Title: Stability study of a new formulation for the off label use of cyclosporine

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Abstract:
Introduction  Cyclosporine is frequently used as an off label drug for the treatment of vernal keratoconjunctivitis refractory to steroids. Being a lipid soluble drug, cyclosporine collyrium is often prescribed in a lipophilic base. However, appropriate sterile pharmaceutical oils are not available in the market. The aim of this study is to verify the sterility and stability of castor and olive oil, after dry heat sterilization, and their compatibility and stability with cyclosporine in concentration varying from 1 to 2%. Materials and methods  The following quality characteristics were evaluated: physicochemical properties of the two oils, the efficacy of the dry heat sterilization (in ventilated oven 160°C for 2.5h), the peroxide number, the solubility and extent of miscibility of cyclosporine (50 mg/ml vial) in the oils. Spectrophotometric analysis were conducted in the dry heat sterilized oils and non. Samples were diluted 1:100 in isopropyl alcohol and absorbance was measured from 320 to 200 nm. Gas chromatographic analysis of fatty acids were carried out before and after the sterilization. Sterility control was performed in all batches. Results  The oils resulted considerably stable after the sterilization treatment. The peroxide number in olive oil was reduced from 20 to 10, while remaining unvaried in castor oil. Spectrophotometric analyses confirmed the stability of the oils under investigation. It was observed that castor oil was more stable than olive oil, maintaining the maximum absorbance values at 259, 268, and 279 nm. Microbiological controls demonstrated that the oils were sterile. Stability and miscibility studies of cyclosporine in the oils revealed a better behaviour of the castor oil. Quantitative analysis of the fatty acids (palmitic, palmitoleic, stearic, oleic, linoleic, arachidonic, ricinoleic, eicosanoic and beenic) revealed a substantial stability in both oils, before and after sterilization. Conclusions  This study indicates castor oil as the appropriate lipophilic base for the off label use of cyclosporine. Furthermore, it emphasizes the fact that, magistral galenic preparations should be given more credit and considered therapeutically valuable. In any case, the procedure of preparation should be in accordance with the quality assurance policy. This leads to improved efficacy and safety for single patient's benefit. In this manner, the Laboratory of Hospital Pharmacy can respond to the requests of different therapeutic areas.