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Pre-formulation and early formulation development: Assessing risks and strategies

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Pre-formulation and exploratory formulation development studies are critical in defining drug product strategies for first in human studies leading to commercial dosage form development. Exploratory development is a dynamic phase of development with limited API, tight timelines, limited knowledge of material properties and process scale up and the impact of dose change, formulation and physiological variables on bioavailability being unknown. Using an integrated approach to assess risks related to bio-pharmaceutics, material (form) and drug product processing is critical to design appropriate formulation strategies. Use of in vitro tools, in silico absorption modeling along with in vivo studies and high throughput screening techniques not only provide a robust design space early on but also lead to focused formulation development with shorter timelines. Through various case studies, this talk will cover tools and workflows that can be implemented in the pre-formulation and early formulation development space to assess bio-pharmaceutics, API form and phase transformations and drug product processing risks, highlighting a qbD approach to early development.

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Emu oil based nano-gel for topical delivery of curcumin to treat chronic inflammatory diseases

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Purpose: The major limitations for the therapeutic use of curcumin are poor permeability through biological membranes, low bioavailability and photodegradation. Emu oil has been reported for having anti inflammatory properties and claimed to possess excellent skin-permeation properties. Aim of the present study was to formulate a nanoemulsion of curcumin for transdermal delivery to increase its photostability, and enhance its anti-inflammatory activity by using emu oil as a carrier and permeation enhancer.

Methods: Curcumin loaded nanoemulsion was prepared by employing emu oil as the oil phase and Cremophor RH 40 and Labrafil M 2125 CS as surfactant and co-surfactant respectively. The nanoemulsions were characterized by droplet size analysis, TEM, refractive index, pH, photostability by HPLC analysis. In vivo anti-inflammatory activity for nanoemulsion in 1% carbopol gel was evaluated by using croton-oil induced dermatitis model, carrageenan induced rat paw edema and adjuvant induced arthritis model in male SD rats. The effects of treatment in arthritic rats were assessed by biochemical (TBARS, GSH, and MPO), inflammatory mediators (IL-6, IL-1βand TNF-α), radiological and histological studies in joints.

Results: Droplet size of curcumin loaded nanoemulsion was found to be 62.06±0.52 nm with a size distribution of 0.206. The pH of the formulation is in the acidic range which is favourable for the stability of curcumin. In vitro skin permeation studies revealed that curcumin loaded nanoemulsion enhanced the penetration of curcumin by 4-folds in comparison to curcumin suspension. Results of croton oil induced ear edema model for anti-inflammatory activity indicated a significant decrease in ear thickness. Curcumin nanoemulsion gel applied topically significantly ($p<0.001$) reduced the paw volume, pro-inflammatory mediators like IL-6, IL-1, TNF-αand biochemical parameters such as TBARS, GSH, and MPO in synovial tissue when compared to arthritic control animals.

Conclusions: The investigation described above provided evidence for the use of emu oil as a drug carrier in pharmaceutical formulations. To our knowledge, this is the first report in the direction of development of novel formulations employing emu oil to address the problems of poor permeation properties for bioactive compounds such as curcumin.

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