

Physicochemical Stability of Microemulsions and Microemulsion-Based Gels Containing Clotrimazole

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SUMMARY. This study aimed to determine physicochemical stability of clotrimazole microemulsions (CTZ-MEs) and clotrimazole microemulsion-based gels (CTZ-MBGs). Two CTZ-MEs (ME1-C, ME2-C) and two CTZ-MBGs (MBG1-3-C, MBG2-2-C) were prepared and then kept in clear-glass containers under three different conditions, *i.e.*, 4 °C, room temperature (28 ± 2 °C), and 45 °C for three months. Afterwards, they were evaluated for physicochemical changing. The results showed that temperatures of 4 °C and room temperature were suitable for storage of the samples while high temperature (45 °C) resulted in adverse changing. After kept at 4 °C and room temperature for 3 months, chemical stability of all samples was in acceptable range, *i.e.*, the drug content was higher than 90% of the initial value. However, ME2-C and MBG2-2-C exhibited more physical changing and less acceptable appearance than ME1-C and MBG1-3-C. Hence, ME1-C and MBG1-3-C were considered as stable formulations having high possibility to be further investigated for efficacy in topical drug delivery to the skin and buccal.

RESUMEN. Este estudio tuvo como objetivo determinar la estabilidad fisicoquímica de las microemulsiones de clotrimazol (CTZ-ME) y los geles basados en microemulsión de clotrimazol (CTZ-MBG). Se prepararon dos CTZ-ME (ME1-C, ME2-C) y dos CTZ-MBG (MBG1-3-C, MBG2-2-C) y luego se guardaron en recipientes de vidrio transparente en tres condiciones diferentes, es decir, 4 °C, temperatura ambiente (28 ± 2 °C) y 45 °C durante tres meses. Posteriormente fueron evaluados los cambios fisicoquímicos. Los resultados mostraron que las temperaturas de 4 °C y la temperatura ambiente eran adecuadas para el almacenamiento de las muestras, mientras que las altas temperaturas (45 °C) daban lugar a cambios adversos. Después de mantenerse a 4 °C y temperatura ambiente durante 3 meses, la estabilidad química de todas las muestras estaba en un rango aceptable, es decir, el contenido de fármaco era superior al 90% del valor inicial. Sin embargo, ME2-C y MBG2-2-C mostraron un cambio más físico y una apariencia menos aceptable que ME1-C y MBG1-3-C. Por lo tanto, ME1-C y MBG1-3-C se consideraron como formulaciones estables que tenían una gran posibilidad de ser investigadas adicionalmente para determinar su eficacia en la administración tópica de fármacos en piel y cuero cabelludo.

KEY WORDS: antifungal drug, clotrimazole, microemulsion, microemulsion-based gel, stability

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