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Investigation on the heat change during the disintegration process of pharmaceutical tablets

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The disintegration process of pharmaceutical solid dosage forms refers to a mechanical break-up of an intact tablet into smaller fragments to enhance the drug substance's contact with the dissolution medium. This process is particularly critical for immediate-release dosage forms to ensure the end product's bioavailability and efficacy. Despite the significance of disintegration, the assessment methods specified by the regulators provide little scientific insight into the mechanisms of the process. This lack of insight is not surprising as the methods are very simple. However, tablet disintegration is a highly complex process due to the wide range of particle types being used, each exhibiting their own time dependence in swelling and dissolution behaviour and the impact of processes such as granulation or direct compaction. Previous studies have therefore focused on the micro-structure of the tablets by considering factors such as porosity, pore size distribution, pore connectivity, tortuosity, permeability, hydrophilicity, and so on for different pharmaceutical excipients and manufacturing conditions, but the mechanistic link to disintegration is not fully established yet [1].

In this study, we investigated the tablet's wetting process from a thermodynamic point of view by monitoring the temperature change of 1 ml of distilled water in which a sample tablet was immersed. In 1959 Claxton reported the observation of a temperature rise during spontaneous imbibition of a porous medium, which was explained by a decrease of free energy in the system [2]. Claxton's experiment, and subsequent studies, focused on the temporal and spatial evolution of released heat at the liquid front. Instead, we measured the total heat released during the wetting process as a function of time using an adiabatic chamber. As a result, we obtained different profiles of how temperature changes as a function of porosity in tablets of the same formulation. Measuring the temperature change of the dissolution medium showed potential as a novel approach to quantifying the hydrophilicity of complex compounds and estimating the liquid penetration into the porous media by analysing the correlation between the amount of heat released and the properties of the media.

Participation

In-Person

References

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[2] Claxton, G., 1959. Detector for liquid-solid chromatography. Journal of Chromatography A, 2, pp.136-139.

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