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Effects of droplet size and turbidity of ibuprofen micro-emulsion on its stability and human bioavailability

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Objective: To study the effects of droplet size and turbidity of ibuprofen micro-emulsion on its stability and human bioavailability.

Methods: Ibuprofen self-emulsified systems were optimized to get the lowest turbidity (F1) and the smallest droplet size (F2) on emulsifying with water, applying Face Centered Experimental Design. F1and F2 consisted of 50 mg ibuprofen each and 90 and 9.98 parts of soybean oil, 8 and 72 parts of Cremophore EL and 11.06 and 18 parts of Capmul MCM-C8, respectively.The stability study was conducted at 4°C, room temperature and 37°C for eight months. The stored formulations were examined visually for physical changesand evaluated for particle size, turbidity and drug release after 0, 1, 2, 4, 6 and 8 months of storage. Bioavailability was assessed after a single oral dose of HPMC capsules containing F1 and F2 and compared with reference (50 mg ibuprofen dissolved in soybean oil), with 7-days washout period using six human volunteers. Drug in plasma was measured by HPLC.

Results: F1 and F2 were physically stable. The changes in turbidity, particle size and dissolution rate for samples stored at 4°C were less compared to those stored at room temperature or 37°C. The pharmacokinetic parameters obtained were: The C_{max} was 0.707, 0.936 and 0.468 ug/ml, the $T_{max}$was 1, 1 and 1.5 hr and the $AUC_{0-\infty}$ was 3.78, 3.96 and 1.99 mg.hr/ml for F1, F2 and reference, respectively. The relative bioavailability of F1 and F2 against the reference was 190.25 and 199.11% respectively.

Conclusions: The optimized ibuprofen formulations stored at 4°C were more stable compared to those stored at room temperature or 37°C. The test formulations showed higher rate and extent of drug absorption and higher bioavailability compared to the oily drug solution.

Biography

Abdelazim Zaghloul is an Associate Professor of Pharmaceutics at Faculty of Pharmacy, Kuwait University. He obtained his MSc and Ph.D. degrees from Faculty of Pharmacy, Al-Azhar University, Egypt. In 1999, he joined School of Pharmacy, Texas Tech University as a Postdoctoral Research Fellow and in 2003, he joined Kuwait University. He has published more than 30 research and review articles in peer reviewed international journals and presented more than 50 oral and poster presentations. His research interests are design and evaluation of different drug delivery systems as well as evaluation of critical process and formulation variables by optimization procedures and neural networks.

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