Solubility and Stability Studies of Benzoyl Peroxide in Non-Polar, Non-Comedogenic Solvents for Use in Topical Pharmaceutical Formulation Developments

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SUMMARY. Non-irritant, non-comedogenic and non-polar emollients were pre-selected for determinations of relative dielectric permittivity and solubility of benzoyl peroxide (BP). Those solvents capable of solubilizing BP in concentrations commonly utilised in topical formulations (between 1 and 10 %) were taken into account for stability studies. The developed pre-formulations were also studied for acute irritation both clinically and instrumentally. Even though the solubility of BP in the solvents studied had relatively low values; in some cases, such as with caprylic/capric triglyceride (CapCap) and dicaprylyl carbonate (DicCar) it has been possible to obtain acceptable concentrations of BP from a therapeutic viewpoint (19.9 and 19.5 mg/mL, respectively). Two BP pre-formulations (PBCapCap and PBDicCar) with enhanced stability and with the capability to decrease adverse application site reaction by maintaining moisture in the *stratum corneum* were developed with potential application in topical formulations of BP with solvents of low relative dielectric permittivity (CapCap and DicCar, respectively).

KEY WORDS: Benzoyl peroxide, Pre-formulation, Solubility, Stability, Thermodynamic activity.

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