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Development of a method for industrial production of plga nanoparticles with quality by design (qbd) approach

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Poly-lactide-co-glycolic acid (PLGA) nanoparticles (NPs), which are named as gold standard FDA, are conventionally produced using different methods none of which are suitable for industrial production. o/w or w/o/w emulsification process is the most common method, in which removal of the organic solvent needs an evaporation process in R.T. Furthermore this process needs employing toxic excipients to emulsify the organic phase in aqueous media which are not applicable in production of PLGA NPs in bulk scale.

Microfluidizer instruments (MF) with the principle of homogenization at high pressure, are very convenient devices for industrial production of 'self-assembly, systems, including PLGA NPs. In the present study, PLGA NPs were synthesized using MF while the formulation parameters were optimized by application of Quality by Design (QbD) approach.

In the Central Composite Design (CCD) used for the optimization of PLGA NPs the variable parameters of MF were processing pressure and number of passes, while the formulation variables were PLGA amount (mg) and Tween80 amount (mg). 60 formulations were designed and the optimized formulation was chosen according to the responses including small particle size (PS), high zeta potential (ZP) and narrow Poly Dispercity Index (PDI). The o/w emulsion was prepared using a simple mechanical stirrer prior to MF process and the organic solvent (acetone) was evaporated using spray dryer.

In this study curcumin was used as active ingredient encapsulated in PLGA nano-micelles. As a result injectable, (PS less than 200 nm) and stable (ZP higher than -25 mv) PLGA NPs were obtained with a narrow PDI value (less than 0.2).