

Formulation and Optimization of Topical 5-Fluorouracil Microemulsions Using Central Composite Design

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Abstract : Water in oil topical microemulsions of 5-FU were developed and optimized using face centered central composite design. Topical w/o microemulsion of 5-FU were prepared using sorbitan monooleate (Span 80), polysorbate 80 (Tween 80), with different oils such as oleic acid (OA), triacetin (TA), and isopropyl myristate (IPM). The ternary phase diagrams designated the microemulsion region and face centered central composite design helped in determining the effects of selected variables viz. type of oil, smix ratio and water concentration on responses like drug content, globule size and viscosity of microemulsions. The CCD design exhibited that the factors have statistically significant effects ($p < 0.01$) on the selected responses. The actual responses showed excellent agreement with the predicted values as suggested by the CCD with lower residual standard error. Similarly, the optimized values were found within the range as predicted by the model. Furthermore, other characteristics of microemulsions like pH, conductivity were investigated. For the optimized microemulsion batch, ex-vivo skin flux, skin irritation and retention studies were performed and compared with marketed 5-FU formulation. In ex vivo skin permeation studies, higher skin retention of drug and minimal flux was achieved for optimized microemulsion batch then the marketed cream. Results confirmed the actual responses to be in agreement with predicted ones with least residual standard errors. Controlled release of drug was achieved for the optimized batch with higher skin retention of 5-FU, which can further be utilized for the treatment of many dermatological disorders.

Keywords : 5-FU, central composite design, microemulsion, ternary phase diagram

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