POWDER AND PARTICLE PROCESSING
FOR THE PHARMACEUTICAL INDUSTRY

ALPIN E • BEPEX • MICRON • MIKRO • RIEZ • SCHUG • STOTT • VITALAIR • VRIECO • N AUTA®
Pharmaceuticals... 
A Core Business of the Hosokawa Micron Group

ALPINE · BEPEX · MICRON · MIKRO · RIEZ · SCHUGI · STOTT · VITALAIR
VRIECO·NAUTA®

Powder Processing Technology
Expertise in Pharmaceuticals
Hosokawa is a global operation with sales, manufacturing and test centers throughout the world. The pharmaceutical industry is an important business sector for the Hosokawa Group and significant investment has been made, over the years, to enhance and streamline our operations in this area, enabling us to offer increasing levels of expertise, technological development and service. The Hosokawa Group is a recognised world leader in powder processing technology and is highly innovative with developments coming out of its research centres based in Europe, USA and Japan. All products are designed, engineered and manufactured in house by the individual Hosokawa units which gives our customers a single source supply for guaranteed plants with validation documentation.

We can offer the pharmaceutical industry complete systems in the following areas:
- Mixing / Powder Blending
- Vacuum Drying
- Size Reduction / Size Enlargement
- Micronisation / Jet Milling
- Classification
- Compaction / Agglomeration / Low Pressure Extrusion
- Process Containment
- Hygienic Filling and Weighing
Many design standards are used:
- cGMP directives
- GAMP directives
- FDA requirements
- 3-A Sanitary standards
- US. Dairy standards (USDA)
- American Glovebox
  Society Standard
- A.S.M.E. or BS 5500
- DIN/ISO
- Alpine pharma factory standards
- Basel Chemical Industry standards such as BN93, BN94 and others.

System Design for CIP/SIP
An increasing requirement for powder processing systems in the pharmaceutical industry is the need for them to meet CIP and SIP as this has several advantages:
- Reliable calibration, qualification and validation.
- Reproducibility of the cleaning parameters.
- Cleaning agents do not endanger personnel.
- Savings through shorter down times and reduced equipment dismantling times.

Special equipment designs, which facilitate CIP/SIP are offered, such as special seal bearings, one piece construction of equipment machined from a single piece of stainless steel and electropolished or finished surfaces down to Ra = 0.4 microns.

Our philosophy is not to just offer a standard machine but to work alongside our customers and provide tailor made solutions to process problems using our maxim “customer and market orientation. With our in-house expertise, supported by major test centers throughout the world, we are able to supply solutions to even the most challenging processing problems.

Services offered by Group Companies

Basic Engineering
- Conceptual studies
- Flowcharts: System layouts
- Safety concepts
- Project documentation

Detail Engineering
- P & I diagrams
- Calculation and design
- System drawings
- Specification of components
- Controls consultation
- PLC and instrumentation upgrades
- Design, programming and networking of visualisation systems
- Structural steel engineering with static calculations
- Piping & ductwork layouts
- Acceptance inspections on subcontractors’ premises

System Engineering
- Project co-ordination
- Turnkey projects
- Construction site management
- Assembly - Commissioning
- CE certification

Rental Machines

Pharma-Tech Center
Contract Processing

Technical Services
- System optimisation
- System upgrades
- Mechanical start-up and commissioning
- On site repairs
- Maintenance Contracts
- Servicing: Spare Parts

Analysis
- Particle size analysis
- Air jet sieving
- Sympatec (Helos/Rodos)
- In-situ particle size analysis
- Malvern Master Sizer
- Coulter Counter: Sedigraph
- Fischer Sieve Sizer analyses
- Scanning electron microscopy
- BET
- Vibrating screen: Wet screening
- Thermal Analysis TG/DTA and DSC

Documentation
- Preparation of documentation (operating manuals, as-built documentation, qualification documentation, DQ, IQ, OQ)
- Implementation of IQ and OQ

Quality Control
- Surface roughness measurements
- Welding seam inspection
- (X-radiology + ultrasound)
- Fluorescent penetration processes
For pharmaceutical applications, Hosokawa Micron B.V. supplies a unique upgrade of original Nauta® mixer technology. Established features of the Nauta conical mixer, including gentle mixing to protect product integrity, complete discharge to eliminate potential cross contamination and maximum homogeneity, make it ideal for pharmaceutical applications. Special pharma design enhancements of the mixer incorporate dry, lubricant-free operation of the orbital arm, integral sampling devices and full CIP/SIP capabilities.

