

## Case Study 4: Pharmaceutical Processing

### Case study host:

Industrias Farmacéuticas Almirall, S.A., Sant Andreu de la Barca, Spain

### Case study leader:

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### Case study team:

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### Brief description of process unit(s) of interest for intensification and motivation:

The Almirall case study, CS4.2, concerns drying of a wet granulated material including a binder solution (purified water + povidone), that is currently dried in a multi-stage vibrating fluid bed dryer (Heinen).

The large production volume and energy use from this part of the process are most promising for further optimization and have ample opportunities to benefit from intensification.

### Brief description of PI technology chosen:

In order to minimize energy use and keep residence time within limits, a very suitable option was the spiral flash dryer (SFD). This technology acts as a dryer and separator at the same time, keeping wet particles still inside the dryer whereas dried particles are separated. The use of drying air is minimal, and the equipment size can be reduced, bringing further cost reduction.

### Brief summary of results:

As for the implementation of the concept into the existing process, from an industrial perspective, the comparison of the existing HEINEN dryer and the SFD pilot dryer are summarized as follows:

Current process (HEINEN DRYER).	Differences detected with new TORBED machine.
Inlet air supply and blow air supply.	No critical changes compared to the current equipment
Dryer machine Size.	Considerable reduction in the size of the equipment.
Cylindrical Outlet filters.	The design of the filtration system by means of cyclones and filters increases significantly the size of the equipment layout. This topic introduces a critical point to discuss.

Indeed, the SFD provides a significantly smaller equipment size, but the filtration system becomes larger and this largely defeats the purpose of the SFD, while the particle properties have different characteristics as measured (flow properties, granule size), as mentioned above. Also, there is no

cleaning in place system according to the pharmaceutical standards and, moreover, setting up a new drying equipment comes with its own costs, such as variation in the Marketing Authorization Application and risks of losing years of experience with the current drying system; the Almagate product has production requirements and the risk of having less control over the process does not outweigh the potential benefits. These reasons alone already make it hard to justify an implementation of the SFD in the existing process.

Moreover, prior to additional processing, granule characterisation using the FT4 Powder Rheometer<sup>®</sup> demonstrated clear differences between samples of Almagate dried using the Heinen and TorBed dryers. Therefore, this analysis indicated that the use of different dryers had a measurable impact on the rheological properties of the Almagate granulate directly out of the dryer.

The technology is considered as a suitable technique for drying of powders and provides a novel route compared to classical drying equipment for granulate drying processes in general. Almirall has stated that, if a process would have to be designed from scratch for a new product, the SFD would be taken into consideration again.

**Final conclusions from case-study:**

IMPROVEMENT	Status	Effect
Reduction in the amount of water	Verified	Reduction in cost and time
Increase specification for water content in final granulate	Verified	Reduction in cost and time
Use the hot air from the dryer to heat the air blown in.	Implemented	Reduction in cost and time
Eliminate the drying stage	Planned	To be studied

In order to assess the saving, the energy consumption has to be related to the kg of product produced per hour. As the processing time for one complete granulate batch is one half that of the Heinen unit using the spiral flash dryer, the energy consumption will be reduced by 50% per dried kg.

The SFD drying concept should be considered for drying of granular materials for novel processes, not for replacement of existing processes. The control procedures may then be adequately adapted to the new process. Especially when a constant inlet quality is expected, the SFD concept may pay off due to the lower overall energy consumption. However, it should be taken into consideration that pilot trials are still required before implementation in industrial processes. Nevertheless, the comparison of the Target Goals with the SFD performance achieved, summarised in the Table below, is highly encouraging.

TARGET GOALS	SFD PERFORMANCE
Higher process capacity	Achieved
Improved quality and Robustness	Quality acceptable; robustness improvable
Reduce occupied area	40% area reduction achieved
Less analytical workload and lead time	Lead time reduced
Reduction in cost	Energy consumption reduced

**TRL of PI Technology:**

The spiral flash dryer can now be considered TRL 6-7 for drying of wet granulate.

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