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Optimization of SMEDDS orodispersible tablet formulation

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Self-microemulsifying drug delivery systems (SMEDDS) have numerous advantages, as formulations developed for solubility enhancement of poorly water-soluble drugs, though their solidification is still challenging the field of pharmaceutical technology. Lately, large progress was made by improving the flow properties of self-microemulsifying powders by wet granulation, using high-shear and fluid-bed equipment [1, 2]. Obtained granules exhibited the flow characteristics suitable for further tableting, yet low hardness and large mass of single dose SMEDDS tablet proved to be a major drawbacks. Thus, the aim of the present study was to optimize the amount of SMEDDS in tablets, while obtaining appropriate mechanical properties. Additionally, produced SMEDDS tablets were characterised regarding disintegration time, friability, self-microemulsifying and *in vitro* dissolution properties.

Within this research, different tableting mixtures were prepared, containing 25-50 % of SMEDDS granules. Increasing granule amount found to have a negative influence on SMEDDS tablet hardness, which was in agreement with our expectations, given the granules' high liquid SMEDDS content. An adequate hardness ≈100 N was achieved only with the tablet formulation containing 25 % of granules, in addition to lamination occurring with other tableting mixtures, due to use of high compression forces. Produced tablets preserved self-microemulsifying properties of liquid SMEDDS, as upon dispersion in water media the average droplet diameter was <100 nm. Due to short disintegration time (<2 minutes), prepared orodispersible SMEDDS tablets exhibited similar *in vitro* dissolution profile as corresponding SMEDDS granules, with complete drug release achieved within tested time interval.

References:

1. Kovačević M et al. Pharmaceutics. 14, 2077 (2022)
2. Mandić J et al. Int. J. Pharm. 583 (2020)