The Centromix CM series of Truncated Cone Mixers offers space saving advantages and highly efficient mixing while the innovative Schugi Flexomix range of compact continuous mixer/agglomerators completes our programme and the Rietz Extrudomix offer alternative mixing/powder blending technology.

Fig. 1 Rietz Extrudomix EM6 for continuous mixing
Fig. 2 Vrieco-Nauta® Mixer
Fig. 3 Schugi Flexomix Mixer FX 100
Fig. 4 Centromix Truncated Cone Mixer CM 15 Pharma Design, effective volume 1500 l
Actively involved in the developments in pharmaceutical process equipment requirements, Hosokawa’s state-of-the-art conical vacuum dryer has evolved into a total solution for practically any drying problem known in the hygienic processing industry.

Originally used for mainly temperature sensitive fine chemical drying applications, the combination of the unique conical shape and gentle agitator without direct contact between product and shaft seals means the Vrieco-Nauta® conical Vacuum Dryer is ideal for a wide range of fine bulk pharma chemicals and excipients.

As the conical shaped vessel together with the cantilevered agitator design ensures maximum discharge and minimum heal the basis of an efficient cleaning procedure is there. Following typical cGMP design recommendations, the design of this Vrieco-Nauta® contact dryer made it possible to enter pharma processing with the higher requirements in terms of CIP/SIP cleaning and full containment issues. Vrieco-Nauta® dryers are frequently used in processing intermediate and final pharmaceutical drug formulations for aerosols, pills, tablets and capsules.

Apart from cleaning and containment issues, special attention is given to the exclusion of cross contamination risks or any other potential contamination by foreign material. For that reason, the orbital arm, being presented inside the drying chamber, has no gears inside but a dry timing belt transmission for the auger rotation. This belt of course, unlike gears, needs no lubrication, therefore totally excluding contamination risks. Another result of Hosokawa’s hygienic design efforts is the application of unique dry running nitrogen vented mechanical vacuum seals. Again no foreign material, in this case seal lubricant, can drop into the batch.
Nearly every stage of drug manufacture involves some comminution with raw materials, additives and active ingredients processed to the required particle size. This means that a whole range of requirements needs to be fulfilled, from pure disagglomeration and coarse grinding right through to ultrafine comminution. Hosokawa has the systems which meet the latest requirements as stipulated in the cGMP and FDA standards.

Fine impact mills are suitable for the fineness range between approx. 30 µm and 1 mm. A range of different equipment variants forms the basis for the universal application of this mill type. Modern classifier mills make it possible to generate steep particle size distributions with exact top size limitation. Fineness of $d_{97} = 10$ µm can be achieved. Machine size range and special designs permit a wide range of applications, from lab to production-scale applications of several 100 kg/h.
Various types of jet mills are employed for micronising active ingredients. This type of impact comminution in a gas jet generates end fineness of between 1 and 30 µm. The classic exponent of this type of mill is the spiral jet mill which is characterised by its ease of operation, excellent cleaning possibilities and the lack of rotating parts.

The new product line developed by Hosokawa Alpine retains all the time-proven elements but integrates a whole battery of new features to meet the requirements of the pharmaceutical industry, i.e. ease of dismantling, cleaning and sterilising, right up to CIP and SIP capability.

