

“Shield 10” Granulation Suite

With pharmaceutical fraternity innovating new chemical entities (NCEs); safety standards for oral solid dosages (OSDs) have come in intense focus. Keeping up with needs to deliver solution Tapasya introduces SHIELD-10 with synergy of latest technology – a suit with tolerance for 10 bar explosion and through the wall designed close loop containment manufacturing.

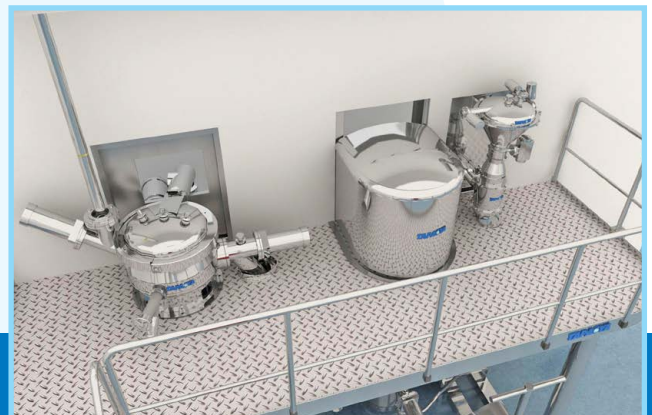
Need in Previous Design:

A. Safety for integrated granulation and drying suites

- Safety of integrated systems with respect to pressure enhancement is not confirmed by the conventional design as the line has been designed for low pressure tolerance i.e. approximately 2 Bar
- The creation of static charges or the use of organic solvent in the process may lead to explosion
- The explosion leads to increase in pressure in the processing area or closed loop of machine, if the machine design is not according to capacity of pressure tolerance, the explosion may affect the user or the nearby area
- It leads to major accident in processing area
- The main objective of the integrated granulation and drying suites is the safety of the operator and the area
- Contamination of the product due to conventional granulation suites is also one of the factor which induces need/ challenges for innovation of this technology

B. Safety and the environment

- The exposure of oncology products to the environment leads to its adverse effects on human being as well as to the environment
- The main risk of material escaping into the environment exists whenever a connection between those pieces of equipment needs to be made or broken, when a sample needs to be taken, and last, but not least, when the machines need to be cleaned after the end of a manufacturing campaign



Key Features:

A. Improved safety for integrated granulation and drying suites

- Extensive safety confirms pressure enhancement effects and identifies safe design limits for integrated systems
- This research has shown conclusively that if an explosion occurs during the transfer operation in an integrated system where a granulator is connected directly to a fluid bed dryer without an explosion isolation valve, the secondary explosion pressures in the granulator can be significantly higher than in the fluid bed

B. Safety when using organic solvents

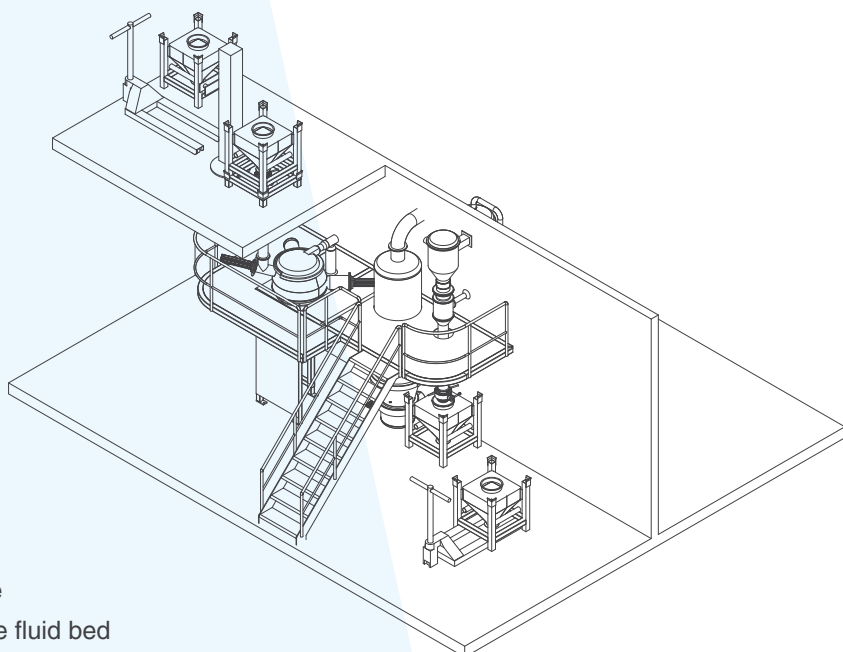
- Explosion pressure in the granulator is dependent on the volumes of the two vessels and that the length and diameter of the interconnecting duct is critical in ensuring that the pressure remains within safe limits

C. Safety and the environment

- Full compliance with national, local and in-house regulations, 10 Bar Systems offers a range of emission control options including solvent recovery systems, outlet filters and full containment plants
- Equipment can be supplied to meet explosion-proof and pressure shock standards as required

D. Integrated granulation and Drying suites:

- Special integrated system for sampling of the product during formulation of oral solid dosage form has been introduced
- Special provisions for cleaning operation have been introduced



Quantitative Results:

- Improved safety for integrated granulation and drying suites
- Safety when using organic solvents
- Safety to the user as well as environment
- Integrated granulation and Drying suites (Containment)

