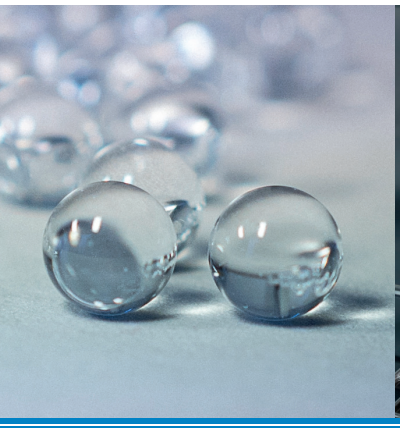
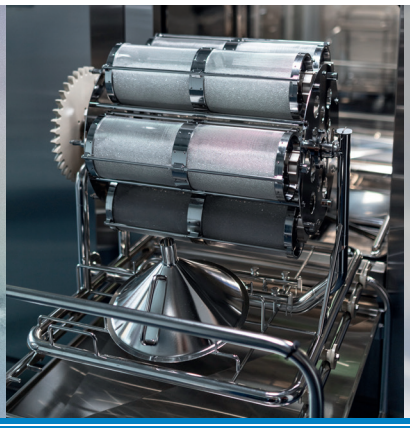
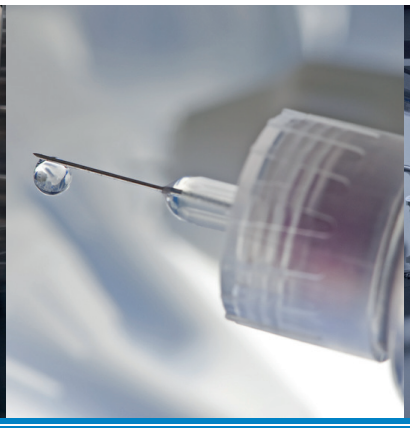
The German spirit of quality since 1854

SiLi® SIGMUND LINDNER

SiLibeads®

…more effective drugs


SiLibeads® Type P Pharma

Product Contact Component

Glass beads made of soda-lime glass or high-quality borosilicate glass (1.5mm-6.00mm)

Material properties:

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

Chemical Resistance according to DIN methods: (Borosilicate)

- Hydrolytic Resistance HGA 1 (DIN ISO 720)
- Acid Class S1 (DIN 12116)
- Alkaline Class A2 (DIN ISO 695)

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

Cleaning Process and applied regulations:

Water Quality

- Highly Purified Water (HPW) in accordance with the European Pharmacopoeia (Ph.Eur.)

Washer

- Washer meets GMP, GAMP and FDA 21 CFR Part 11 requirements.

Cleanroom

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

Packaging:

- Customised packaging for sterilization

Applications:

- Mechanical cell disruption
- Mixing drugs

Soda-lime glass beads

Chemical Analysis	Weight %
Silicon dioxide SiO_2	69.30
Sodium oxide Na_2O	10.30
Calcium oxide CaO	4.90
Potassium oxide K_2O	6.10
Barium oxide BaO	4.80
Further	4.60

Borosilicate glass beads

Chemical Analysis	Weight %
Silicon dioxide SiO_2	81
Boron oxide B_2O_3	13
Sodium oxide $Na_2O + K_2O$	4
Potassium oxide Al_2O_3	2

The heavy metal content (Pb, Cd, Hg, Cr-VI) is below 100 ppm

Size Range: 1.5mm - 6.00mm

Toleranze: +/- 0.02mm
+/- 0.2

For more technical information please contact:

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SiLibeads®

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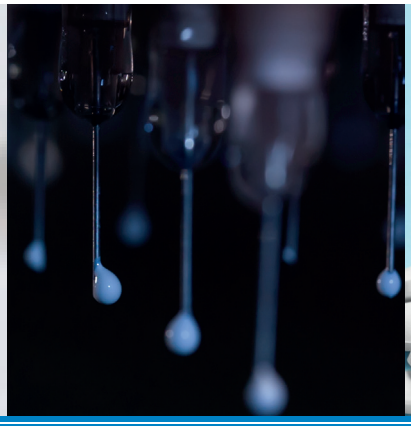

SiLibeads® Type ZY-P Pharma

Product Contact Component

Ceramic beads made of zirconium oxide / yttrium stabilized (0.08mm-1.6mm)

Material properties:

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

Chemical Resistance according to DIN methods:

- Hydrolytic Resistance HGA 1 (DIN ISO 720)
- Acid Class S1 (DIN 12116)
- Alkaline Class A1 (DIN ISO 695)

Regulatory requirements:

- In accordance with ICH Q3D(R1) guidelines
- Special cleaning process according to GMP, ISPE, FDA guidelines
- In accordance with FDA (Drug Master File)

Cleaning Process and applied regulations:

Water Quality

- Highly Purified Water (HPW) in accordance with the European Pharmacopoeia (Ph.Eur.)

Washer

- Washer meets GMP, GAMP and FDA 21 CFR Part 11 requirements.

Cleanroom

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

Packaging:

- Customised packaging

Applications:

- Mechanical cell disruption
- Particle size reduction (nano size)

Chemical Analysis	Weight %
Zirconium oxide Yttrium stabalized	99.70
Others	0.30

The heavy metal content (Pb, Cd, Hg, Cr-VI) is below 100 ppm

Technical Data	
Specific Weight	6.05 kg/l
Young's-Modulus	215 GPa
Microhardness	1400 HV_{10}

Size Range: 0.08mm - 1.60mm

For more technical information please contact:

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SiLibeads®

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