DEVELOPMENT OF A SELF-EMULSIFYING DRUG DELIVERY SYSTEM CONTAINING COQ10

Zapico V.\textsuperscript{a}, Glujoy M.\textsuperscript{a}, Buontempo F.\textsuperscript{a}, Flor S.\textsuperscript{b}, Lucangioli S.\textsuperscript{b}, Carlucci A\textsuperscript{a#}

\textsuperscript{a}Department of Pharmaceutical Technology. \textsuperscript{b}Department of Analytical Chemistry and Physicochemistry Faculty of Pharmacy and Biochemistry. University of Buenos Aires, Argentina. Junín 954, (1113) Buenos Aires.

INTRODUCTION
Ubiquinone (CoQ10) deficiency is associated with five clinical presentations which showed clinical improvements after oral drug administration (1). Co-Q10 exhibits extreme lipophilicity and high molecular weight, therefore it is necessary to develop special formulations for its bioavailability. It is well-known that bioavailability can significantly improve using dosage forms which contain CoQ10 dissolved (2). SEDDS (Self-emulsifying drug delivery system) are isotropic mixtures of oil, surfactant, co-surfactant and drug with the ability to form oil in water emulsion upon mild agitation following dilution with aqueous phase (3). The objective of the present work was to optimize a liquid auto emulsifying formulation so as to load a clinical relevant CoQ10 dose to be administered in pediatric patients.

MATERIALS AND METHODS
Materials: Cetiol OE (Dicaprylyl Ether), Imwitor 408 (Propylene Glycol Caprylate), Isopropilyc myristate, Miglyol 812 (Caprylic/Capric Triglyceride), Laureth-4 and Propylene glycol (PG).

Methods: these excipients were chosen from previous CoQ10 solubility experiments, so a wide range of binary mixtures (oil phase: surfactant) could be obtained. PG was added and Ternary phase diagrams were used to evaluate the isotropic domain. To determine the equilibrium solubility, drug in excess was added. The samples were left to equilibrate using a Rotating Bottle apparatus and then filtered. Samples were analyzed by HPLC (Waters, MI, USA). Compositions with highest capacity of drug solubilization of each one of the oil phase used were selected for physicochemical (viscosity, rate and capacity of emulsification) characterization. A stability test that included microscopic observation was carried out during a month.

RESULTS
Imwitor 408 was the oil phase which showed the biggest region of isotropic ternary mixtures and Cetiol OE the one with the smallest one. The dissolved concentrations obtained were equal or even higher than the ones previously presented in literature (6% w/v). No significant changes in physicochemical parameters or in physical stability were observed in the selected composition.

CONCLUSION
CoQ10 belongs to Class II in BCS Classification, nowadays SEDDS are considered to be a promising way to administer this kind of drugs. Their optimization can be carried out properly if the main physicochemical characteristics of the involved components are considered. In this way, an appropriate liquid dosage form for oral administration of CoQ10 for pediatric patients in a hospital environment could be proposed.

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REFERENCES
* Corresponding author. Tel-fax +54 11 49648271; e-mail: amcarlucci@gmail.com.