

## EQUIPMENT FOR CONTINUOUS MANUFACTURING OF OSD

The Gericke Formulation Skid GFS is a fully automated new production method for blending excipients and API upstream compaction, available in 2 versions: Continuous or Mini-Batch-Blending.



# A NEW CONCEPT FOR ACHIEVING HIGHER BLEND UNIFORMITY, CAPACITY AND SHORTENING TIME TO MARKET

## + New integrated production method for OSD - continuous feeding & blending skid GFS by Gericke.

The FDA has started years ago an initiative to promote, investigate and realise continuous manufacturing for producing pharmaceuticals. In other industries like chemical or food this continuous production has been state of the art for creating powder blends since many years. Continuous manufacturing will improve product quality like blend uniformity, reduce product losses and raise overall efficiency. In addition, time to market for new medicaments is shortened, since equipment for first tests and final production is the same. A validation of bigger scale equipment is avoided. The Gericke Formulation Skid GFS has been developed based on this initiative and offers a fully automated solution for supplying inline a powder blend to:

- direct compression
- wet or dry granulation
- hot melt extrusion
- sachet or capsule filling

The GFS skid covers the functions recipe preparation and blending of excipients and lubricant with the active pharmaceutical ingredient API. Upstream material dispensing can be integrated. In contrast to the existing formulation processes for OSD, the processes material dispensing, feeding, blending and compaction are realised inline.

## + Gericke offers inline equipment for continuous manufacturing in 2 process versions named Gericke Formulation Skid GFS-C and GFS-B.

Both solutions are fully automated from material dispensing to recipe preparation and blending. The formulation skids combine 2-6 high precision loss-in-weight feeders for automated dosing of excipients, lubricants and API. For the variant GFS-C these feeders supply constant feed streams of excipients and API the materials to the continuous mixer type GCM.

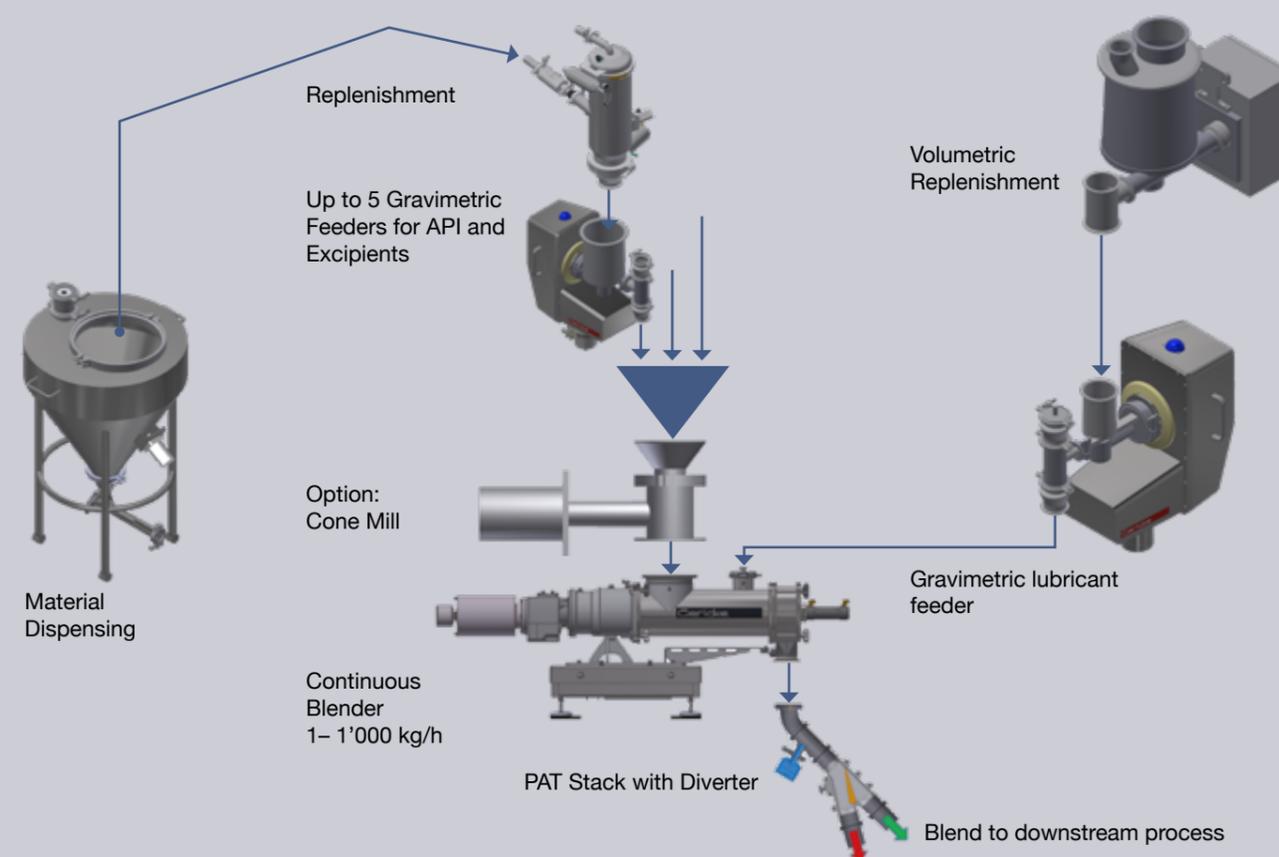
The blender size is selected according to the processing capacity of the downstream process and is available in 3 sizes. The variant GFS-B is the Mini Batch Blending variant of the Gericke skid. The loss-in-weight feeders supply now a required batch quantity for each ingredient instead of a continuous stream; the batch blender is filled, then the material is mixed and then discharged. The blending cycle restarts with the feeding again. This mini batch blending is chosen for continuous production of OSD if low dosage rates, small overall capacity or highly potent APIs shall be realised.

