

GKF Powder Microdosing Technology

BACKGROUND

Market trends towards smaller batches, higher value products and on-line quality inspection require production solutions that ensure stable, monitored processes to achieve high dosing accuracy, high yield and high OEE. GKF powder micro-dosing technology covers these needs – read more:

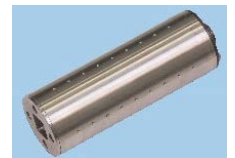
GKF POWDER MICRODOSING TECHNOLOGY

The GKF vacuum dosing wheel is a volumetric dosing system designed for highly precise dosing of small powder quantities e.g. for dry powder inhalation products or low volumes of highly active pharmaceutical ingredients. The GKF powder micro-dosing system covers a filling range from appr. 1 - 30 mg, allowing single and multiple dosages with an output of up to 156.000 caps. per hour (GKF2600). Depending on the powder characteristics, different stirrer types, geometries and customized solutions are available. With an integrated product hopper containing appr. 5kg of product, most batches can be handled without peripheral powder dosing equipment. An accurately controlled homogeneous powder bed height supports an excellent dosing accuracy.



GKF VACCUM DOSING WHEEL

In addition to the fixed dosing wheel, the patented adjustable dosing wheel allows a fast and easy adjustment of the fill range (up to 60%) without dismantling any parts. Due to the low number of format parts, a fast and simple changeover is possible. Further, the newly developed fixed vacuum dosing wheel with moving filter allows for a filter change with the wheel in working position and without emptying the product hopper. This results in considerable time and product savings.



INTEGRATED IN-PROCESS CONTROL (IPC)

The integrated IPC takes weight samples using a highly precise integrated lab scale (weighing repeatability of 50 µg) at both the start of a batch and during the batch to calibrate the NWDS indirect quality inspection system (electromagnetic field sensor). In operation, the IPC checks the weight of each empty capsule in an entire segment. After dosing, the same capsules are weighed again. The result is the accurate weight of each capsule. With these results the NWDS is calibrated before starting the batch and checked every 6 minutes throughout the entire batch. This allows a high process reliability, an automated process regulation (vacuum) as well as a recurring adjustment of the net weight detection system.



100% PROCESS MONITORING BY NET WEIGHT DETECTION SYSTEM (NWDS)

The 100% process monitoring by the NWDS (electromagnetic field sensor) ensures a reliable dosing weight detection and rejection of faulty products. All individual weight values are stored in the GKF batch report. Depending on the powder characteristics, the capacitive NWDS sensor has an accuracy of 1 - 3% RSD. A specially developed cleaning system for the NWDS sensor as well as different sleeve materials of the NWDS measuring channels ensure a stable process throughout the entire batch. The completely automated adjustment procedure of the NWDS sensor via the IPC provides an accurate and time-saving process from batch set-up to end of batch.

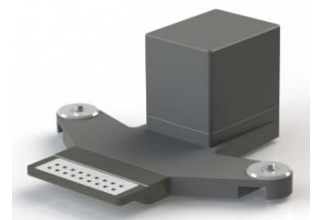
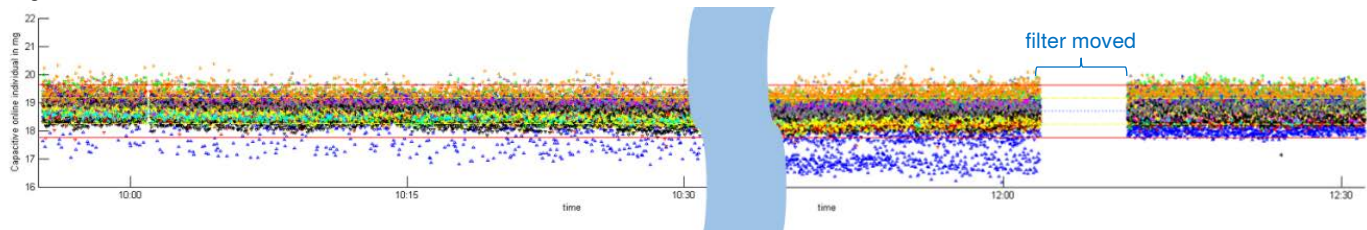


