




*The German
spirit of quality
since 1854*



SiLibeads[®] PHARMA Beads offer solutions to fundamental challenges in pharmaceutical manufacturing, produced in strict accordance with Good Manufacturing Practice (GMP) guidelines.

They ensure the industry's need for product integrity, process reliability, precision and operational efficiency.



SiLibeads[®]
...more effective drugs

Type P Pharma, Type S and Type M

Glass beads made of high-quality Borosilicate or Soda Lime Glass

Advantages of SiLibeads® Pharma Glass Beads in Pharmaceutical Applications

Inert Material

SiLibeads® Pharma Glass Beads made from Borosilicate Glass, do not react with drug formulations and are compatible to sensitive APIs.

Mixing and Homogenization

SiLibeads® Pharma Glass Beads aid in the efficient mixing of formulations, such as insulin suspensions, ensuring homogeneous mixture.

Multifunctional Applications

SiLibeads® Pharma Glass Beads are used in various applications, including carriers for active ingredients, for mechanical cell disruption and are used in injectable drug delivery solutions.

Enhanced Processing

SiLibeads® Pharma Glass Beads facilitate easy modification in cell culture systems and efficient extraction for research purposes.

Material properties

- High purity
- Highly spheric and uniform
- Pure and very smooth surface

Regulatory requirements

- Comply with 2011/65/EU RoHS (Limited Values for Heavy Metals)
- Comply with the requirements § 31 of the German Food and Feed Code (LFGB) and of the European Food Regulation 1935/2004/EC, Article 3
- Obligation according to Article 33 of Regulation (EC) No. 1907/2006 (REACH) Substances of Very High Concern (SVHC)
- Free from BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy). Glass beads does not contain any animal material

Applications

- API comminution (nanosuspensions)
- Diagnostic (Bead Beating, cell lysis, cell disruption)
- Mixing drugs /Mixing insulin
- Production of vaccines
- Injectable drug delivery solutions

Certification

- ISO 9001; ISO 15378
- DMF (FDA)
- Pharma documentation
- Individual analysis, CoA, CoC on request



Type ZY-P Pharma

Ceramic beads made of Zirconiumoxide / Yttrium stabilized

Advantages of SiLibeads® Pharma Ceramic Beads in Pharmaceutical Applications

Exceptional Durability

SiLibeads® Ceramic Beads exhibit extremely low wear and tear due to the use of fine crystalline and pure raw materials in their production.

Precision Engineering

The precise roundness and smooth, polished surface of the SiLibeads® Pharma Ceramic Beads significantly contribute to their low wear rate.

Advanced Nanotechnology

SiLibeads® Pharma Ceramic Beads are ideal for nano grinding, facilitating the production of active pharmaceutical ingredients, excipients and nanosuspensions.

Efficient Mixing Solutions

SiLibeads® Pharma Ceramic Beads are effective for mixing and dispersing active substances in various high-speed mixers.

Safety and compliance

SiLibeads® Pharma Ceramic beads are free from radioactivity and conform to food legislation standards, ensuring their safety and suitability for use in pharmaceutical, biotechnological and diagnostics applications.

Material properties

- High purity
- Highly spheric and uniform
- Pure and very smooth surface

Regulatory requirements

- Comply with the requirements § 31 of the German Food and Feed Code (LFGB) and of the European Food Regulation 1935/2004/EC, Article 3
- Obligation according to Article 33 of Regulation (EC) No. 1907/2006 (REACH) Substances of Very High Concern (SVHC)
- Free from BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy). Ceramic beads does not contain any animal material or had been produced from any animal product

Applications

- API comminution (nanosuspensions)
- Diagnostic (Bead Beating, cell lysis)

