TOPICAL COMPOUNDED CLINDAMYCIN SOLUTION MADE FROM ORAL DOSAGE FORMS, CONTROL AND STABILITY STUDY

Aldina Kurbegović

aldina_1987@hotmail.com

Clinical Center University of Sarajevo, Clinical Pharmacy, Sarajevo, Bosnia and Herzegovina

BACKGROUND AND IMPORTANCE

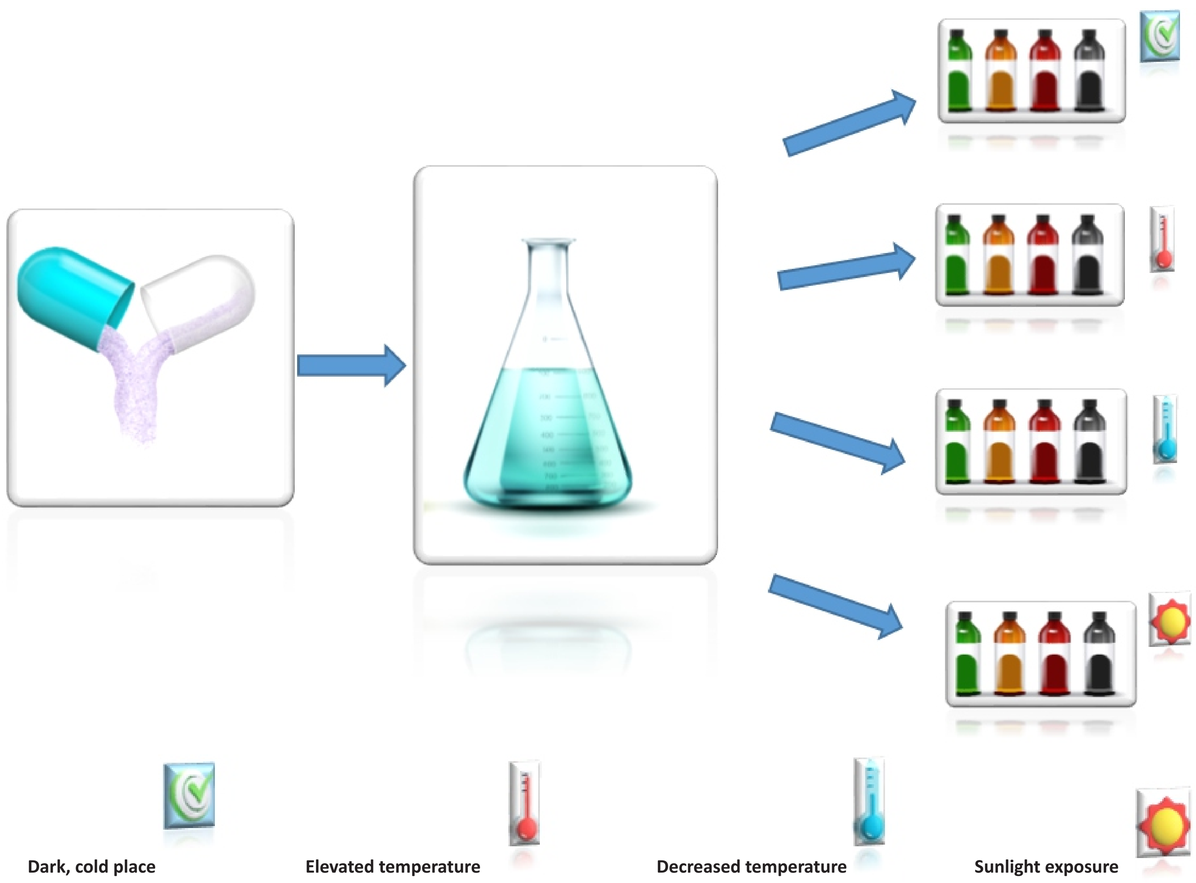
Approved and available medicine are often used as a starting material in compounding process. Diverse storage conditions such as variable temperature, humidity, sunlight exposure can stimulate changes in all pharmaceutical forms, especially in solutions. Primary packing material should provide protection of compounded dosage forms and ensure compatibility.

AIM AND OBJECTIVES

Aim of this study is to estimate effectiveness of compounding process on the assay clindamycin hydrochloride in topical solution made from oral dosage forms. Considering glass and plastic primary container closure system, in use product stability was evaluated in different storage conditions such as dark and cold place, elevated and decreased temperature and sunlight exposure.

MATERIALS AND METHODS

Assay of Clindamycin topical solution made from oral dosage forms was determined using HPLC reversed phase technique with UV detector. Peaks of active pharmaceutical ingredients (API) and related substances were evaluated.