With the fluidised bed opposed jet mills, even micronisation of extremely “difficult” products down to the µm range is possible. The integration of a dynamic air classifier in this jet mill guarantees reproducible ultra-steep particle size distributions with exact top size limitation. The wide range of machine sizes permits laboratory and pilot applications equally as well as production-scale applications of several 100 kg/h.

Fig. 1 Alpine Spiral Jet Mill 100 AS. Grinding Chamber manufactured as monoblock component.

Fig. 2 Alpine 100 AFG Jet Mill. Millbody designed for CIP/SIP applications.

Fig. 3 Alpine Fluidised Bed Opposed Jet Mill 200 AFG Pharma Monoblock Design
Dry Compaction  
Most problems in processing tablet masses are caused by poor flow characteristics of the product, as evidenced by the dosing difficulties encountered in feeding tablet presses. These unfavourable characteristics of finely powdered solid materials can be decisively improved through agglomeration. The most economical way for this particle size enlargement to be done is by using dry press agglomeration. Finely dispersed bulk materials are compacted and pressed into flakes, without using a fluid binding agent. Either smooth or profiled rolls are used. These flakes are crushed and screened to dust-free, easy-flowing granules. The criteria for the machine design is easy cleaning and quick roll and predensifier screw replacement. A variety of screw and roll configurations are available to optimise the process.

Agglomeration  
The Schugi process for production of free flowing, closely sized granules with very good dispersing properties is well known and the FLEXOMIX continuous process can also be used for bulk pharmaceutical manufacture. A liquid binder(s) is sprayed into the flexing mixing chamber where adjustable blades or knives create a highly turbulent powder flow regime. Evenly sized granules mainly ranging between 0.5 to 1.5 mm are produced.

Bepex Compactor Model K 200/100  
Side view of system showing separation of processing area from clean process/non-hazardous area.

For the production of cylindrical pellets with diameters between 0.7 and 3 mm the BEXTRUDER will be used.

The basis of these systems is the low pressure extrusion of products with sufficient gliding characteristics.

For the production of spherical granules the BEXROLLER should be used. The batch sizes of this equipment are in the range from 0.2 ltr. to 50 ltr.
**Batch Fluidbed Processing**

The Agglomaster is our innovative modular multi-purpose batch fluidbed processor developed for drying, agglomeration, coating, layering, micro granulation and spray-agglomeration. Its unique fluid bed bottom design, with rotating slit disk and agitation blades together with its opposed pulse jet mechanism and the facility for liquid injection in different positions, creates a wide range of control of not only the particle size, but also the shape and density of the particles.

The Hosokawa Agglomaster, type AGM-2PJ&SD batch fluidbed processor, is a multi-purpose twin-unit. It is provided with „Opposed Pulse Jet“ Technology and also with „Spray Drying“ Technology. This smaller unit is especially designed for research and development work.

**Extrud-O-Mix**

Designed to continuously mix, agglomerate and extrude, the Rietz Extrud-O-Mix operates with a kneading action making it suitable for use with materials ranging from light pastes to heavy doughs. Dry materials may be mixed and extruded with small quantities of liquid for agglomeration with additional liquids introduced through injection points along the Extrud-O-Mix barrel.

- Split barrel for easy cleaning and plate changes
- Negative pressure dust elimination for clean environments
- Secondary discharge for out of specification material
Hosokawa Stott have extensive experience providing hygienic filling, weighing and powder and granule handling systems for the pharmaceutical industry. Incorporating a wide range of inflatable and extraction type sealing heads the filling and weighing systems when combined with a Vitalair downflow booth maintain the highest levels of dust control, hygiene and product integrity. Accurate, integrated weighing platforms ensure critical and repeatable packing specifications can be met. These facilities are suitable for use with a range of bags, sacks, drums and boxes with or without liners, both the Stott filling systems and Vitalair booths are available for manual or automated operation.

**Micron Denspack**
The Denspack is a small and simple densifier, which deaerates powders prior to filling. It is capable of handling materials with a cohesive nature and offers improvements in powder characteristics which reduce flushing and dust emissions.

