

Granulation Technology by Bohle

Bohle Fluid Bed System BFS | Bohle Uni Cone BUC® | Compact Unit | High Shear GMA | Single Pot VMA





Bohle Fluid Bed System BFS

Using a tangential fluid bed system represents state of the art technology in pharmaceutical manufacturing for particle coating, granulation and drying. With the innovative Bohle Uni Cone BUC® a complete fluidization is assured which leads to high coating uniformities and high yields in the final product due to the absence of particle twinning.

Benefits:

- inline sieving and product transfer
- 12 bar pressure shock resistant – optimum conditions for containment applications, no effect on environment in case of accident
- integration of PAT, NIR and WIP
- filter cleaning by patent / patented diffuser
- electrical drop down filter movement
- filter cartridges with spindle drive
- InTouch HMI: the powerful user interface
- vacuum changing
- removable bottom plate

Technical information:

BFS series	BFS 3	BFS 30	BFS 60	BFS 120	BFS 240	BFS 360	BFS 480
GMA series	GMA 20	GMA 70	GMA 150	GMA 300	GMA 600	GMA 800	GMA 1200
Working volume product bowl [L]	0.9–9	9–90	30–120	60–240	120–480	180–720	240–960
Air flow [m³/h]	200	1200	2800	4500	7000	9000	11000
Supply air [C]	30–80	30–80	30–80	30–80	30–80	30–80	30–80
Qty. of product filter bags	4	6	6	9	12	10	14
Approx. height Fluid Bed [mm]	1980	2930	3600	3920	4570	4990	5370
Number of nozzles (tangential spray)	1	2	3	4	5	6	8

Bohle Uni Cone BUC®

L.B. Bohle developed the Bohle Fluid Bed Systems with tangentially mounted spray nozzles and the Bohle Uni Cone BUC®. This equipment is available for batch sizes ranging from 1 to 500 kg.

Built in 12 bar shock resistant execution, organic and water based processes are always accessible. Short product transfer times and effective cleaning offer opportunities for additional savings in production time and costs.

By design all size fluid beds are geometrically similar which enables an easy scale up procedure. Dust-free suction and discharge of the product bowl is performed through the use of a newly developed patented multi-functional valve directly above the distributor plate.

The overall design of the BFS types results in substantial ergonomic benefits, which means major advantages in cleanability and processing in comparison to other existing fluid bed systems on the market. In addition, the low position of the valve allows easy operator access. Bohle Fluid Bed Systems contain fewer gaskets, valves and vents, which makes cleaning fast and easy.

All Bohle systems utilize a very efficient use of space.





Bohle High Shear GMA

The Granumator GMA is a granulating system specifically optimized for pharmaceutical applications. The Impeller is designed for high shear and compression, ensuring effective granulation. The chopper prevents excessive granule growth and distributes the granulating liquid within the product.

Benefits:

- less liquid consumption
- good discharging conditions
- closed system
- granulation can be time, amount or power controlled
- easy cleaning, no remaining of rinsing water

Technical information:

GMA type	GMA 70	GMA 300	GMA 600	GMA 1200
According fluid bed type	BFS 30	BFS 120	BFS 240	BFS 480
Batches [L]	20–55	90–240	180–480	360–960
Impeller [rpm]	15–400	5–220	5–173	5–145
Chopper [rpm]	150–500, variable adjustable			
Impeller torque measurement	Patented measurement of mechanical torque/power			
Control system	PLC controlled, Touchpanel operated			



Bohle Single Pot VMA

Bohle Vagumator single pot systems are designed for closed, dust-free processing of pharmaceutical granules from charging through discharge including in-line milling. Mixing, granulation and drying cycles are completed in a single machine under contained conditions.