For both skid variants the automated feeding system is the same, only operating either in continuous or batch mode. The skid integrates PTA solutions of various vendors via the Gericke HMI. The QbD approach is realised with our controllers. Critical quality attributes (CQAs) are guaranteed by modifying critical process parameters (CPPs). Automated DOE runs validate the material traceability based on residence time distribution or mechanistic models. The results are implemented in our batch reporting tool.



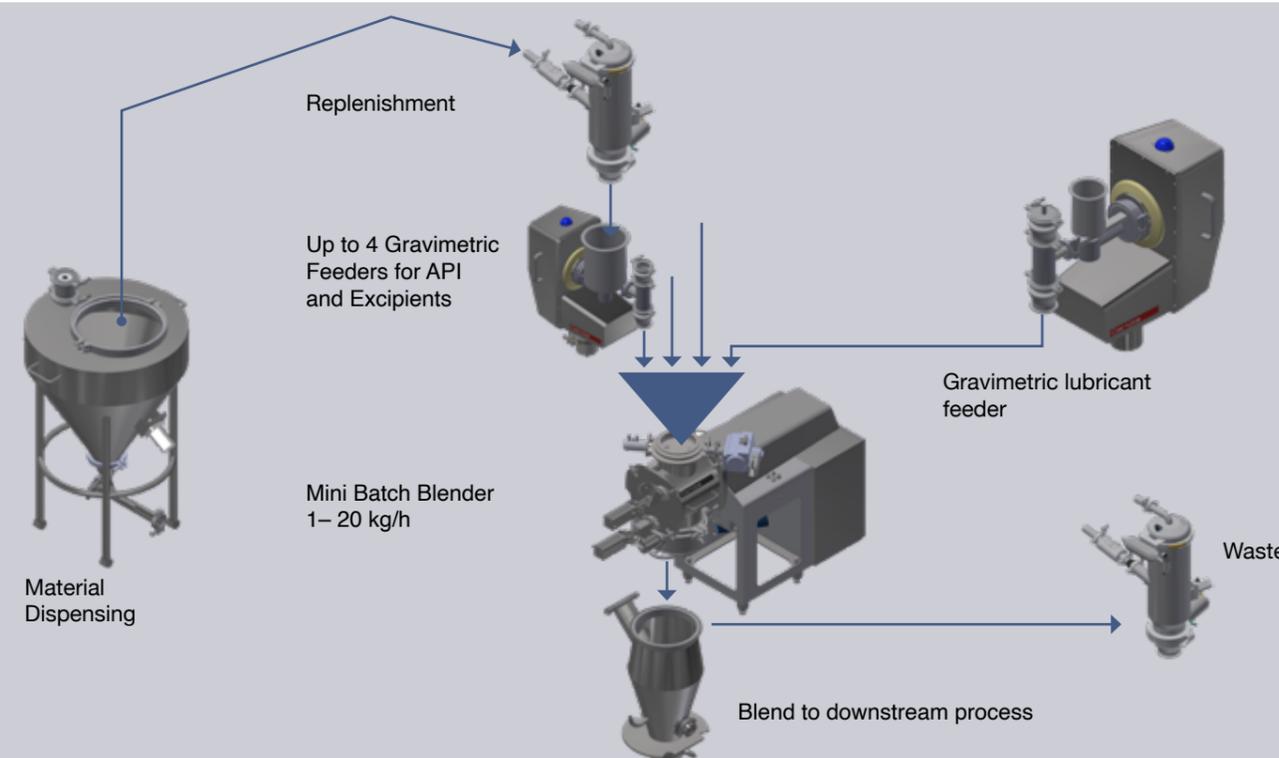
## Gericke Formulation Skid GFS-C: The continuous feeding - blending solution

