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ЗБІРНИК ТЕЗ НАУКОВИХ РОБІТ

УЧАСНИКІВ МІЖНАРОДНОЇ
НАУКОВО-ПРАКТИЧНОЇ КОНФЕРЕНЦІЇ

«МЕДИЧНА НАУКА ТА ПРАКТИКА В УМОВАХ СУЧАСНИХ ТРАНСФОРМАЦІЙНИХ ПРОЦЕСІВ»

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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-aminooctose lincosamine, methyl 6-amino-6,8–dideoxy-N-[(2S,4R)-1-methyl-4-propylprolyl]-1-thio-D-erythro-α-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,

streptococci, and pneumococci, and is generally reserved for patients who are allergic to penicillin [3]. Lincomycin is a basic compound in which the tertiary amino group has a pKa of 7.6.

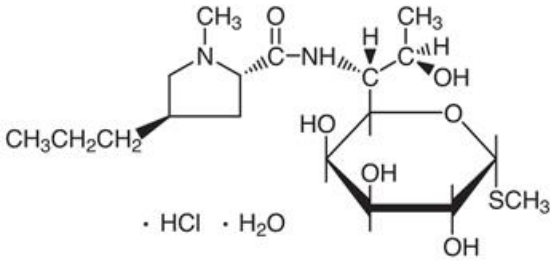

Fig. 1. Molecular structure of lincomycin hydrochloride

It is approved in European Pharmacopoeia [4], The State Pharmacopoeia of Ukraine (SPhU) [5] and United States of pharmacopoeia and National formulary [6]. A few analytical methods have been stated for its quantitative determination in pharmaceutical formulations like GC [5], HPLC [4,7,8] liquid chromatography with pulsed electrochemical detection [9], liquid chromatography-mass spectrometry (LC-MS), thin layer chromatography (TLC), UV spectrophotometry, Colorimetry, lateral flow immunoassay (LFIA), electrochemiluminescence (ECL), electrochemical method and atomic absorption spectroscopy, capillary electrophoresis (CE). The determination of lincomycin by iodometric titration of the methanethiol that is formed as a result of the destruction of lincomycin in very acidic medium is known. At the same time, series analyses by this method are difficult because of the difficulty involved in trapping the CH_3SH, which must be carried out at low temperatures. In recent years, the assay methods in the monographs include titrimetric, spectrometry, chromatography, and capillary electrophoresis; also, the electro-analytical methods can be seen in the literature [10].

HPLC is efficient and fast, but its sensitivity is limited by the UV absorption of Lin. LC-MS methods are quite sensitive, but the expensive equipment needs to be handled by trained staff, limiting the application for small farms or in-feld tests. TLC methods have strong separation capability and only need small amount of sample, but suffer from poor reproducibility.

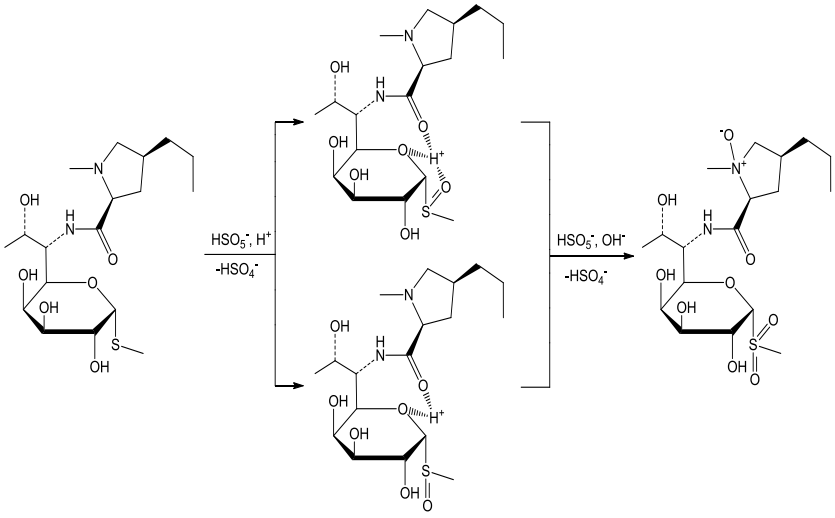

Fig. 2 Scheme of S, *N*-oxidation of LMH with $KHSO_5$

In the light of the view above, so sensitive and rapid analytical methods are in need for the quantitative determination for lincomycin hydrochloride. In the present work aims to develop an accurate, simple, precise, and validated, iodometric method for the estimation of lincomycin hydrochloride in capsules dosage form.

