

The German
spirit of quality
since 1854



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

- 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).

Packaging:

- Customised packaging for sterilization

Applications:

- Mechanical cell disruption
- Mixing drugs
- Production of vaccines

Soda-lime glass beads

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
Further	4.60

Borosilicate glass beads

Chemical Analysis	Weight %
Silicon dioxide SiO ₂	81
Boron oxide B ₂ O ₃	13
Sodium oxide Na ₂ O + K ₂ O	4
Potassium oxide Al ₂ O ₃	2

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

Size Range: 1.5mm - 6.00mm

For more technical information please contact:

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