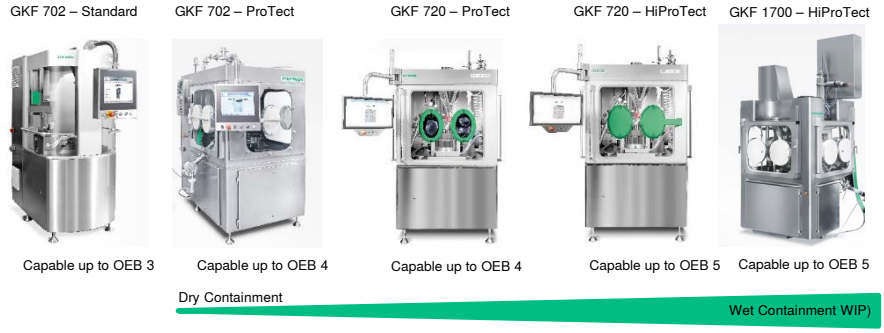
PHARMA SOLID KNOWLEDGE REPORT

SYNTEGON
PROCESSING & PACKAGING

Containment Interfaces and Peripheral Equipment.

Containment in the pharmaceutical industry has to protect the health of employees and to protect the pharmaceutical product processed in the enclosed machine or plant against external contamination. The number of high potent active pharmaceutical ingredients, as well as the legal requirements, have been growing in the past years, therefore the need for contained solutions is increasing. A system is as good as the weakest link – means the peripheral equipment units, the mechanical connections with these units, as well as the control of the entire system needs to be considered thoroughly together.

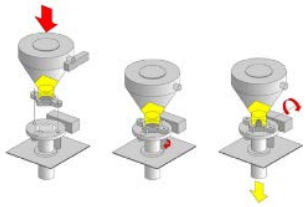
Machine Design



Infeeds

Capsule feeder

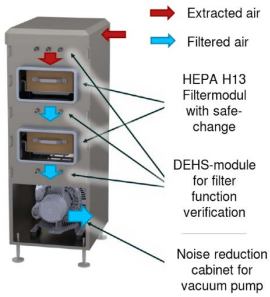
- Exhaust air is connected to the central air exhaust system
- Transfer of capsule by positive air pressure impulse from the feeder to the GKF => avoiding particle contamination of the feeder
- Static sealing



- Product container lift with active/passive valve

Filter units for vacuum pump and air exhaust system

- Integration with automatic mode in the system
- H13 and H14 combination with filter control system
- Bag-In/Bag-out system
- Pressure control and filter monitoring



Capsule deduster with metal check and KKE checkweigher

- Negative pressure inside the capsule deduster with HEPA air inlet filter
- WIP (execution for automatic wash down) or WOL (wash offline for dry containment) for capsule deduster
- Dust tight execution of 100% capsule checkweigher
- Closed system for containment protection with endless liner for rejected capsules and closed capsule transfer to upstream equipment
- Exhaust air to be connected to the central air exhaust system

Containment Interfaces and Peripheral Equipment

Wetting and Washing-in-Place

- Combined cleaning process with wetting and washing procedure via glove parts
- In-house WIP-center for automated cleaning process
- Alternative to WIP center, simple cleaning liquid tank with overpressure to wash the machine with manual input
- Waste water will be collected in independent water tank

SMEPAC-Test

- The main purpose of the SMEPAC test is to prove that the complete containment system with all units and chambers reduces the presence of potentially hazardous particles in the air during work processes
- Limits are defined in the ISPE Good Practice Guide - Assessing the Particulate Containment Performance of Pharmaceutical Equipment
- Typical test material are sodium naproxen and lactose
- Recommended or reasonably defined places for sampling, sampling pumps and special sampling heads with test filter
- Analysis in accredited laboratory
- Syntegon offer a full on-site service together with subsidiaries like Valicare and partners

Conclusion

- Peripheral equipment from capsule and product feeding system to deduster and WIP skids can easily be integrated in a full contained capsule fillling system for automated mode operation
- Control of entire system centralized on / from the GKF capsule filler
- Different containment classes and requirements from dry to wet cleaning are available
- Customer standards could be considered selecting peripheral equipment
- Full qualification and validation package is available

Your need is our passion!

You also have processes for optimization?
Please contact us. Our "Engineering Pharmaceutical Service" team will be available with all our experience of over 50 years:

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