Gericke Continuous Mixers GCM offer the optimum combination of radial and axial mixing (dispersion), ensuring highest homogeneity with low RSD.



## Gericke Formulation Skid GFS-B: The mini batch blending solution

The Gericke Mini Batch Blender is a semi-continuous process suitable for low dosage, low volume, highly potent products.



# STRONG IN ALL DISCIPLINES

Equipment – Process Know-How – Integration – Automation

## Gericke Formulation Skid for Mini Batch and/or Continuous Blending

The Gericke Formulation Skid GFS is a turnkey solution: Skid mounted system, including loss-in-weight feeders, contained refilling equipment with material handling, continuous mixer and PAT solutions for quick and seamless start-up. It can be operated both in truly continuous as well as a semi continuous mode for low dose low throughput applications. It can be used as standalone unit operation or integrated into your already existing continuous processes.



## Loss-in-weight Feeders

Whether integrated into our Gericke Formulation Skid GFS or as standalone feeder accurate metering of bulk solids is key to process control and ensures highest product quality standards. Designed for most cohesive powders and with the latest technology advancements in drive and weighing equipment Gericke loss-in-weight feeders offer highest accuracy and consistency.



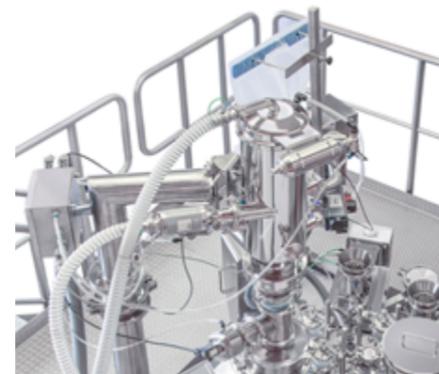
## Continuous Blender GCM

Gericke Continuous Mixers GCM offer the optimum combination of radial and axial mixing (dispersion), ensuring highest homogeneity with low RSD. The shape, layout and adjustment of the Gericke mixing tools have been developed based on upon 50 years of experience in continuous mixing and in collaboration with universities. The residence time and the energy input can be adjusted easily.



## Mini Batch Blender GBM

The Gericke Mini Batch Blender is a semi-continuous approach to make continuous manufacturing suitable for low dosage, low volume, highly potent products. It combines advantages of the traditional batch and true continuous manufacturing processes to generate a simplified system. Choose between the integrated Gericke Formulation Skid GFS or standalone equipment for early phase development.