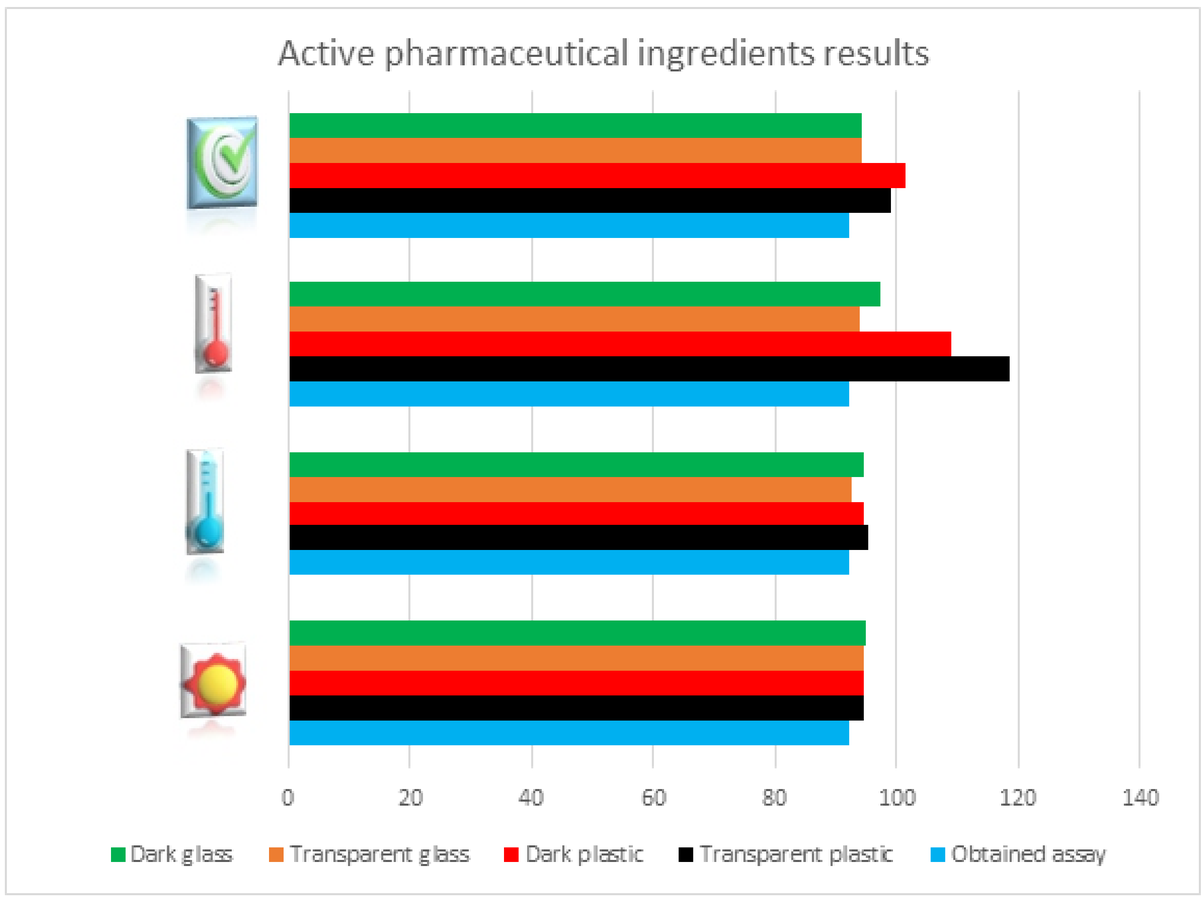


Solution was divided in glass (amber and transparent) and plastic (dark and transparent) bottles and stored at dark and cold place, elevated and decreased temperature.

Sampling was according to free judgment.

RESULTS

Sample solution meets the assay requirements with 92%. Acceptance criteria is 90-110%. No significant API degradation and related substances were noticed.



Samples stored in plastic bottles showed assay increase up to 26% in compared to samples in glass bottles where reported growth is up to 5%.

CONCLUSION

- *Clindamycin hydrochloride solution for topical use can be made from oral pharmaceutical forms.*
- *Molecule is stable at least 112 days under different conditions with no or little degradation of API.*
- *Assay increase was noticed in plastic HDPE bottles due to vehiculum evaporation which is more expressed in samples conditioned in elevated temperature.*
- *Container closure system should enable adequate closing between cap and bottle which is key parameter to be considered.*

REFERENCES

1. *European Medicines Agency, Committee for proprietary medicinal products (CPMP), In-use stability testing of human medicinal products - Scientific guideline*

Poster number: 3PC-001

ATC CODE: D06-ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE