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Title:THz spectroscopy: An emerging technology for pharmaceutical development and pharmaceutical Process Analytical Technology (PAT) applications

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Abstract:As an emerging technology, THz spectroscopy has gained increasing attention in the pharmaceutical area during the last decade. This attention is due to the fact that (1) it provides a promising alternative approach for in-depth understanding of both intermolecular interaction among pharmaceutical molecules and pharmaceutical product quality attributes; (2) it provides a promising alternative approach for enhanced process understanding of certain pharmaceutical manufacturing processes; and (3) the FDA pharmaceutical quality initiatives, most noticeably, the Process Analytical Technology (PAT) initiative. In this work, the current status and progress made so far on using THz spectroscopy for pharmaceutical development and pharmaceutical PAT applications are reviewed. In the spirit of demonstrating the utility of first principles modeling approach for addressing model validation challenge and reducing unnecessary model validation "burden" for facilitating THz pharmaceutical PAT applications, two scientific case studies based on published THz spectroscopy measurement results are created and discussed. Furthermore, other technical challenges and opportunities associated with adapting THz spectroscopy as a pharmaceutical PAT tool are highlighted. Published by Elsevier B.V.

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