The Microbiological & Chemical Stability of Sterile Chloramphenicol Ophthalmic Solutions

Idris M. El-Mahdi, Tauwfik M. Salih, Salha F. Ben-Gweirif

Dept of Pharmaceutics, Faculty of Pharmacy, Benghazi University, P.O.Box 7020, Benghazi – Libya. idris.elmahdi@benghazi.edu.ly.

Chloramphenicol is a broad spectrum antibiotic which is more commonly used in ophthalmic dosage forms. It is advised that chloramphenicol when formulated as an eye drop solution that the product should be stored at low temperature of 2-8°C. However, there is a common observation of non-compliance of this specific storage condition among pharmacists. And that chloramphenicol eye solution is stored similarly to its ophthalmic ointment dosage form at room temperature. Such noncompliance could result in potential reduction in product shelf-life. However, there are some mathematical models which can be used to estimate the "true" shelf-life of a dosage form based on its actual storage temperature. Hence, the aim of this work is to predict the true (remaining) shelf-life of chloramphenicol eye drops (commercially marketed) using the "Longland – Rowbotham model", followed by confirmation of findings by the assay of the active ingredient, sterility testing and MIC evaluation using official methods during 6-months storage at variable temperatures (4, 25, 37°C). The prediction estimates indicated that, in pessimistic conditions of the used model, the remaining shelf-life was reduced to a merely one month following production (this is versus the 2-year expiration date given by manufacturer. However, the samples analyzed throughout a 6-month stability study revealed that storing chloramphenicol solution at 4 or 25°C does not produce any statistical difference regarding drug content, MIC or sterility.