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Abstract

Formulation Screening of Stearic Acid-Based Solid Lipid Microparticles on Gram-Scale †

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Abstract: As a nature-derived lipid, stearic acid (SA) has been widely recognized as a safe pharmaceutical excipient. One of the most potent application of SA in pharmaceutical aspect is its feasibility for constructing a versatile drug delivery system with translational potential, solid lipid microparticles (SLM). In this work, the formulation of SA-based SLM was screened and optimized on gram-scale (>2 g), so as to boost the industrialization of related products. Melt-sonication method was employed for SLM production. Four critical parameters were set at five levels, viz. Lipid amount 2.0~4.0 g, sonication time 10~50 min, aqueous solution volume 60~300 mL and surfactant concentration 0~1.00% (W/V), and SLM were accordingly prepared. Reproducibility and yield were two criteria for formulation screening, and a high reproducibility and yield would be satisfactory. Herein, reproducibility and yield was determined by size deviation (reflexed by an index C) and recovered weight (reflexed by an index Y), respectively. To be specific, $C = RSD^2_{Size} + RSD^2_{PDI}$ and $Y = m_a - m_b$, where RSD_{Size}, RSD_{PDI}, m_a and m_b represented relative standard deviation of particle size, relative standard deviation of polydispersity index, initial weight and obtained weight, respectively. The results showed that lipid amount 2.5 g, sonication time 30 min, aqueous solution volume 120 mL and surfactant concentration 0.75% (W/V) established the optimal formulation. We believe that this work can provide useful information for the (pre-)industrial-scale development of SA-based SLM.

Keywords: solid lipid microparticle; formulation screening; gram-scale; pharmaceutical translation

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