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Project Title: Microwave-based Fluid Bed Drying
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Problem Statement: Current drying technologies being implemented for continuous solid dose manufacturing systems using conventional heated air drying do not operate on the same time scale (fractions of an hour or more) as other unit operations within the overall process (minutes or less). Drying using conventional methods is inherently slow due to its reliance on diffusion, which leads to characteristic response times that are not ideally suited for control of continuous manufacturing processes. Microwave drying presents an interesting alternative to traditional methods due to the speed in which the material can be heated. This occurs because conventional drying heats the material from the outside whereas microwave energy heats the entire volume of material. Microwave drying is not new though, and has been utilized in industries outside of pharma for similar materials. In pharma, this technology may never have been fully explored for solid dose manufacturing applications because of the fear of product degradation. Today, while this concern may still remain, the process can be monitored and controlled much more tightly PAT and feedback control.

Objectives: Demonstrate the feasibility of utilizing microwave based drying modifications to traditional fluid bed drying unit operations that allows for drying times that more closely match the timescales of the other unit operations within a typical solid dose process.

Methods and Materials: A commercially available fluid bed dryer will be mounted with variable power magnetrons. The fluid bed dryer air will be used to aid in the transport of moisture from the particles, but the heating will be disabled. Granulated compounds with well-known thermal properties and degradation products, including common pharmaceutical polymeric binders, will be chosen so that these aspects can be explored. DoEs will be performed on a range of selected materials to explore the effects of microwave intensity, duration, air-flow, and mass loading. Process temperature will be initially a dependent variable to be monitored, but may be added into future studies. A combination of Raman and Infra-red spectroscopy will be used offline to determine if any degradation products arise from any of the experimental points. Both types of spectroscopy will be used due to the fact that additional sensitivity will be available with Infra-red, but it would not be suitable for a PAT application. Looking ahead though, Raman will be ideal for future in-process control.

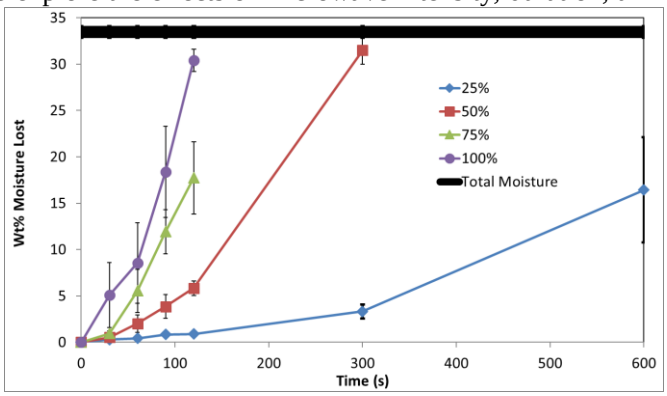

Figure of preliminary static microwave drying results of APAP-Lactose-PVC granules at 25-100% of 1250kW

Anticipated Impact: This research will facilitate the development of continuous wet granulation processes with more efficient control strategies, ideally taking the response time from on the scale of 30 minutes to less than 5 minutes. This is a proof of concept demonstration that will hopefully lead to the development of a partnership to develop a commercial implementation of the technology.

- Reduced granulation drying times
- Greater process control
- Reduced energy consumption