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ORIGINAL ARTICLE

Stability studies on florfenicol using developed derivative spectrophotometric methods

Les études de stabilité sur florfénicol l'utilisation des méthodes de spectrophotométrie dérivées développées

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KEYWORDS
Derivative spectrophotometry;
Florfenicol;
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Summary
Objectives. — This study aims to investigate the stability of florfenicol using previously developed derivative spectrophotometric methods (D^1 and D^2).
Methods. — The studied stability-indicating pararmeters included alkali (NaOH, 1 M), acid (HCl, 1 M), pH changes (buffer pH 2.2—11), temperature (80 °C and 100 °C at pH 10) and light.
Result. — A constructed pH profile for the drug degradation rate revealed a significant effect of pH on the drug stability between pH ranges 8 and 11. The obtained profile indicated first order dependence of K_{obs} on [OH^-]. Arrhenius plot at pH 10 was found linear at temperatures 80 °C and 100 °C with estimated activation energy of 19.35 kcal/mol. The calculated rate constant (K_{obs}), $t_{1/2}$ and t_{90} at 25 °C were found to be 1.8×10^{-3} h, 385 h and 58.3 h, respectively. The photostability of florfenicol was also studied by exposing the drug solution to direct sunlight during mid-day time.
Conclusion. — The obtained results reflected the instability of florfenicol under the study conditions.
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MOTS CLÉS
Dérivé spectrophotométrie ;
Florfénicol ;
Études de stabilité

Résumé
Objectifs. — Cette étude a pour but d'enquêter la stabilité du florfénicol en utilisant les méthodes précédemment développées sur les dérivées de spectrophotométrie (D^1 et D^2).
Méthodes. — Les paramètres de la stabilité indicateurs étudiée inclus un alcalin (NaOH, 1 M), acide (HCl, 1 M), pH changements (tampon pH 2,2—11), température (80 °C et 100 °C au pH 10) et lumière.
Résultats. — Un profil de pH construit pour le taux de dégradation du médicament a révélé un effet significatif de pH sur la stabilité du médicament entre pH 8—11. Le profil obtenu a indiqué une dépendance de premier ordre de K_{obs} sur [OH^-]. Le plan d'Arrhenius sur pH 10 a trouvé une linéarité de températures de 80 °C et 100 °C avec de l'énergie d'activation estimée de 19 kcal/mol. Le taux constant calculé (K_{obs}), $t_{1/2}$ et t_{90} a 25 °C ont été trouvés équivalent à $1{,}8 \times 10^{-3}$ heures, 385 heures et 58,3 heures, respectivement. La photostabilité du florfénicol a été aussi étudiée exposant le médicament directement à la lumière du soleil durant la journée (à midi).
Conclusion. — Les résultats obtenus reflètent l'instabilité du florfénicol sous les conditions de l'étude.
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Introduction

Florfenicol (Fig. 1) is a fluorinated synthetic analog of thiamphenicol [1]. Florfenicol is currently indicated for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica* (Pasteurella), *Pasteurella amultocida* and *Haemophilussomnus* for treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

Florfenicol is also used in aquaculture, and is licensed for use in the United States for the control of enteric septicemia in catfish [2].

Literature review revealed different methods for the analysis of florfenicol [3—8]. However, most of these methods were applied for the analysis of florfenicol in biological fluids.

Derivative spectrophotometric methods have proved to be accurate stability-indicating methods [9]. Therefore, the aim of our work is to study the effect of different factors affecting the stability of florfenicol using our recently developed derivative spectrophotometric methods applied for its quantitative analysis [10].

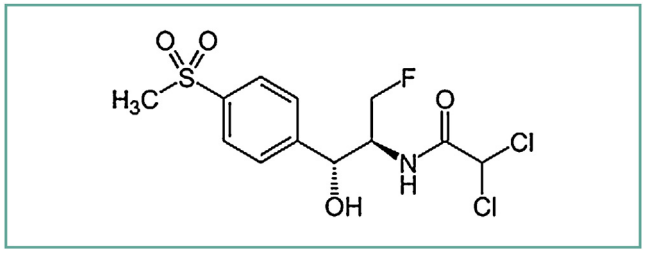

Figure 1. Chemical structure of florfenicol.
Structure chimique du florfénicol.

Experimental

Apparatus

UV spectrophotometric studies were carried out on Shimadzu UV — 1800ENG240V, (Kyoto, Japan). The operating conditions were as follows:

- wavelength range: 250—400 nm;
- scan speed: medium, 0.2 nm/s.

Reference, sample and reagents

Florfenicol reference standard was kindly provided by colleagues in King Saudi Arabia. Florfenicol sample (Norflor® injection solution, 300 mg/mL) was obtained from Schering-Plough Santé Animale, La Grindoliere, Serge, France. Disodium orthophosphate, sodium hydroxide and hydrochloric acid (36%; 1.18 g/mL) were obtained from British Drug House (BDH), Poole, England. Mcllvaine universal buffer (pH range 2.2—8) and phosphate buffer (pH range 9—11) were prepared according to methods in references [11,12].

Preparation of sample stock solution

One milliliter of florfenicol solution was accurately pipetted and transferred into 100 mL volumetric flask. The volume was completed to mark with distilled water. One milliliter of the resultant solution was further diluted to 100 mL with distilled water (solution A; 30 μg/mL).

Procedures

Effect of alkali and acid (1 M NaOH; 1 M HCl) on florfenicol stability

Aliquots of solution A (2 mL) were transferred into four stoppered glass tubes. One milliliter of 1 M NaOH was added

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