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Precision 3D Printing Method for Customizable Pharmaceutical Mini-Tablets

A novel drop-on-demand 3D printing method produces customizable mini-tablets with precise dosing and controlled release profiles, solving challenges in personalized pharmaceutical manufacturing, especially for low-dose patient groups.

Traditional manufacturing methods struggle to offer personalized dosages, often following a 'one-dose-fits-all' model which does not suit specific patient groups like children, the elderly, and individuals with unique metabolic or organ functions. The industry's challenge is further compounded in pediatric medication (comprising less than 10% of the overall drug market share). Pediatric patients require flexible, low-dose, and palatable medications due to their distinct physiological responses. Traditional delivery solutions, such as crushed tablets or liquid medicines, are fraught with issues like altered dissolution rates, and dosing inaccuracies, and limited active pharmaceutical ingredient (API) stability respectively. Mini-tablets, which are small-form dosages, have been proposed as a solution. Their production however is hindered by the challenges of direct compression and the temperature-sensitive nature of hot melt extrusion.

Researchers at Purdue have developed a new method for manufacturing mini-tablets that ensures precise doses, content uniformity, and the controllable dissolution behavior. The method uses a drop-on-demand (DoD) three-dimensional (3D) printing system that consists of preparing a drug formulation by mixing an active pharmaceutical ingredient (API) with one or more excipients. The formulation can then be used to obtain either a melt-based suspension or solution, which can then be printed as droplets via the DoD printing system. Each droplet is solidified in an inert solvent bath, and isolated as ready-to-use drug product after washing and drying. This developed method allows for the production of mini-tablets with high content uniformity and customizable release profiles, which meets regulatory requirements on these metrics.

Technology Validation:

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Category
Pharmaceuticals/Drug Discovery & Development
Pharmaceuticals/Pharmaceutical Packaging & Delivery Systems
Pharmaceuticals/Computational Drug Delivery & Nanomedicine
Pharmaceuticals/Drug Delivery & Formulations
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- Mini-tablets comprising of different types of polyethylene glycols (polypropyleneglycols, kolliphorÂ® D-Î±-tocopherol polyethylene glycol succinate (TPGS), gelucireÂ® 44/14, food oil) were developed

- Various formulations of the mini-tablets to ensure uniformity in the distribution of the active pharmaceutical ingredient (API) within each tablet

- Dissolution profiles of the mini-tablets were tested, which determined how quickly and completely the mini-tablets released their medication when exposed to an appropriate solvent

- Ultra-pressure liquid chromatography (UPLC) was used to confirm the amount of API present in each mini-tablet

Advantages:

- Personalized, customizable dosages of mini-tablets

- High degree of uniformity in the active pharmaceutical ingredient (API)

- Customized release profiles, such as fast-release or extended-release

Applications:

- Pharmaceutical tablets

Related Publications:

1. Sundarkumar, V., Wang, W., Nagy, Z., & Reklaitis, G. (2023). Manufacturing pharmaceutical mini-tablets for pediatric patients using drop-on-demand printing. International Journal of Pharmaceutics, 644, 123355.

2. Sundarkumar, V., Wang, W., Mills, M., Oh, S. W., Nagy, Z., & Reklaitis, G. (2023). Developing a Modular Continuous Drug Product Manufacturing System with Real Time Quality Assurance for Producing Pharmaceutical Mini-Tablets. Journal of Pharmaceutical Sciences.

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