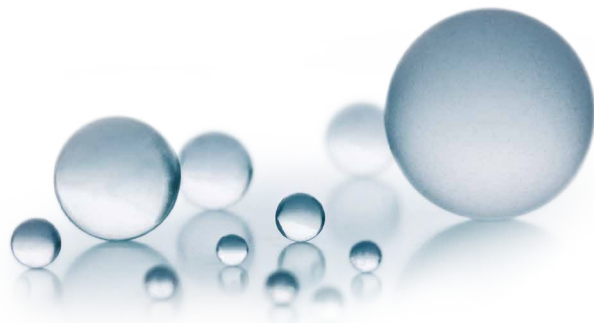
Certification

- ISO 9001
- DMF (FDA)
- Pharma documentation
- Individual analysis, CoA, CoC on request



SiLibeads®

...more effective drugs



TYPE P Pharma, Borosilicate Glass

Chemical Analysis	Weight %
Silicon dioxide SiO ₂	81.00
Boron oxide B ₂ O ₃	13.00
Sodium oxide Na ₂ O	4.00
Potassium oxide K ₂ O	
Aluminum oxide Al ₂ O ₃	2.00

Chemical Data		
Hydrolytic Resistance	HGB 1	DIN ISO 720
Acid Class	S1	DIN 12116
Alkaline Class	A1	DIN ISO 695



55-02500-90 RTS
Ø 2.5 mm

TYPE P
Pharma
Size range
2.0 – 6.0 mm

TYPE M, Borosilicate Glass

Chemical Analysis	Weight %
Silicon dioxide SiO ₂	81.00
Boron oxide B ₂ O ₃	13.00
Sodium oxide Na ₂ O	4.00
Potassium oxide K ₂ O	
Aluminum oxide Al ₂ O ₃	2.00

Chemical Data		
Hydrolytic Resistance	HGB 1	DIN ISO 720
Acid Class	S1	DIN 12116
Alkaline Class	A1	DIN ISO 695



55-06000-89-GMP-DW
Ø 6.0 mm

TYPE M
Size range
2.5 – 10.0 mm

TYPE M, Soda Lime Glass

Chemical Analysis	Weight %
Silicon dioxide SiO ₂	69.30
Sodium oxide Na ₂ O	10.30
Calcium oxide CaO	4.90
Potassium oxide K ₂ O	6.10
Barium oxide BaO	4.80
Others	4.60

Chemical Data		
Hydrolytic Resistance	HGB 1	DIN ISO 720
Acid Class	S2	DIN 12116
Alkaline Class	A1	DIN ISO 695



5009-99-5-GMP-DW
Ø 4.0 mm

TYPE M
Size range
2.0 – 10.0 mm

TYPE S, Soda Lime Glass

Chemical Analysis	Weight %
Silicon dioxide SiO ₂	69.30
Sodium oxide Na ₂ O	10.30
Calcium oxide CaO	4.90
Potassium oxide K ₂ O	6.10
Barium oxide BaO	4.80
Others	4.60

Chemical Data		
Hydrolytic Resistance	HGB 2	DIN ISO 720
Acid Class	S2	DIN 12116
Alkaline Class	A1	DIN ISO 695



4502-GMP-DW
Ø 0.50 - 0.75 mm

TYPE S
Size range
0.25 – 2.0 mm

TYPE ZY-P Pharma, Zirconiumoxide / Yttrium stabilized

Chemical Analysis	Weight %
Zirconiumoxide ZrO ₂	95.00 +/- 0.50
Hafniumoxide HfO ₂	
Yttriumoxide Y ₂ O ₃ stabilized	5.00 +0.20/- 0.60
Others	0.30

Chemical Data		
Hydrolytic Resistance	HGB 1	DIN ISO 720
Acid Class	S1	DIN 12116
Alkaline Class	A2	DIN ISO 695
Specific Weight	-	≥ 6.0 kg/l
Young's-Modulus	-	≥ 210 GPa
Microhardness	-	≥ 1300 HV ₁₀