**Dust Free Tipping Booths**
Safe, hygienic discharge of drums or bags can be achieved within a purpose designed, manual action or automated Stott drum tipping booth. Container disposal and cleaning can be incorporated into this system for increased product containment and operator safety.

**Laminar Flow Booths**
For increased levels of environmental protection, operator safety and product integrity the range of Stott laminar flow booths with their single pass, non-turbulent air flow and entrance protecting air curtain can be utilised in conjunction with the Stott filling and weighing systems. They are also suitable for inspection, product transfer or liquid pumping applications.
Hosokawa Stott and Vitalair are setting the standard for innovative, high quality process containment for the pharmaceutical industry. As the requirement for greater levels of containment increases Hosokawa specialist barrier/isolation technology is more widely used to safe guard the environment, personnel and maintain product integrity.

Hosokawa’s extensive experience of clean air environments and associated technology means we are able to work closely with our customers from initial specification to commissioning to ensure individual requirements.

**Dispensing suite incorporating Vitalair Downflow Booths.**

**Downflow Booths**

Fully self contained areas for the handling of hazardous powders and liquids, downflow booths use the vertical passage of clean air from the booths ceiling plenum to push dust or vapours away from the operators breathing zone. Achieving a minimum 99.99% filtration performance the high levels of operator protection and product integrity offered makes them ideal for all dispensing, transfer, sampling, mixing and weighing applications.

**Process Equipment Isolators**

Where pharmaceutical companies wish to retain a shirt sleeve environment without the need for operators to wear protective suits, isolators offer an ergonomic option. Positive or negatively charged sealed isolator booths enable product and equipment to be handled through rubber gloves.

Recent breakthroughs from Hosokawa have incorporated process equipment inside isolators to provide the ultimate clean environment for processing, cleaning and maintenance.

**Process integration incorporating equipment into Stott Isolator.**

**Integration of Alpine 315 UPZ into Stott Isolator.**
Particle Separation and Product Collection

Frequently, powdered pharmaceutical products need to be separated from process air or gas streams and the MicroPul reverse jet filter units are available in special pharma design to meet requirements such as CIP/SIP/explodible dusts. The filter unit was the original design using reverse pulse jet cleaning and as such, Hosokawa experience spans decades and many application areas.

Cyclone Collectors

A range of pre-filtration high efficiency easy clean cyclones are also available for collection of pharmaceutical products and they are sometimes used prior to the final product filtration unit to collect the majority of product.

HEPA Filters

Responding to customer needs we offer a safe change push-push technology HEPA/ULPA filter unit, designed for all toxic or sterile systems. Elements specially designed for fitting to the units can be supplied up to grade EU14. Filter housings manufactured in a variety of materials, from stainless steel to special chemic ally inert polymers, tailored to suit individual customer processes. Special design for inline filtration up to 10 bar g PSR with CIP options

MikroPul Pharma-Design reverse jet filter delivered to ZENECA/UK
Because state-of-the-art GMP-compatible process solutions demand sophisticated and integrated automation, Hosokawa has extended its range of products and services beyond the supply of mere hardware.

The connection of field measurement technology to the control unit is being realised increasingly via communication systems such as Profibus DP, FMS, and PA or via the industrial Ethernet. Intelligent network components which can also be used in potentially explosive areas minimise the amount of wiring necessary, thus contributing to a reliable and moreover visually aesthetic solution.

The lifecycle model as described in the GAMP directives is our model in elaborating this solution. The scope of activities ranges from preparing the hardware and software specifications to writing programs based on PLC systems or also highly integrated visualisation systems. Great store is set by data integrity and data archiving as well as error message protocols and batch records. The integration of electronic signatures is being realised according to the requirements stipulated in 21 CFR Part 11.