Benefits:

- small footprint
- easy through-the-wall-assembly
- gravity feeding is standard
- installation in hazardous areas
- switch cabinet on board

Technical information:

VMA type	VMA 70	VMA 300	VMA 600	VMA 1200
Batches [L]	20–55	90–240	180–480	360–960
Impeller [rpm]	15–400	5–220	5–173	5–145
Chopper [rpm]	150–1500, variable adjustable			
Liquid dosing	Piston membrane pump, included in control panel			
Bowl/lid temperature control	10–80 °C			
Vacuum [mbar]	< 10			
Vacuum feeding	For easy, fast and low dust emitting feeding			
Control system	PLC controlled, visualisation by In Touch from Wonderware			



Compact Unit

The individual components of the High Shear Granulator GMA, wet sieve BTS, Fluid Bed System BFS and Bohle Uni Cone BUC®, cyclone separator and dry sieve BTS are optimally integrated into the Compact Unit. This integration covers process, cleaning, control and explosion protection as well as qualification.

The Compact Unit is a compelling solution when traditional wet granulation must be realized economically and ergonomically. Featuring many technological advances and inherent safety considerations, the Compact Unit creates an industry benchmark.

Benefits:

- GMA and BFS built into the wall right next to each other
- small footprint and minimized room height
- multipurpose use for various processes
- single operator panel to serve both machines
- single WIP-skid to serve both machines
- 12 bar pressure shock resistant design

Small footprint, high quality

The systems require a minimal footprint due to the close arrangement of the components. Additionally, direct product transfer from the outlet valve of the GMA via a stainless steel pipe to the suction valve of the BFS is possible. The proven tan-

gential sieve can also be integrated into this pipe system. An additional discharge valve is integrated in the process container of the BFS eliminating the need to refit the transfer line and discharge line during processing.

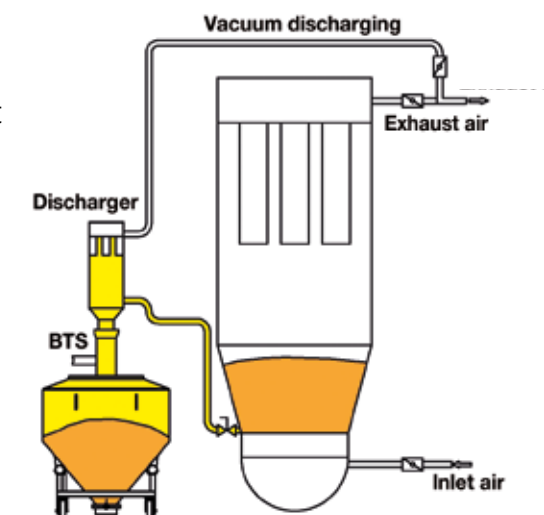
Wet tangential sieve – patented

The Bohle tangential sieve is exclusively designed for wet sieving of granules. The sieve is attached to the GMA base and situated directly below the GMA discharge. The impeller presses the wet granules through the tangential sieve directly into the transfer line.

This design reduces construction height and virtually eliminates transfer line obstructions and blockage of wet granules in the sieve.

Discharge cyclone

- one level operation
- short process times
- completely pressure resistant
- completely closed process
- short transfer routes means safe transfer
- short cleaning process
- small footprint



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System-VAGAS®

Introduction

The drying of granulates is an important basic operation in pharmaceutical production. Due to growing cost-pressure, greater environmental awareness, heightened standards of occupational safety and, last but not least, rising quality requirements, very high demands are made of modern production machines nowadays.

These demands include:

- protection of the personnel against the product
- protection of the product against environmental influences
- cost-effectiveness of the process in terms of investment and operating costs
- environmental compatibility, i.e. the avoidance of emissions (emissions of particles and possibly emissions of solvents)
- uncomplicated validation procedures
- reproducible results
- possibility of process automation
- high yield with minimal product loss
- safe process technology that is gentle to the product
- design according to GMP and possibility of CIP (cleaning in place)
- small space requirement

None of the known and established processes can optimally fulfill all of these requirements. In view of the ever more stringent environmental requirements and the growing cost pressures in pharmaceutical production, several renowned pharmaceutical companies have carried out cost and risk analyses which project great future opportunities for the single-pot process over a broad application range. This technique is particularly promising when there is a demand for flexible and economical manufacture of different products in one installation.

