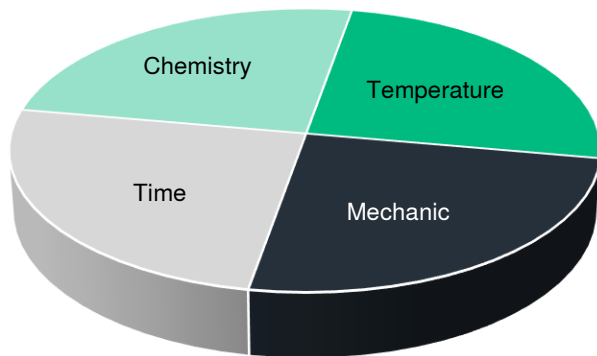


Cleaning of Capsule Filling Machine (GKF)

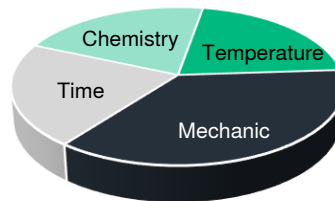
Introduction - why do we have to clean?

Cleaning is an essential part of the pharmaceutical manufacturing process. Not only to fulfill the requirements of guidelines, authorities and auditors, but also to avoid cross-contamination. This means to avoid risks for the following manufacturing process (e.g. safety, process stability, etc.) and, in consequence, to **avoid any risk for the patient**.

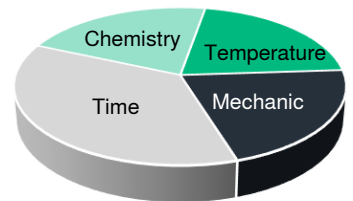
Sinner circle – the decisive role of four factors



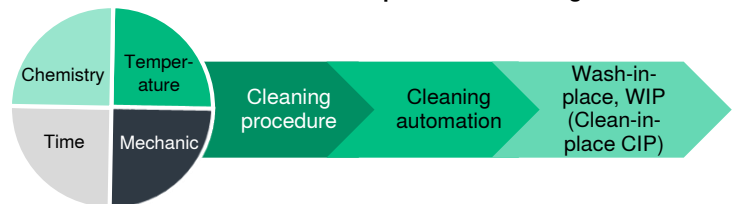
Manual cleaning by “hand”



Automated washing process



3D-Sinner circle – process controlling



Cleaning is influenced by

- ❑ Product (API) and formulation (excipients)
- ❑ Cleaning detergents (+ sanitation, if needed)
- ❑ Cleaning procedure
- ❑ Equipment for cleaning (suction hose, spray gun, brushes, wipes, etc.)

Polymers

- ❑ PEEK, PE-UHMW, PTFE, PVDF, PC preferred for critical components / components which remain in machine during cleaning
- ❑ EPDM, PUR and VQM silicon preferred for less critical components / components, which are dismantled during cleaning
- ❑ Polymers with high stability against cleaning detergents used

Metals

Aluminum:

- ❑ Low in weight, but soft material, coating recommended
- ❑ Different sensitivities against detergents, other than stainless steel
- ❑ Sensitive for scratches, which are difficult to clean

Stainless Steel:

- ❑ Robust parts, high in weight, more costly
- ❑ 316L preferred for product contacting parts

General

- ❑ Machine vendor to provide samples to test the suitability of detergents
- ❑ Material combinations within one part / parts group to be avoided
- ❑ Temperature effect to be considered for all media (incl. drying air) as well as in combination with time effect (temp over time)

	Manual Cleaning off Place	Wetting	WIP (Washing-in-Place)
Definition	Entire manual cleaning (machine in place, parts in separate washing area)	Spraying of water to bind airborne particles, afterwards COP is required	Automated cleaning with some manual steps (e.g. drying or secondary cleaning)
Suitable for OEB	All	All	All
Temperature	10 – 40 °C	10 – 90 °C	10 – 90 °C
Detergent	4-9 pH	4-9 pH	1-13 pH (stainless steel)
Investment (cost & effort)	[Progressive bar chart showing increasing investment from Manual to WIP]		
Running costs	[Progressive bar chart showing increasing running costs from Manual to WIP]		
Water/air demand	[Progressive bar chart showing increasing water/air demand from Manual to WIP]		
Time for cleaning	[Progressive bar chart showing increasing time for cleaning from Manual to WIP]		
Cleaning validation effort	[Progressive bar chart showing increasing validation effort from Manual to WIP]		
Operator safety	[Progressive bar chart showing increasing operator safety from Manual to WIP]		
Use case	Universal	Universal	High potent / toxic API

Cleaning and Machine Design

GKF 702 – Standard



Capable up to OEB 3

GKF 702 – ProTect



Capable up to OEB 4

GKF 720 – ProTect



Capable up to OEB 4

GKF 720 – HiProTect



Capable up to OEB 5

GKF 1700 – HiProTect



Capable up to OEB 5

Dry Containment

Wet Containment

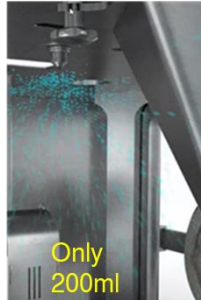
Dismantle and external manual washing and cleaning



Vacuum hose for manual suction



Wetting with integrated spray ball



Spray gun for manual pre-cleaning



Servo driven ring system with three cleaning arms



Conclusion

- Cleaning is a complex process that requires a high degree of pharmacological, chemical and process engineering knowhow
- Alternative and customized cleaning solutions from manual cleaning, wetting and pre-cleaning to automated wash-in-place
- Already in the development phase of capsule filling machines (as well as tablet presses) Syntegon does consider the prevention of product loss, contamination and best accessibility (incl. weight and number of parts and cleanability of parts and materials)
- Our engineering and process expertise complements your pharmaceutical knowledge and requirements and leads to economical, ecological and validatable cleaning solutions

Please contact us!

Cleaning is an essential part of production. Do you have cleaning 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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