NETZSCH

Proven Excellence.

Agitator Bead Mill *DELTAVITA®*

Agitator Bead Mills for Your Pharmaceutical Applications

PHARMA & COSMETICS | a Business Field of NETZSCH Grinding & Dispersing

NETZSCH *DeltaVita*®
Agitator Bead Mills for Your Pharmaceutical

Pharmaceutical manufacturing processes require the utmost care and precision - from initial laboratory testing to full-scale production. In this tightly regulated industry, special machines are required that facilitate production in accordance with Good Manufacturing Practice (GMP) guidelines through every step of the process.

NETZSCH understands and respects the special requirements and highly confidential nature of pharmaceutical applications. When working with high-quality, high-cost materials, there is no room for error or loss. There are specific standards: safe, cost-effective, easy-to-clean equipment that provides reproducible results with every batch.

As the world's leading supplier of technological solutions and machines for fine and ultra-fine particle reduction, NETZSCH offers customized solutions for drug development and manufacturing. Our specialists in the Pharmaceutical Competency Center are also experienced in every aspect of pharmaceutical machinery testing, certification, validation and documentation.

Advantages of Grinding Active Ingredients

More than 90% of drugs approved since 1995 exhibit poor solubility, poor permeability, or both. More than 40% of the newly-discovered active ingredients also display poor to very poor water solubility, which is a serious challenge for the successful development and marketing of new drugs in the pharmaceutical industry.

Most of the New Chemical Entities (NCE) are not considered for pre-clinical studies due to the formulation hurdles presented by drugs that are not readily soluble in water.

With the increased particle surface area associated with particle size reduction, the dissolution rate, and thus the bioavailability, of the active ingredients, can be drastically increased, regardless of how a drug is administered. This means that the drug takes effect more rapidly. And, due to the increased bioavailability, smaller amounts of the API are required, leading to a more reasonably priced product with fewer risks and side effects for the patient.

NETZSCH works closely with pharmaceutical companies to transform this experience into pharmaceutical products – resulting in medical as well as commercial benefits.

Applications

Nanotechnology Leadership & Technology

The groundbreaking NETZSCH grinding technology makes it possible to manufacture active ingredients in the nanometer range that comply with pharmaceutical standards. *DeltaVita*® agitator bead mills were specifically designed to meet the requirements of the pharmaceutical market.

NETZSCH offers industry-leading agitator bead mills for true comminution and for the wetting and dispersion of API particles in a wide range of pharmaceutical products. With the *DeltaVita*® grinding and dispersion system, it is possible to achieve reproducible nanoparticles with narrow particle size distributions.

NETZSCH *DeltaVita*® 2000

NETZSCH *DeltaVita*®
Technology

The NETZSCH-engineered *DeltaVita*® mills are based on the proven *Zeta*® mill technology. Thanks to the high level of energy efficiency, high throughput rates and multi-pass or circulation modes of operation, it is possible to achieve high-quality stable, homogeneous dispersions with excellent reproducibility.

This superior technology prevents excessive heating of the product. The unique grinding media separation system impedes blockage of the screen at the outlet of the mill and guarantees reliable operation.

Among other impressive features, the *DeltaVita*® line offers the following advantages for pharmaceutical applications:
- a single-tank process to prevent contamination
- precise temperature control
- ease of operation and easy-to-clean design

NETZSCH Technical Center

NETZSCH is committed to providing optimal solutions to the pharmaceutical industry. We have our own laboratories around the world available for testing and trials. Our teams are experienced in the industry-specific requirements of the pharmaceutical market which include:

- URS (User Requirements Specification)
- FS (Functional Specification)
- SDS (Software Design Specification)
- DQ (Design Qualification Execution Support)
- FAT (Factory Acceptance Test)
- COMM/SAT (Commissioning and Site Acceptance Test)
- IOQ (Installation and Operational Qualification)
- Assistance with PQ (Performance Qualification)

Our facilities are ISO 9001 certified and we design and build in accordance with the guidelines of FDA, cGMP and all regulatory standards currently applicable for the pharmaceutical industry. All machines are either UL or CE certified.

NETZSCH *DeltaVita*®
Agitator Bead Mill for the Laboratory

R&D in small batches is an essential part of the process when developing new drugs. The market demands the ability to confirm process feasibility without wasting scarce, costly materials. NETZSCH provides the solution. The laboratory machines from NETZSCH are ideal for testing where only the smallest batch sizes are needed to achieve significant test results with minimal product loss within a short period of time.

The laboratory agitator bead mills from NETZSCH offer:
- Repeatable results - batch after batch
- Scale-up to full-size production machines
- Easy to clean and autoclavable

DeltaVita® 1

When faced with developing a nanoformulation of Active Pharmaceutical Ingredients (API), innovative strategies and laboratory equipment in the early stages are essential to the success of your project. The possibility to extensively screen the product formulations in a fast and economical way is one of the most important steps in bringing your product through the development phase.

