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### The influence of SMEDDS composition and the water ratio in granulation dispersion on attributes of granules prepared by wet granulation

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Self-microemulsifying drug delivery systems (SMEDDS), as formulation strategy developed for solubility improvement of poorly water-soluble drugs, are composed of lipids, (co)surfactants, hydrophilic cosolvents (optional) and drug, that is dissolved within the mixture (1). As such, SMEDDS are liquid dosage forms and therefore require transformation into solids, to achieve higher patient compliance, better stability, lower production cost in comparison to soft gelatine capsule filling (2). Within the present study, wet granulation was used as solidification technology, with SMEDDS water dispersion used as granulation fluid and mesoporous Syloid® 244FP as solid carrier. The purpose was to investigate whether granulation dispersion composition (different lipid/surfactant ratio in SMEDDS and different water dilution ratio) influence granules quality attributes, with special attention given to particle size, flowability, dissolution and self-microemulsifying properties.

Lipid/surfactants ratio in SMEDDS formulation impacted granules particle size in terms of positive correlation with  $d_{50}$  value. Likewise, particle size was affected by water/SMEDDS ratio in granulation dispersion with respect to higher SMEDDS share. Particle size with  $d_{50}$  227-578  $\mu\text{m}$  ensured excellent and good flow properties (Ph. Eur. criteria), despite high SMEDDS content (up to 2.91g SMEDDS/1g carrier) and consequently high drug loading. However, there were no big differences between granules *in vitro* dissolution properties, as the exhibited profiles were similar (81-88% drug released in first 5 minutes), but still faster than pure drug, with all formulations releasing full extent of the drug.

#### References

1. Pouton CW et al. Eur J Pharm Sci. 11, 93-98 (2000)
2. Mandić J et al. Int. J. Pharm. 533(2), 335-345 (2017)