### Basis for Automation

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Hosokawa offer a total engineered solution from initial process conception to final validated plant. We are your single source supply for integrated powder and particulate processing systems and component machinery. We offer a range of services to ensure your pharmaceutical processing needs are met:

- Laboratory testing
- Full scale trials or site trials
- Process design
- Procurement
- Engineering and project management
- Installation
- Commissioning

**Materials of construction**
High quality stainless steel such as AISI 304, 304L, 316, 316L, or even Hastalloy® or Titanium are used. One piece construction of individual machines using CNC machining to create Hosokawa’s unique "mono-block" designs is used wherever appropriate.

We provide a complete service and give documentation and assistance with the four basic stages of our customer’s validation namely DQ, IQ, OQ, and PQ.

**Operational Trial Equipment**
Hosokawa are able to offer a range of equipment on loan/rental to pharmaceutical companies to enable operational trials to take place. This ensures that process parameters can be finalised and production flows monitored prior to equipment and process layout finalisation. At this stage the highly experienced Hosokawa engineers will work very closely with your in-house engineering team to advise and develop the best solution to your processing requirements.

**Service**
Hosokawa is committed to providing continual customer support, long after the plant has been installed and commissioned. We have highly skilled Service engineers to cover machinery breakdowns, routine inspections and servicing on site. Whilst our experienced technical engineers can provide both process and maintenance advice.
The integration of several powder processing operations into one turnkey system calls for carefully managed and executed engineering and it is in this field that Hosokawa units have extensive experience.

Process Guarantees can be given after testwork in our Group Test Centres hence, a one source totally engineered package is offered.

CAD systems are used to create flow-sheets, P and ID drawings, layouts, detailed designs to whatever code is being employed and units operate to the Quality System ISO 9001.

The design of a safe system is of paramount importance and dust explosions with organic pharmaceutical powders are nearly always a real risk. This risk can be minimised by avoiding a source of ignition but this is frequently not possible in high speed rotating equipment and then the system has to be designed to contain any explosion.

Normally explosion relief by venting is not usual in the pharmaceutical field but if this is acceptable then this method too can be designed in.

A pressure shock resistant (PSR) design is more usual and here the system is designed to withstand the maximum explosion pressure, usually under 10 bars, without rupture. A typical design code is the German VDI 2263 and this calls for all vessels to be specially strengthened and in some cases full pressure vessel design codes may be specified.

Explosion Activated closure valves or barrier valves are manufactured and tested to high standards and these are used in process ductwork to stop the propagation of any flame front following a dust explosion therefore isolating the danger.

Running systems under an inert gas such as nitrogen is also frequently used to stop any explosion from occurring and Hosokawa has supplied many such systems for size reduction, blending and drying.
Lab and Pilot Plant Equipment

ALPINE · BEPEX · MICRON · RIETZ
SCHUGI · STOTT · VRIECO-NAUTA®

Complete Product Range
Laboratory and small scale equipment is readily available covering the main Hosokawa product range. This means that when a process is scaled up to full production from laboratory trials, the same equipment type can be used which frequently makes validation somewhat easier. Small scale mixers, impact mills, classifier mills, micronisers, roller compactors, fluidbed processors and vacuum dryers can be supplied or in some cases rented out for site trials if the products are particularly hazardous.

Particle Size Analysis and Powder Properties
The Alpine Air Jet Sieve 200 LS-N is well known for accurate particle size sieve analysis in the particle size range from approx. 10 micron up to 4 mm. It is complete with an integral calculator and processor which converts sieve residue in grams from an external balance into percentage and can be supplied with Alpine’s software LS-PRO to transmit information to remote data logging devices.

Powder Characteristics Measurement
The Hosokawa Powder Characteristics Tester PT-R is also becoming widely used in the pharmaceutical industry to measure certain powder characteristics which helps in quality control of powdered products. One compact unit can measure:

- Angle of repose
- Compressibility
- Angle of spatula
- Cohesiveness
- Angle of fall
- Dispersibility
- Angle of difference

Bulk density and some particle size analysis can also be carried out.

Fig. 1 New 5 litre Vrieco-Nauta® Lab. Mixer with timing belt design. 10 l and 20 l versions also available.