The dual centrifuge *DeltaVita*® 1 is based on the further development of a classical centrifuge. In contrast to a conventional centrifuge rotor, the rotor is equipped with two rotary plates at a specific angle to allow for the proper rotation of the grinding media in the sample vessels to reduce the particle size similar to agitator bead mills. The sample vessels are 2 ml Twist-Top Vials - the ideal vessel for formulation development in the context of nano-grinding - as well as 10 ml injection vials, 15 ml and 50 ml FalconTubes or for 125 ml beakers are currently available as standard.

Features:

- **Small batch sizes:** Batch size with 0.1 -1 g API
- **Flexibility:**
  - Different sizes of grinding chambers available
  - Suitable for grinding media up to 2 mm
- **Screening:** Test up to 40 samples at one time
- **Scale-up:** Similar results on all sizes of the *DeltaVita*®-series
- **Coolable production room**
- **Current available adapters for:** 2 ml vial, 10 ml injectable bottle, 125 ml PP-bottle, 15 ml PP-tube and 50 ml PP-tube

Applications:

- Nano grinding: Production of nano-suspensions
- Homogenization: Production of liposomes or emulsions
- Mixing of difficult mixable materials, e.g. high viscous components
- Improving of mixing processes

NETZSCH *DeltaVita*®
Agitator Bead Mills for the Laboratory and

DeltaVita® 15 - 300

The NETZSCH *DeltaVita*® 15 - 300 laboratory agitator bead mills operate with extremely small batches between 50 ml and 2,000 ml, making them ideal for feasibility studies. They can achieve particle reductions to below 200 nm.

NETZSCH *DeltaVita*® 15 - 300

Features:

- Agitation system with improved centrifugal separation device for the use of small grinding media from 0.05 mm - 0.8 mm in diameter
- Easy scale-up
- Double-acting mechanical seal
- Safe, simple and clean operation
- Variable-speed drive via frequency inverter
- Flexible mode of operation - suitable for batch and circulation operation
- Four different grinding chamber volumes: 15 ml, 50 ml, 150 ml and 300 ml
- Operator management with password protection for various access levels
- IP 65 / NEMA 4X machine stand for complete wash down
- Optional NETZSCH-*Ceram* Z, NETZSCH-*Ceram* C, AISI 316 L or NETZSCH-*Ceram* N grinding chamber designs
- Documentation required for validation supplied with the machine

Technical data		Laboratory series				
		DeltaVita® 1	*DeltaVita*® 15	*DeltaVita*® 50	*DeltaVita*® 150	*DeltaVita*® 300
Grinding chamber volume	ml	2 - 125	15	51	142	286
Drive power	kW	2.2	2.2	2.2	2.2	2.2
Speed range	min^{-1}	-	1 000 - 4 200	1 000 - 4 200	1 000 - 4 200	1 000 - 4 200
Batch size (min - max)	ml	1 - 100	35* - 150	97* - 300	200 - 500	300 - 2 000
Grinding media diameter	mm	0.05 - 2.5	0.05 - 0.5	0.05 - 0.5	0.05 - 0.8	0.05 - 0.8

Pilot Plant

DeltaVita® 600

The *DeltaVita*® 600 is a machine for batch sizes from 1 l to 6 l to support the clinical trial trials, or small scale production.

Features:

- Interchangeable grinding chamber designs
- Optional explosion-proof design for installation in hazardous areas
- PLC control with optional interface for data acquisition
- Optional CIP and SIP function
- Available with 100 ml and 200 ml grinding systems

NETZSCH *DeltaVita*® 600

Pilot plant series *DeltaVita*® 600
600
3
1 000 - 4 500
1 000 - 6 000
0.05 - 2.0

*with batch mode components

NETZSCH *DeltaVita*®
Production Machines

NETZSCH *DeltaVita*® 60000

DeltaVita® 2000 - 60000

The *DeltaVita*® product line can be scaled up from the *DeltaVita*® 300 to full- scale production models up to 4,000 liters.

The production systems are available in two frame designs. The flexible portable design is a complete machine located within the process suite. The fixed installation option is a split frame design with all mechanical components outside the clean room and only the wetted components in the process suite.

Technical data		*DeltaVita*® 2000	*DeltaVita* 4000	*DeltaVita*® 10000	*DeltaVita*® 25000	*DeltaVita*® 60000
Grinding chamber volume	ml	1 600	4 000	10 000	25 000	62 000
Drive power	kW	5.5	15	18 / 22	37 / 45	75 / 90
Speed range	min^{-1}	1 200 - 2 500	900 - 1 800	700 - 1 300	550 - 900	350 - 700
Batch size (min - max)	l	4 - 50	8 - 100	20 - 500	50 - 2 000	120 - 4 000
Grinding media diameter	mm			0.1 - 2.0		
Bead size	mm			0.1 - 2.0		

Materials & Surface Finish

- Stainless steel with moderate surface finish roughness of Ra = 0.4 µm
- High-tech and high-strength ceramic materials for metal-free processing
  - NETZSCH-*Ceram* Z
  - NETZSCH-*Ceram* N
  - NETZSCH-*Ceram* C
- All product-wetted parts can be sterilized with SIP or autoclave (depending on machine size)
- Food / pharmaceutical grade elastomers and lubricants

Features

- Fully CIP and SIP capable
- PLC control
- Optional data acquisition and process parameter set-point management
- Double-acting mechanical seal
- Choice of grinding chamber materials
- Batch sizes from 4 liters to 4 000 liters

NETZSCH *DeltaVita*® 10000 production machine

NETZSCH-*Beads*®

NETZSCH-*Beads*® – Always the Right Choice!

