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Orodispersible films: product transfer from lab-scale to continuous manufacturing

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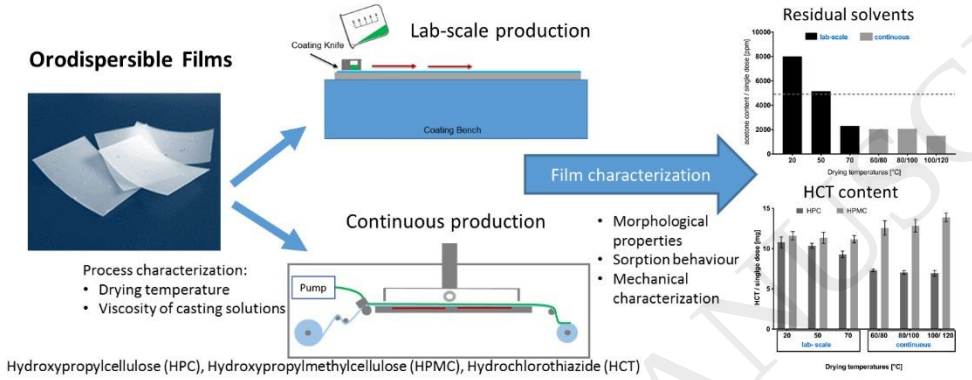
Graphical abstract



Abstract

Orodispersible films have been described as new beneficial dosage forms for special patient populations. Due to various production settings, different requirements on film formulations are required for non-continuous and continuous manufacturing. In this study, a continuous coating machine was qualified in regards of the process conditions for film compositions and their effects on the formed films. To investigate differences between both manufacturing processes, various film formulations of hydrochlorothiazide and hydroxypropylcellulose (HPC) or hydroxypropylmethycellulose (HPMC) as film formers were produced and the resulting films were characterized.

The qualification of the continuously operating coating machine reveals no uniform heat distribution during drying. Coating solutions for continuous manufacturing should provide at least a dynamic viscosity of 1 Pa*s (wet film thickness of 500 µm, velocity of 15.9 cm/min). HPC films contain higher residuals of ethanol or acetone in bench-scale than in continuous production mode. Continuous production lead to lower drug content of the films. All continuously produced films disintegrate within less than 30 s. There are observed significant effects of the production process on the film characteristics. When transferring film manufacturing from lab-scale to continuous mode, film compositions, processing conditions and suitable characterization methods have to be carefully selected and adopted.