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Modelling and Simulation Efforts in Scale-Up and Characterization of Semi-Solid Dosage Forms

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Abstract : Generic pharmaceutical industry has to operate in strict timelines of product development and scale-up from lab to plant. Hence, detailed product & process understanding and implementation of appropriate mechanistic modelling and Quality-by-design (QbD) approaches are imperative in the product life cycle. This work provides example cases of such efforts in topical dosage products. Topical products are typically in the form of emulsions, gels, thick suspensions or even simple solutions. The efficacy of such products is determined by characteristics like rheology and morphology. Defining, and scaling up the right manufacturing process with a given set of ingredients, to achieve the right product characteristics presents as a challenge to the process engineer. For example, the non-Newtonian rheology varies not only with CPPs and CMAs but also is an implicit function of globule size (CQA). Hence, this calls for various mechanistic models, to help predict the product behaviour. This paper focusses on such models obtained from computational fluid dynamics (CFD) coupled with population balance modelling (PBM) and constitutive models (like shear, energy density). In a special case of the use of high shear homogenisers (HSHs) for the manufacture of thick emulsions/gels, this work presents some findings on (i) scale-up algorithm for HSH using shear strain, a novel scale-up parameter for estimating mixing parameters, (ii) non-linear relationship between viscosity and shear imparted into the system, (iii) effect of hold time on rheology of product. Specific examples of how this approach enabled scale-up across 1L, 10L, 200L, 500L and 1000L scales will be discussed.

Keywords : computational fluid dynamics, morphology, quality-by-design, rheology
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