminary derivatization and adjustment of the experimental conditions, which increases the complexity and time of the method. After examining the literature, we found that there were practically no reports of a titrimetric method for CLD analysis, and the other methods described were complex and required expensive equipment. This has attracted our attention to the development of a simple, cheap, fast, selective, accurate and accurate method for the determination of CLI in pure form and in pharmaceutical dosage forms without preliminary pretreatment steps. Redox titrimetry may serve as useful alternative to many of the aforesaid sophisticated techniques because of their cost effectiveness, ease of operation, sensitivity, remarkable accuracy and precision, and wide applicability.

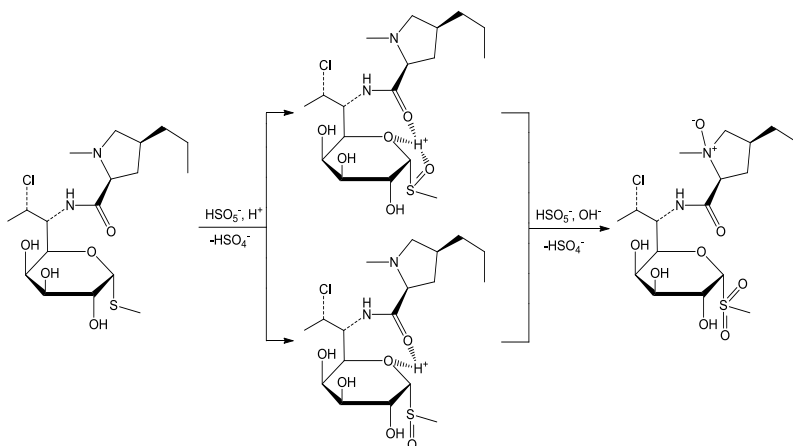


**Fig. 1. Molecular structure of Clindamycin hydrochloride**

There are two possible sites for oxidative attack in CLI: the thiomethyl group and pyrrolidine tertiary nitrogen. Sulfide sulfur is known to be oxidized readily by peroxy acid. The oxidation of CLI described here using oxone yielded *R*- and *S*-diastereoisomeric of CLI sulfoxides (on first stage under mild acid); neither a higher

concentration of oxone nor a prolonged reaction time led to a further oxidation of sulfoxide giving rise to a higher yield of sulfone. We looked for reaction conditions, which would also lead to the oxidation of the tertiary amine in CLI. It was alkaline media conditions with a sufficient excess of oxidant. Thus, oxidation of CLI with oxone in alkaline media leads to *N*-oxide, besides the conversion of thiomethyl group into sulfone (Fig. 2).

The method involves the use of potassium hydroperoxomonosulphate ( $\text{KHSO}_5$ , PMS) in form oxone (the triple salt  $2\text{KHSO}_5 \cdot \text{KHSO}_4 \cdot \text{K}_2\text{SO}_4$ ) as the titrant. A known excess of either reagent (PMS) is added and, after the complete reaction between CLI and PMS, the unreacted PMS is determined by iodometric back titration. In the present investigation, PMS was found to react quantitatively with CLI in alkali medium to form the sulfone-*N*-oxide. A stoichiometry of the reaction between PMS and CLI showed that for oxidation of 1 mol CLI 3 mol of PMS were required (Fig. 2). The relationship between the titration end-points obtained by the proposed method and the CLI amounts was examined. The linearity between the amount of CLI and titration end-point is apparent from the correlation coefficient. To prove the validity and applicability of the proposed method, four replicate determinations at different concentration levels of CLI was carried out. The within-day RSD values were within 2%.



**Fig. 2** Scheme of *S*, *N*-oxidation of Clindamycin with  $\text{KHSO}_5$

*Assay procedure.* A 10 ml aliquot of solution containing 10.0–50.0 mg of CLI was placed in a 100 ml volumetric flask with a followed by the addition of 1 ml H<sub>2</sub>SO<sub>4</sub> (0.01 M) and 10 ml KHSO<sub>5</sub> (0.02 M) and allowed to stand for specified time at room temperature. The solution was alkalinized by adding 5 mL of 5 mol L<sup>-1</sup> sodium carbonate to raise the pH to 9 followed by the addition of double distilled water to the mark (100 mL). The content was mixed well and the flask was kept aside for 30 min under occasional swirling. Then, 10 ml aliquot of solution was transferred by means of a pipette into a 100 ml Erlenmeyer flask and 5 mL of 10% sulfuric acid and 5 mL of 5% potassium iodide were added to the flask and the liberated iodine was titrated with 0.01 mol L<sup>-1</sup> sodium thiosulphate to a starch end point. A control titration was run under the same conditions. A control (blank) experiment was carried out without CLI drug.

For the amount of drugs estimated by the proposed methods was in good agreement with the label claim. The proposed methods were validated. The accuracy of the methods was assessed by recovery studies at three different levels. Recovery experiments indicated the absence of interference from commonly encountered pharmaceutical additives. The method was found to be precise as indicated by the repeatability analysis, showing %RSD less than 2. All statistical data proves validity of the methods and can be used for routine analysis of pharmaceutical dosage form.

**Conclusion.** The proposed analytical methods are simple, rapid, accurate, Clindamycin hydrochloride pharmaceutical preparations. The sample recoveries from all preparations were in good agreement with their respective label claims, which suggested non-interferences of formulations excipients in the estimation.

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## **TITRIMETRIC MICRO-DETERMINATION OF LINCOMYCIN USING OXONE**

Lincomycin (LMH) belongs to lincosamide class of antibiotics. Lincomycin is naturally produced by bacteria species, namely *Streptomyces lincolnensis*, *S. roseolus*, and *S. caelestis* [1]. Chemically Lincomycin is a 6,8-dideoxy-6-amino-octose lincosamine, methyl 6-amino-6,8-dideoxy-N-[(2S,4R)-1-methyl-4-propylprolyl]-1-thio-D-erythro- $\alpha$ -D-galacto-octopyranoside hydrochloride monohydrate (Fig. 1) [2].

It is indicated for the treatment of serious infections due to susceptible strains of Gram-positive aerobes, such as staphylococci,

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