A new and impressive single-pot technology developed by the L. B. Bohle Maschinen + Verfahren, the **System-VAGAS®** offers an innovative approach to the production of granulates in a process which is cost-effective, flexible and easy to validate.

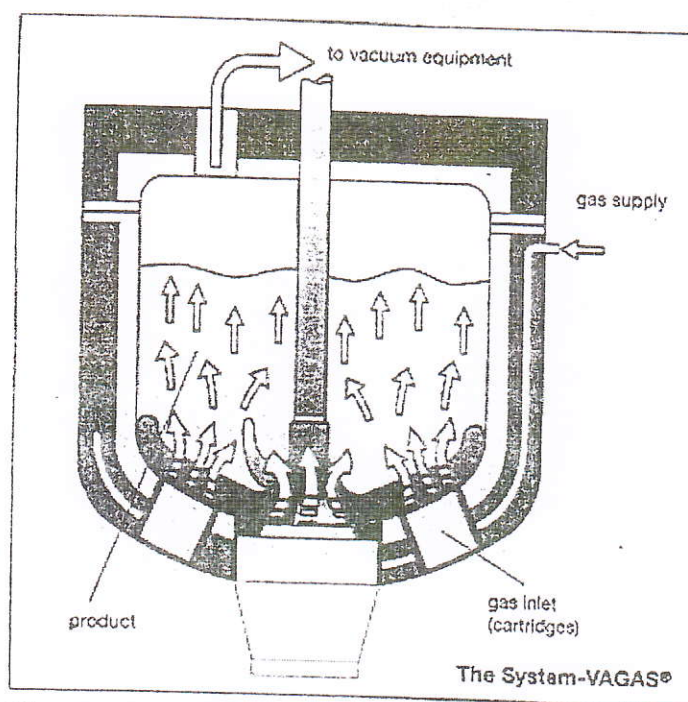
The drying principle *+ 1st. Service*

Vacuum drying has been in use in the pharmaceutical production of solids (e.g. for drying granulates) for a long time. The essential principle of this process lies in working under reduced pressure to below the boiling point of the liquid which is bonded to the solid. In this

manner, the pharmaceutical active ingredients, which are frequently very temperature-sensitive ($T_{\max} < 50^{\circ}\text{C}$ [122°F]), can be dried without severe thermal stress. The disadvantage of pure vacuum drying lies in the long drying times since heat can only be applied via the process bowl wall (heat conduction) or by means of heat radiation of the heated process bowl surfaces.

In order to speed up this drying process, microwave energy has been in use for some time now. By using microwaves, the energy needed for drying is generated directly in the product itself and does not have to be applied to the product by means of heat transfer. This direct method of applying energy is very effective and shortens the drying time to about 25% of that of pure vacuum drying. However, this method has encountered considerable acceptance problems with existing recipes because of the additional work it entails for validation and, in some cases even re-registration. As a result of which, in most cases, microwave drying is only registered for new products.

The System-VAGAS® stands out as an optimal single-pot process wherever already registered products are to be produced by means of a modern future-oriented process which fulfills the above mentioned requirements.



Diagrammatic view of gas distribution

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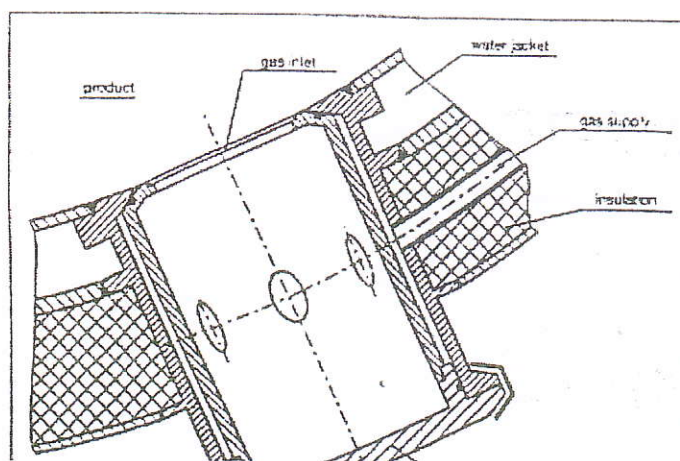
System-VAGAS®

