

The German
spirit of quality
since 1854



SiLibeads®

...more effective drugs



SiLibeads® Type ZY-P Pharma Product Contact Component Ceramic beads made of zirconium oxide / yttrium stabilized (0.10mm-2.00mm)

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

- Water for Injections (WFI) in accordance with the European Pharmacopoeia (Ph. Eur. Monograph 0169) and USP requirements.

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) in preparation.

Packaging:

- Customised packaging

Applications:

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

Chemical Analysis

	Weight %
Zirconiumoxide ZrO_2 +	$ZrO_2 + HfO_2$:
Hafniumoxide HfO_2	95.00 +/- 0.50
Yttriumoxide Y_2O_3 stabilized	Y_2O_3 : 5.00
	+ 0.20/- 0.60

Others	0.30
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The heavy metal content content of the Glass beads keeps the permitted limits of EU directive 2011/65/EC (RoHS).

Technical Data

Specific Weight	≥ 6.0 kg/l
Young's-Modulus	≥ 210 GPa
Microhardness	≥ 1300 HV ₁₀

Size Range: 0.10mm - 2.00mm

For more technical information please contact:

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