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Development of a Solid-Type IV Self-Emulsifying Drug Delivery System of BCS Class II Drug †

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† Presented at the 1st International Electronic Conference on Pharmaceutics, Switzerland, 1–15 December 2020; Available online: https://iecp2020.sciforum.net/.

Abstract: Self-emulsifying systems (SEEDS) are becoming increasingly popular for the preparation of oral dosage forms of low-water-soluble drugs. SEEDS are divided into subgroups according to their components; type IV formulations that are prepared using only surfactants and/or co-surfactants. The aim of the study was to increase the solubility of tadalafil, a class II drug according to the BCS, by preparing a type IV formulation. In the study, Labrasol, Kolliphor PS 20, Kolliphor PS 60, Kolliphor PS 80, Kolliphor CS 12, Kolliphor CS 20, Kolliphor HS 15, Kolliphor EL, Kolliphor ELP, Kolliphor PEG400, Gelucire 44/14 and Gelucire 48/16 were used as surfactants; Transcutol was used as a co-surfactant. The Kolliphor PS 80, Kolliphor EL, and Kolliphor HS 15 formulations were prepared in a ratio of 2:1 with Transcutol to form droplet sizes less than 50 nm and PDI values below 0.2. The formulations sensitivity to heat change and pH change was analysed by performing stability tests. Stable formulations of tadalafil formulations were obtained using Transcutol and Kolliphor PS 80 or Kolliphor EL. Solidifications of the optimum type IV formulations were made using fluorite, Neusilin US2, Neusilin FL2, Syloid 3050, and Syloid 3150. Dissolution studies of the prepared solid type IV formulations were first performed in 0.1 N HCl, and the dissolution profiles were examined by analysing the optimum solid type IV (s-type IV) formulations in pH 4.5 and pH 6.8. It was determined that the s-type IV prepared with Neusilin US2 and Neusilin UFL2 (2:1) had provided a dissolution of over 80% at the end of the first minute. The results indicated the potential bioavailability improvement of s-type IV for the BCS class II drug, Tadalafil, due to great enhancement in its dissolution rate.

Keywords: self-emulsifying drug delivery systems; tadalafil; lipid-based drug delivery systems; dissolution; solidification; porous carriers

Citation: Husuzade, G.; Mesut, B.; Güngor, S. Development of a Solid-Type IV Self-Emulsifying Drug Delivery System of BCS Class II Drug. **2021**, *78*, 32. https://doi.org/10.3390/IECP2020-08670

Published: 1 December 2020

Funding: This study was supported by Istanbul University Scientific Research Projects Coordination Department. Project number: TYL-2020-35176.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Not applicable.

Data Availability Statement: No new data were created or analyzed in this study. Data sharing is not applicable to this article.