Design of the System-VAGAS®

In this process, a small gas flow is fed continuously through the product in order to accelerate the drying. The volume of fed-in gas ranges from 1 to 20 m³/h, depending on the size of the installation. Consequently, no fluid bed is created as is the case with fluid bed technology, but rather, a slight gas stream flows evenly through the product. Despite the continuous gas flow, the vacuum system absolute pressure is about 30 mbar in the process bowl. Consequently, the drying takes place at temperatures which are very gentle to the product. The vacuum and the gas flow can be regulated and adapted to the specific product properties.

First of all the continuous stream of gas generates a "dry atmosphere" around the individual granulate grains, which manifests itself in an elevated partial pressure gradient between the granulate surface as it dries and the moister granulate core. Secondly, the constant flow through the granulate improves the transport of the moisture from the product to the vacuum equipment. In comparison to pure vacuum drying, both mechanisms lead to considerably accelerated drying without process-related risks for the product, and this is done with a minimum amount of technological input.

This translates into a clear financial advantage for the user as well as into high product safety. The gas (e.g. sterile compressed air or nitrogen) is introduced via cartridges which are installed in the bottom of the process bowl. These cartridges ensure an optimal, uniform distribution of the gas in the product and thus a homogeneous effect of the gas flow. Metal membranes with a permeability less than/equal to 10 µm, which are arranged flush with the bottom of the process bowl, form the separation to the product space in the process bowl, preventing the escape of product and thus the contamination of the cartridges.





Schematic view of gas inlet

Features:

- rinsable gas inlet pipes in the insulating shell of the container
- can be demounted without tools

The cartridges are attached in the process bowl by means of rapid-action closures and they can be dismantled without tools for simple cleaning validation. Although the bottom of the process bowl is permeable to gases, it has a smooth surface which is easy to clean, thanks to the fine membrane. This assures that no abrasion of the granulate occurs and, thanks to an ingenious flushing mechanism, the membrane remains free of caked-on product during the entire process.

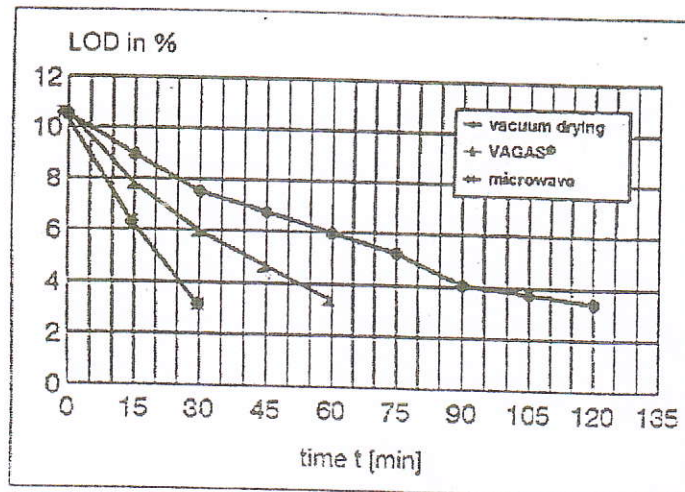


Figure of drying graph

In comparison to the established drying processes of single-pot technology, the System-VAGAS® constitutes an optimal compromise between drying speed, complexity of the installation and process technology as well as the costs. Under ideal conditions, the drying speed is nearly on par with microwave drying. This opens up new perspectives in evaluating single-pot technology in comparison to the established drying processes.