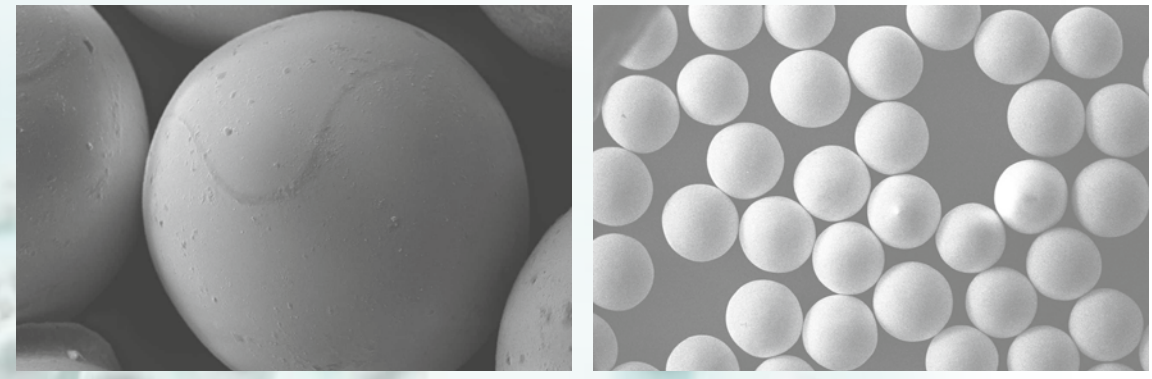
The selection of suitable grinding media represents an excellent optimization feature in dispersing and wet-grinding processes with agitator mills. With the use of NETZSCH-*Beads*® you will achieve optimal results.

- Ideally compatible grinding media for NETZSCH agitator bead mills
- Optimum combination of machine, grinding tool and application
- Process optimization and performance enhancement
- Increased energy efficiency
- NETZSCH service worldwide from a single source
- Comprehensive test certificates (LOT -related)

Ceramic Grinding Media

VitaBeads Nano® Yttrium-stabilized zirconium oxide grinding beads

When it comes to wear and breaking resistance as well as sphericity and finish quality, *VitaBeads Nano*® are the highest-quality grinding beads currently available on the market. These properties reduce the contamination of pharmaceutical products during the grinding process to a minimum. *VitaBeads Nano*® are available in the following sizes: 0.1 mm, 0.2 mm, 0.3 mm, 0.5 mm, 0.8 mm and 1.0 mm.



VitaBeads Nano® 0,3 mm SEM micrograph

NETZSCH Service

Technical assistance must arrive quickly and work perfectly. That's why we offer an extraordinary range of services with the assurance that highly-qualified NETZSCH personnel perform these services all over the world. Our specialists provide quick andreliable assistance. We advise you in your own language, wherever you are.

The NETZSCH service network extends to all corners of the globe. As a result, we strengthen the competitive capacity of our customers, facilitate trouble-free, efficient processes and ensure maximum machine availability.

Our range of services includes

- Procedural commissioning
- Inspection
- Maintenance
- Modifications
- Overhauls
- Process optimization
- Spare parts

Our Global Service Expertise Gives You Peace of Mind for Your Production

The NETZSCH Group is an owner-managed, international technology company with headquarters in Germany. The Business Units Analyzing & Testing, Grinding & Dispersing and Pumps & Systems represent customized solutions at the highest level. More than 3,800 employees in 36 countries and a worldwide sales and service network ensure customer proximity and competent service.

Our performance standards are high. We promise our customers Proven Excellence – exceptional performance in everything we do, proven time and again since 1873.

Proven Excellence.

Business Unit Grinding & Dispersing – The World's Leading Grinding Technology

NETZSCH-Feinmahltechnik | Germany
NETZSCH Trockenmahltechnik | Germany
NETZSCH Vakumix | Germany
NETZSCH Lohnmahltechnik | Germany
NETZSCH Mastermix | Great Britain
NETZSCH FRÈRES | France
NETZSCH España | Spain
ECUTEC | Spain

NETZSCH Machinery and Instruments | China
NETZSCH India Grinding & Dispersing | India
NETZSCH Tula | Russia
NETZSCH Makine Sanayi ve Ticaret | Turkey
NETZSCH Korea | Korea
NETZSCH Premier Technologies | USA
NETZSCH Equipamentos de Moagem | Brazil

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