## Material Handling

Material handling is very often overlooked in continuous manufacturing. Refilling of loss-in-weight feeders without impacting its performance is key. The safe and contained handling of our material is in all areas of Gericke's expertise. Whether you receive your API and excipients in drums, containers, or poly bags Gericke has the right solution. Integrated into our automation system, it also allows full traceability of raw materials.



## Automation

Based on the ISA88 Batch Standard our automation solution provides maximum flexibility as the configuration of the skid can be changed based on a control recipe without losing its validated state and using minimal custom coding. Data collection and integrity is fully compliant with Code 21 Part 11 /Annex 11 and Part 11.

The vendor neutral OPC UA interface allows access to all our parameters in real-time. It can either be setup up in standalone mode, forwarding live process and batch data to a historian, or integrated into a supervisory system, taking full control of our system without a user having to access our HMI.



## PAT Process Analytical Technology

PAT is often seen as a must for continuous manufacturing. As standard we can integrate a Near Infrared Sensor at the outlet of the blender including special device, ensuring a representative sample size as well as avoiding any probe fouling. The spectrometer can either be directly integrated into control system automatically forwarding a qualitative or quantitative value or fully integrated with a PAT-Management software that can be controlled through a dashboard from our HMI.



## Operational safety

By design the Gericke Formulation Skids are dust tight and guarantee no dust during processing, starting from material dispensing to blending. For operator safety during cleaning the skid can be automatically rinsed by a series of nozzles, before a safe dismantling is started. In addition the skid can be executed for handling potent materials, with main parts or the skid integrated in an isolator.



# MORE THAN 40 YEARS OF EXPERIENCE - GERICKE MILESTONES IN EQUIPMENT DEVELOPMENT AND SUPPLY FOR CONTINUOUS MANUFACTURING OF ORAL SOLID DOSAGE MEDICINES

## TURNKEY SOLUTION

Reliable and contained material transfer of excipients and API from material dispensing towards the gravimetric feeders is an integral part of our GFS.

## MODULAR AND COMPACT

Flexibility with downstream processes such as direct compression, wet/dry granulation, or as individual unit. Compact mixer for even lower throughputs with minimal start-up losses with easily adaptable residence time and energy input. Modular design with interchangeable feeders to suite needs of various processed materials and throughput rates.

## ADVANCED PROCESS CONTROL

Advanced control system, ensuring highest product quality and reduced waste. Open automation interface to PAT-Management and Advanced Process Controllers.

## HIGHLY DEVELOPED YET SIMPLE

Optimized access to equipment to allow fast cleaning and product changes with minimal down time and high containment.

- **Since 1960 Gericke has developed, designed and manufactured continuous feeding blending installations. With over 40 references in the pharmaceutical industry, we have become the leading supplier for feeding and blending equipment.**
- **1980**  
First continuous blending systems upstream continuous wet granulation supplied.
- **2002**  
Delivery of a continuous feeding blending GFS for dry Granulation of Acetylsalicylic Acid with a line capacity of 1000 kg/h upstream dry granulation.
- **2005**  
First “miniature” continuous blender for OSD supplied to Pharma USA for direct compression line.
- **2006**  
Gericke becomes a Member of the ERC Center for Organic Particulates (USA) supporting the work for the following universities: Rutgers, Purdue, NJIT; Puerto Rico.
- **2015**  
Development and supply of portable feeding blending unit upstream hot melt extrusion (Germany).
- **2016**  
Development and supply for highly modular feeding blending unit for large CDMO (USA).
- **2016**  
Delivery of high-volume continuous line for OTC products in Latin America.
- **2017**  
First FDA approval of a drug made with Gericke Formulation Skid GFS.
- **2019**  
Development and supply of Mini Batch Blending for Low Dosage – Low Volume – High Containment application.
- **2021**  
The Medicines Manufacturing Innovation Centre, a collaboration between CPI, the University of Strathclyde and founding industry partners, GSK and AstraZeneca has accepted Gericke as a partner to advance pharmaceutical manufacturing for integrated systems for continuous and mini batch blending.

# GERICKE FORMULATION SKID GFS:

A state-of-the-art solution, proven around the globe, ready today!



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