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Development of a novel direct compressible co-processed excipient and its application for formulation of Mirtazapine orally disintegrating tablets

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Abstract
Introduction: Orally disintegrating tablets (ODTs) are designed to dissolve in the oral cavity within 3 min, providing a convenient option for patients as they can be taken without water. Direct compression is the most common method used for ODTs formulations. However, the availability of single composite excipients with desirable characteristics such as good compressibility, fast disintegration, and a good mouthfeel suitable for direct compression is limited. Objective: This research was proposed to develop a co-processed excipient composed of xylitol, mannitol, and microcrystalline cellulose for the formulation of ODTs. Methods: A total of 11 formulations of co-processed excipients with different ratios of ingredients were prepared, which were then compressed into ODTs, and their characteristics were thoroughly examined. The primary focus was on evaluating the disintegration time and hardness of the tablets, as these factors are important in ensuring the ODTs meet the desired criteria. The model drug, Mirtazapine was then incorporated into the chosen optimized formulation. Results: The results showed that the formulation comprised of 10% xylitol, 10% mannitol and 80% microcrystalline cellulose demonstrated the fastest disintegration time (1.77 ± 0.119 min) and sufficient hardness (3.521 ± 0.143 kg) compared to the other formulations. Furthermore, the drug was uniformly distributed within the tablets and fully released within 15 min. Conclusion: Therefore, the developed co-processed excipients show great potential in enhancing the functionalities of ODTs, offering a promising solution to improve the overall performance and usability of ODTs in various therapeutic applications. © 2023 Informa UK Limited, trading as Taylor & Francis Group.

Author Keywords
co-processed excipients; direct compression; formulation; Mirtazapine; Orally disintegrating tablets

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