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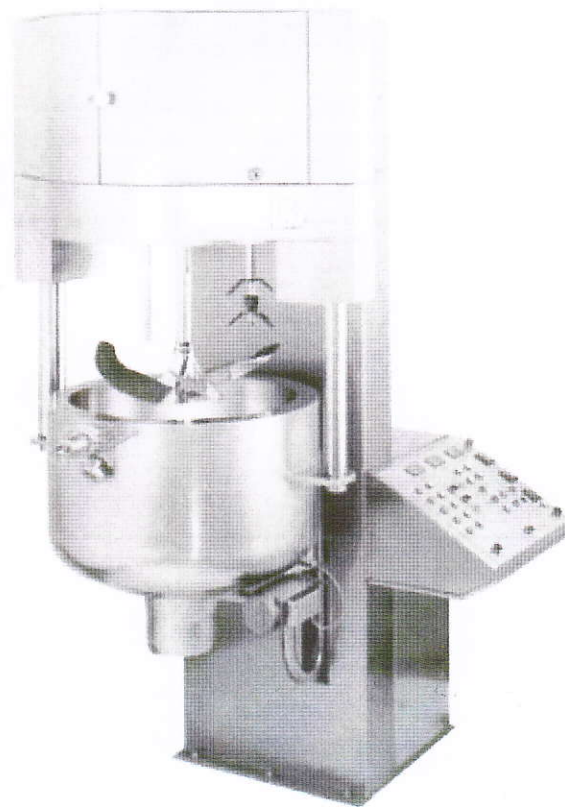
Process Technology

Granumator

LBB Engineering is consistently innovative in the development of the latest production equipment for manufacturing solid products according to economic criteria.

The LBB Granumator System (GMA) is a modular product line designed for the dry mixing, wet granulation and drying sectors. The high speed mixer as the basis of this line can be extended with optional extras into a high shear mixer/ granulator or a single-pot system, i.e. including granulation and drying.

Wet granulation as the important production step which determines the quality of the final product is the central task of this system. Systematic studies and the consistent application of the findings made to produce innovative solutions are features of the Granumator System. The result is a product line with convincing qualities. Flexibility, high product compression thanks to the special bowl and impeller geometry for excellent granulation properties, as well as ingenious design for fast, simple cleaning are the main features.

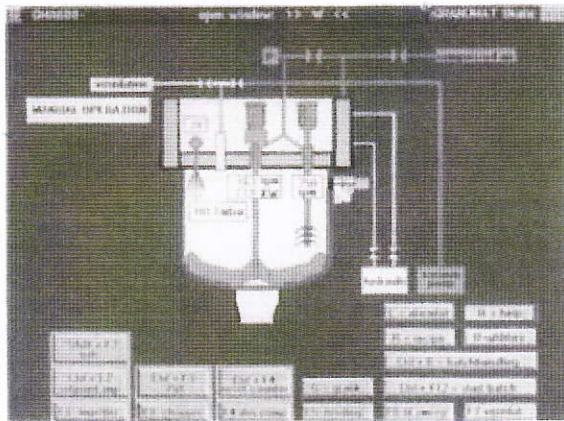


Total containment and reproducible granulation results are demands upon a modern granulating system. The LBB Granumator satisfies these requirements perfectly. Vacuum feeding, output-controlled granulation end-point determination and fully automated processing including batch documentation -- the Granumator System offers every option. Furthermore, this line can also be combined as a single-pot system with drying by the VAGAS® System.

The Granumator is thus a particularly economical and flexible solution for manufacturing granulates in one system under total contained conditions.

ABOVE: Granumator GMA 300 as a single-pot system with vacuum drying and manual control.

Peripherals for the granulating and single-pot systems



The automation package

The main tasks of the option are: Control of the Granumator System, visualization of the processes and documentation of all relevant data. The operator communicating with the equipment - his stored know-how is called during production and translated into reproducible granulate quality. The manufacturing process is transparent and comprehensible.



Granulating agent vessels in various designs and sizes.

The picture shows an example of a heated 250 liter explosion-proof vessel.