990095-GMP-DW
Ø 0.1 mm

TYPE ZY-P
Pharma
Size range
0.1 – 0.5 mm



Washing Processes

**TYPE P
Pharma**
Size range
2.0 – 6.0 mm



55-02500-90 RTS
Ø 2.5 mm

TYPE M
Size range
2.5 – 10.0 mm



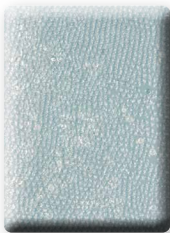
55-06000-89-GMP-DW
Ø 6.0 mm

TYPE M
Size range
2.0 – 10.0 mm



5009-99-5-GMP-DW
Ø 4.0 mm

TYPE S
Size range
0.25 – 2.0 mm



4502-GMP-DW
Ø 0.50 - 0.75 mm

**TYPE ZY-P
Pharma**
Size range
0.1 – 0.5 mm



990095-GMP-DW
Ø 0.1 mm

Glass Beads / Ceramic Beads GMP-DW

Water Quality

- Drinking water according to German drinking water regulations

Parameters	Unit	Value
Conductivity	µS/cm	≤ 2,790 (at 25°C)
TOC	mg/l	≤ 5.0
Nitrate (NO ₃)	ppm	≤ 50
Microbiology/ Purity	CFU/100ml	N/A
Endotoxine (bacteria)	IU/ml	N/A

Washing

- Special device with centrifugal movement of the concentrate
- Deconex® Cip Seven pharma cleaning concentrate

Cleanroom

- Cleanroom conditions ISO 7 in accordance with DIN EN ISO 14644

Customized Packaging

- Plastic bags, produced under cleanroom conditions
- Media bottles (PETG)

SiLibeads® Glass Beads

Size range: 0.5 – 6.0 mm

SiLibeads® Ceramic Beads

Size range: 0.1 – 5.0 mm

Glass Beads / Ceramic Beads GMP-PW-RTS

Water Quality

- Pure water highly deionized

Parameters	Unit	Value
Conductivity	µS/cm	≤ 1.1 (at 20°C)
TOC	mg/l	≤ 0.5
Nitrate (NO ₃)	ppm	≤ 50
Microbiology/ Purity	CFU/100ml	N/A
Endotoxine (bacteria)	IU/ml	N/A

Washing

- Special device with centrifugal movement of the concentrate
- Device Terion CEDI / reverse osmosis
- Deconex® Cip Seven pharma cleaning concentrate

Cleanroom

- Cleanroom conditions ISO 7 in accordance with DIN EN ISO 14644
- Use for Ready-to-sterilize (RTS) possible

Customized Packaging

- Plastic bags, produced under cleanroom conditions
- See-through pouches flat made of paper and film (Stericlin®- meet requirement of DIN EN ISO 11607 and DIN 868-5)
- Media bottles (PETG)

SiLibeads® Glass Beads

Size range: 0.5 – 6.0 mm

SiLibeads® Ceramic Beads

Size range: 0.1 – 5.0 mm

Glass Beads GMP-RTS

Water Quality

- Water for Injections (WFI)

Parameters	Unit	Value
Conductivity	µS/cm	≤ 1.1 (at 20°C)
TOC	mg/l	≤ 0.5
Nitrate (NO ₃)	ppm	≤ 0.2
Microbiology/ Purity	CFU/100ml	≤ 10
Endotoxine (bacteria)	IU/ml	≤ 0.25

Washing

- Washer meets GMP, GAMP and FDA 21 CFR Part 11 requirements
- Deconex® Cip Seven pharma cleaning concentrate

Cleanroom

- Cleanroom conditions ISO 7 in accordance with DIN EN ISO 14644; Grade C (GMP)
- Ready-to-sterilize (RTS) approved

Regulatory requirements

- In accordance with Pharmacopoeia Ph.Eur, USP, JP
- Special cleaning process according to GMP, ISPE, FDA guidelines
- In accordance with FDA (Drug Master File) and CDE (Registration) regulations

Customized Packaging

- Ready-to-use bags, full Tyvek® front and rear from HDPE film, enables sterilization without contamination risk
- Media bottles (PETG)

SiLibeads® Glass Beads

Size range: 2.0 – 6.0 mm



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