UNIVERSITY OF LIMERICK OLLSCOIL LUIMNIGH | Technology Transfer Office

Licensing Opportunity

Continuous Drying of Active Pharmaceutical Ingredients using a Twin Screw Extruder

Overview

Drying crystalline/amorphous active pharmaceutical ingredients (API) is an important operation to produce consistent, stable, free-flowing materials for formulation, packaging, storage and transport. Various types of driers are being currently used by the pharmaceutical industry to dry API material, including vacuum tray driers, fluid bed driers, spray driers and belt driers.

The tray and belt drier technologies, although being relatively simple and reliable, suffer from the space and efficiency limitations; also, operation and cleaning are labour intensive. A common problem of these technologies is that solvent wicking can cause a crust to form on the cake, such that the product often requires milling, screening, blending or other post-drying treatment to ensure homogeneity. On the other hand, the fluid bed driers and spray driers, although allowing overcoming some of the limitations mentioned, are complex and difficult for scaling up; also require a high capital investment and highly specialized workforce.

Technology

The capability of using a twin screw extruder for drying active pharmaceutical ingredients was demonstrated by Gursh and co-workers [1]. However, in their proposed drying technology a combination of a preheated drying gas and a set of heating elements was used. Also, the authors tried various combinations of kneading elements in screw configurations and vacuum pressure aiming to increase drying efficiency. Despite the complex design employed, even for the most optimum set of parameters the drying efficiency was not satisfactory, giving the residual moisture in ibuprofen of 14%. In contrast, our drying technology is much simpler, as it involves only heating elements (no drying gas is used). Also, our process is caried out at ambient pressure (no vacuum pressure employed) and we use conveying elements (the simplest screw configuration) (please refer to Figure 1 for details). When employing our approach, we found that the drying efficiency of a model material (paracetamol/ethanol mixture) is between 98.8% - 100%, thus the residual moisture is between 0% -1.2% (Figure 2).

[1] J. Gursh, R. Hohl, M. E. Armenante et al., Org. Process Res. Dev. 2015, 19, 2055-2066

Benefits

This invention will use the capability of drying (heating) in the twin screw extruder (TSE) barrel to immediately/continuously dry the crystalline/amorphous API material to simultaneously control required moisture content and particle size distribution. This invention will:

- Combine two unit operations (drying and size-enlargement (granulation) of API material) into one system to facilitate continuous pharmaceutical processing
- Solve any agglomeration issues of the dried API material and produce a more uniform particles/granules having a narrow particle size distribution
- Provide the higher yield of drying, as compared to currently used driers, due to the relatively low internal surface of the twin screw extruder and thus less hang-up of the dried material inside the drying chamber
- Mitigate risks associated with handling toxic and/or explosive materials as only a relatively small quantity of API (few hundreds of grams at an industrial scale) will reside in a barrel at a time
- Be relatively easy for scaling-up
- Facilitate the use of PAT tools to monitor the PSD more efficiently
- Ease of implementation of model predictive control
- Decrease material handling
- Decrease energy costs, i.e., direct heating in the extruder is less energy intensive than convective drying in a separate unit operation

Applications

For use in the continuous manufacture of crystalline/amorphous active pharmaceutical ingredients (API).

Commercial Opportunity

The University of Limerick is seeking partners to exploit the commercial potential of these technologies by entering into licensing agreements.

☐Development partner

☐Commercial partner

☒Licensing

☒University spin-out

☐Seeking investment

Patent Filings:

EPO:

"Method and Apparatus", Publication EP3746055 A1

US:

"Method and Apparatus", Patent Application: US201916965828A

Contact

Margaret Lawlor

Technology Transfer Office

University of Limerick

email:

margaret.lawlor@ul.ie

Figures

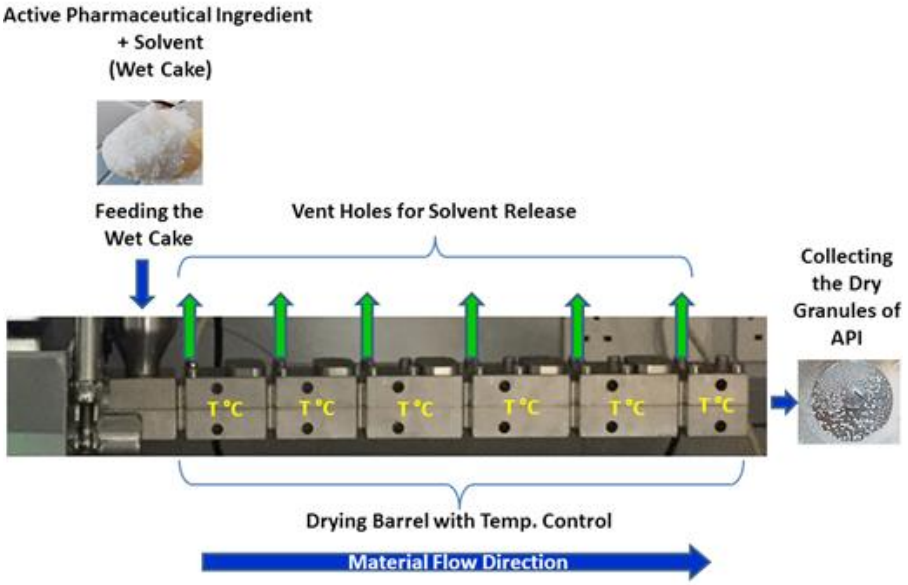

Figure 1. The experimental setup for continuous drying/granulating of active pharmaceutical ingredients in twin screw extruder.

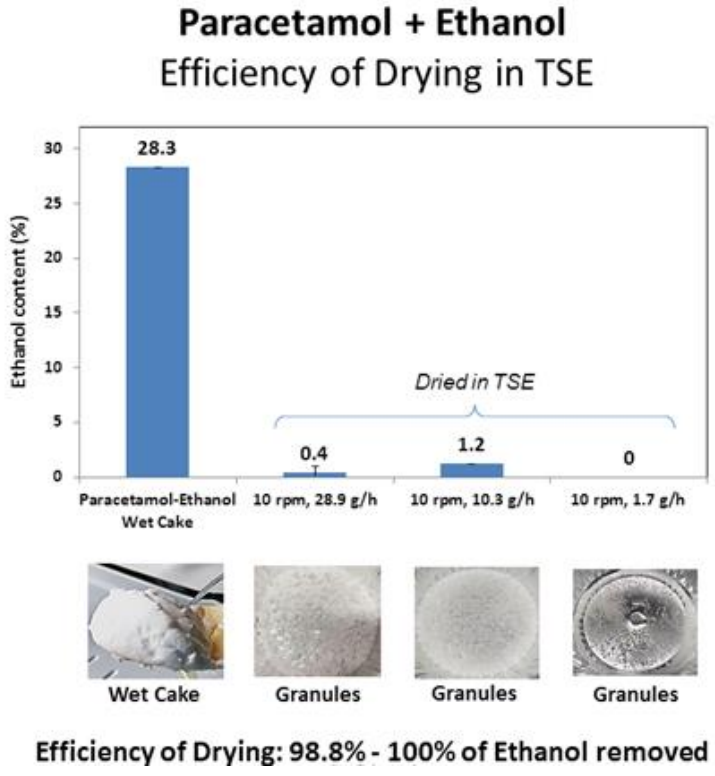

Figure 2. Efficiency of drying in twin screw extruder of paracetamol-ethanol “wet cake” containing initially 28.3 wt% of ethanol.