Fig. 1: NWDS online data for Inhalation Formulation



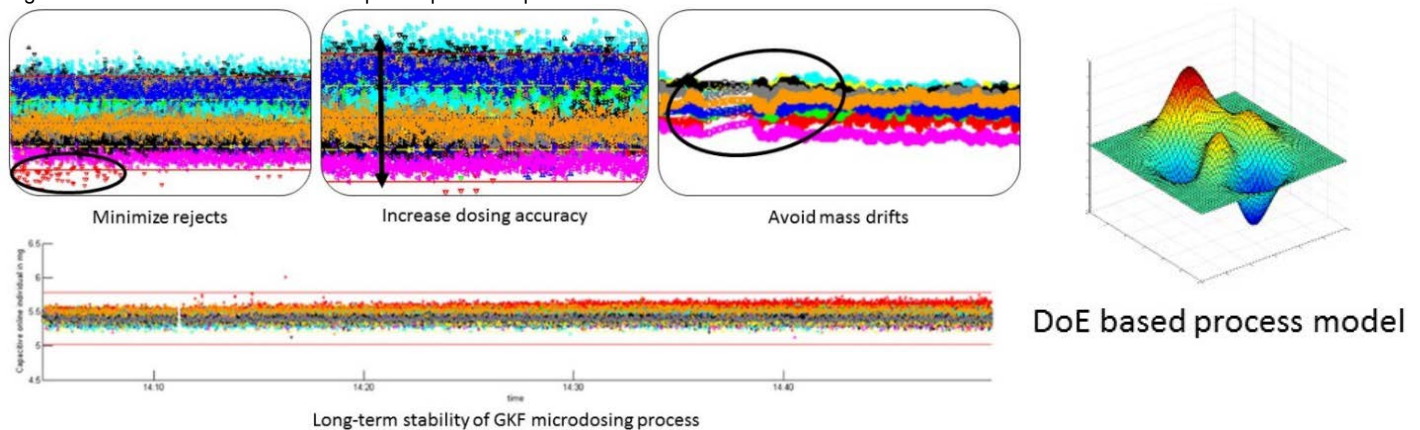
COMPREHENSIVE PROCESS DEVELOPMENT AND OPTIMIZATION

The GKF vacuum dosing wheel principle allows an accurate dosing of powders with differing properties (e.g. particle size, particle size distribution, powder flowability). Due to the complex interactions of powder, equipment and process parameters, process development requires a high level of sophistication. Based on a Design of Experiments (DoE) approach, the optimum parameter combination for a given powder and the dependencies of critical process parameters (CPP's) on the fill weight and dosing accuracy become transparent. In consequence, some GKF product contact parts (e.g. the powder stirrer geometry), as well as the process parameters (vacuum, transfer pressure and powder bed height) will be set in a manner to achieve higher uniformity of product, higher accuracy in weight, higher overall efficiency and an increased yield.

Your product is our focus. Our solutions for all your filling needs.

	Lactopress® Anhydrous Powder (DFE Pharma)	Inhalation Formulation	Respirose® ML001 (DFE Pharma)
Powder description	milled and sieved anhydrous grade lactose	inhalation formulation with narrow particle size distribution	milled inhalation grade lactose with wide particle size distribution
Particle size	x10 = 4 µm; x50 = 30 µm; x90 = 93 µm	x10 = 4 µm; x50 = 56 µm; x90 = 92 µm	x10 = 5 µm; x50 = 49 µm; x90 = 168 µm
Carr's Index	35% (very poor flow property)	32% (very poor flow property)	27% (poor flow property)
Theoretical output	108,000 capsules/hour	108,000 capsules/hour	54,000 capsules/hour
RSD	1,64%	2,22%	1,92%
Concentration of good capsules	98,5% (~ 450.000 produced capsules)	96,9% (~ 900.000 produced capsules)	98,1% (~ 450.000 produced capsules)
OEE performance factor	95% (4h trial)	92% (8h trial)	94% (8h trial)
Powder description	0,0	0,1	0,1

Fig. 2: NWDS online data as an example for process optimization



Conclusion

- The GKF powder micro-dosing system is well suited for the filling of low powder amounts leading to filling accuracies of less than 3% RSD, depending on the powder characteristics.
- In combination with the integrated IPC and the 100% net weight detection system, the micro-dosing system fulfils the requirements of the pharmaceutical industry. The integrated IPC assures a high process reliability and an automatic process regulation. The 100% process monitoring by the NWDS ensures a reliable rejection of faulty capsules.
- The completely automated adjustment procedure of the NWDS sensor via the integrated IPC leads to an accurate and less time-consuming procedure than the commonly used manual method.
- Further benefits of the GKF powder micro-dosing system, such as sophisticated stirrer geometries, the patented adjustable dosing drum, the newly developed fixed dosing wheel with moving filter in combination with a profound process understanding and optimization reduce powder loss, stand-still times and increase process stability. Thus, the overall equipment efficiency and the product yield is increased.

More Questions?

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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