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.

The present investigation aims to develop simple, sensitive, and cost-effective method for the determination of LMH in pure form, capsules and solution for injection using redox titrimetric techniques. The method involves the use of potassium hydrogen-peroxomonosulphate ($KHSO_5$, PMS) in form oxone (the triple salt $2KHSO_5 \cdot KHSO_4 \cdot K_2SO_4$) as the titrant. A known excess of either reagent is added and, after a specified time, the residual reagent is determined iodometrically.

In the present investigation, PMS was found to react quantitatively with LMH in alkali medium to form the sulfone-*N*-oxide. A stoichiometry of the reaction between PMS and LMH showed that

for oxidation of 1 mol LMH 3 mol of PMS were required (Fig. 2). The relationship between the titration end-points obtained by the proposed method and the LMH amounts was examined. The linearity between the amount of LMH and titration end-point is apparent from the correlation coefficient. The correlation coefficient of 0.999 show that the reaction between PMS and the studied LMH proceeds stoichiometrically in a molar ratio of 3 : 1. To prove the validity and applicability of the proposed method, four replicate determinations at different concentration levels of LMH was carried out. The within-day RSD values were within 2%.

Assay procedure. A 10 ml aliquot of solution containing 10.0–50.0 mg of LMH was placed in a 100 ml volumetric flask with a followed by the addition of 1 ml H_2SO_4 (0.01 M) and 10 ml $KHSO_5$ (0.02 M) and allowed to stand 1-2 min at room temperature. The solution was alkalized by adding 5 mL of 5 mol L^{-1} sodium carbonate to raise the pH to 9 followed by the addition of double distillated water to the mark (100 mL). The content was mixed well and the flask was kept aside for 25-30 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^{-1} sodium thiosulphate to a starch end point. A control titration was run under the same conditions. A control experiment was carried out without LMH drug.

In either method, the amount of drug was calculated using the equation: Amount of drug (mg) = $\Delta V \times M \times R \times 10/ n$, where $\Delta V = V_0 - V_1$ is volume of $Na_2S_2O_3$ consumed by the drug (ml); M=molecular weight of the drug; R=molarity of $Na_2S_2O_3$ solution and *n*=number of moles of $KHSO_5$ reacting with 1 mol of drug ×2; 10 – dilution factor.

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, precise and inexpensive and hence can be used for the routine analysis of lincomycin 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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викладач професійних фармацевтичних дисциплін, завідуюча фармацевтичним відділенням

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ОПЛАТА ПРАЦІ ФАРМАЦЕВТИЧНИХ ФАХІВЦІВ

Відомо, що будь-яка робота повинна бути оплачувана відповідним чином. Заробітна плата багатьох висококваліфікованих фармацевтів досить висока. Роботодавці розуміють, що в іншому випадку вони можуть просто втратити цінного працівника. Але розмір заробітної плати залежить від багатьох чинників, таких як: досвід і стаж; специфіка роботи; регіон країни.

Заробітна плата – грошове вираження вартості й ціни товару «робоча сила» та частково результативності її функцій. Заробітна плата – це винагорода, як правило, у грошовому виразі, яку власник або уповноважений орган сплачує працівнику за виконану ним роботу згідно з положенням трудового договору [1].

Фармацевтичні підприємства застосовують дві форми оплати праці – погодинну (проста погодинна та погодинно-преміальна) та відрядну. При погодинній формі оплати праці розмір оплати залежить від відпрацьованого працівником часу і встановлених

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