Fig. 2 Alpine Jet Milling System 100 AFG-M 4
Fig. 3 Alpine Spiral Jet Mill 50 AS
Fig. 4 Alpine Milling System with Fine Impact Mill 100 UPZ
Fig. 5 Mikro ACM 2 Air Classifier Mill
Fig. 6 Alpine Particle Size Analyser 200 LS-N, operating range from 10 µm up to 4 mm.
Fig. 7 Bepex Pharmapactor L200/50 P
Fig. 8 Hosokawa Powder Characteristics Tester PT-R
As the requirements of the pharmaceutical industry become more complex with increased needs for ease and rigour of cleaning and containment, Hosokawa Micron Powder Systems have opened its Hosokawa Pharma-Tech CenterSM, to better serve this important market.

The Hosokawa Pharma-Tech CenterSM is a cGMP facility designed to meet current pharmaceutical and FDA standards. This 1,600 square foot facility is designed for pilot plant production and testing of a diverse range of pharmaceutical products. The facility includes two processing suites, a clean equipment storage area, equipment washroom, material quarantine and release areas, analytical laboratory, and client conference room.

The Hosokawa Pharma-Tech CenterSM provides Hosokawa’s pharmaceutical customers the unique opportunity to explore and develop process solutions to critical processing problems in a controlled environment. Designed as class 100,000 areas, the two process suites incorporate the most advanced levels of engineering design.

Facility Features

- Automated air handling systems with temperature and humidity control for the process areas
- Once through air designed for 20 changes per hour
- HEPA filtration throughout processing areas
- On-site nitrogen supply for inert processing
- Validated equipment operating procedures and control systems
- Analytical lab for on site powder analysis and characterization.

With a commitment to total quality management, Hosokawa Micron Powder Systems seeks to develop and maintain a true partnership by meeting your continuing requirements for superior pharmaceutical powder process technology. We understand the inherent value of testing, and are committed to operating the Hosokawa Pharma Tech CenterSM to the highest industry standards as an extension to our customers’ production and research capabilities.

Alpine Spiral Jet Mill (100 AS) micronising to $d_{97} < 10 \mu m$

Alpine fine grinding Pin Mill (160 UPZ). Versatile grinding PSD’s from 500 micron to 25 micron
Global Facilities
Hosokawa is a truly global operation with many operating units offering not only single machines but complete systems. Research, development, process optimisation, system design/ engineering, project execution, project management, installation and commissioning - all can be provided for complete customer satisfaction.

Full manufacturing programme for each Hosokawa unit on request.

Rental Machines
Many of today’s drugs and pharmaceutical chemicals are toxic and cannot be handled safely away from their manufacturing base. Frequently placebo or similar low risk compounds are used to evaluate machines in supplier test centres. However as a Group we offer a rental machine service where specific equipment can be hired and tested on the customer’s own site using Hosokawa supplied installation/instruction teams.

Testing Facilities
Process guarantees are offered when materials are sent to our many Test Centres for machine/process evaluation. Many units offer this facility and one of the largest and most comprehensive is with Alpine AG in Augsburg, Germany. The multi million dollar Test Centre completed in 1987 is one of the largest of its kind in the world.

Further evidence of Hosokawa’s commitment to pharmaceutical customers is the opening in Spring of 1998 of a comprehensive 1400 square foot special cGMP Pharma Laboratory in the USA. Located at Hosokawa Micron Powder Systems in Summit, New Jersey this will include two equipment/process suites, a clean equipment storage area, an equipment washroom, material storage, analytical testing lab and customer meeting rooms.

Process equipment to pharma standards includes a spiral jet mill, a Pharmaaktor with flakecrusher, 160 UPZ Impact mill, a vacuum dryer and a Stott filling machine.

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The Hosokawa Micron Group will always be the leading global company covering the mountain range of Powder Technologies. The group will achieve peaks of excellence in the development and commercialisation of advanced materials, process equipment and systems engineering.