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Evaluation of the influence of some polymers on the physical stability of lipid self- double emulsifying systems with Alendronate Sodium

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The Self-emulsifying drug delivery systems (SEDDS) containing lipids, surfactants, and co-surfactants are a promising oral platform for drugs with problematic solubility and permeability. However, especially those systems representing a liquid phase may show some shortcomings, such as in vivo drug precipitation, limited lymphatic transport, and storage problems. These shortcomings can compromise their application. The inclusion of some polymers in their composition would increase the system's stability both during storage and during dispersion in the gastrointestinal tract. For example, alendronate sodium, a BCS class III drug, is characterized by low permeability (2.5%) and good solubility (23.7 mg.mL⁻¹).

The present study aimed to investigate the effect of the natural polymer gelatine and co-emulsifier soybean phosphatidylcholine on the physical stability of w/o/w self-double emulsifying drug delivery systems based on coconut oil with Alendronate Sodium (w/o/w SDEDDS-NaALD). For the preparation of the model systems, lipids were used ordinarily present in the diet and surfactants approved for use in the pharmaceutical and food industries.

Four models have been developed containing 70 mg Alendronate sodium and a combination of excipients (Polysorbate 80, Sorbitan Monooleate 80, and soybean phosphatidylcholine) with and without gelatine. For the determination of the excipient ratios of self-emulsification pseudo-phase diagrams were used. The two-phase emulsification technique was used with a high-speed homogenizer (65°C) to obtain the self-emulsifying systems.

Sedimentation analysis (by centrifugation) and spectrophotometric analysis (%T, $\lambda=540$ nm) were used to determine the stability and dispersion of the prepared model systems. In addition, the self-emulsification time of the different self-double emulsifying systems and the average particle size of the dispersed phase was determined by DLS. The self-emulsification time of the systems varies from 70 to 110 min.

As a result of research, it was found that the system containing (w/w): Alendronate sodium 6%, water 17.5%, gelatine 0.6%, Sorbitan Monooleate 80 2.9%, coconut oil 17.5%, Polysorbate 80 51.5% is characterized by mono dispersion, average dispersed phase size 200 nm and the best stability compared to other studied models, which retains its degree of dispersion for one week. Therefore, this model is a suitable candidate for further research and development of a lipid-based dosage form for Alendronate sodium.

Primary author: PEHLIVANOV, Ivaylo (Department of Pharmaceutical Technologies, Medical University of Varna, 9000, Varna, Bulgaria)

Co-authors: Prof. NIKOLOVA, Krastena (Department of Physics and Biophysics, Medical University of Varna, 9000, Varna, Bulgaria); Prof. ANDONOVA, Velichka (Department of Pharmaceutical Technologies, Medical University of Varna, 9000, Varna, Bulgaria)

Presenter: PEHLIVANOV, Ivaylo (Department of Pharmaceutical Technologies, Medical University of Varna, 9000, Varna, Bulgaria)

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