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Mini-tablets with Personalized Dissolution, Prepared by Fluid-Bed Granulation of Drug Nanosuspensions

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Transforming poorly soluble active pharmaceutical ingredients (APIs) into nanoparticulate form is a well-established and effective strategy for enhancing their dissolution characteristics. Among the various methods available, wet-stirred media milling has emerged as a reliable and widely adopted technique for the preparation of API nanosuspensions. However, a significant challenge remains: converting these nanosuspensions into solid oral dosage forms without compromising their key properties, particularly their ability to re-disperse into fine particles upon administration.

In this study, a crude API was converted into a nanosuspension, which was then used in fluid-bed granulation to produce granules with adjustable dissolution properties. Polymeric binders, including hydroxypropyl methylcellulose (HPMC E5) and polyvinylpyrrolidone (PVP K30), were incorporated into the nanosuspension to aid granulation onto microcrystalline cellulose (MCC) or Pearlitol® CR-H substrates, which modulated the drug release rate.

The granules were subsequently compressed into minitablets, serving as modular building blocks for multi-unit dosage form (MUDF) capsules. By combining minitablets with varying dissolution profiles, it was possible to tailor drug release behavior, offering a simple yet powerful approach for personalized therapy.

This strategy not only provides flexibility in customizing dissolution kinetics but also supports the concept of precision medicine, where individualized therapy can be achieved by adjusting the combination of minitablets. The use of fluid-bed granulation with nanosuspension binders thus presents a scalable and adaptable platform for the manufacturing of personalized dosage forms.