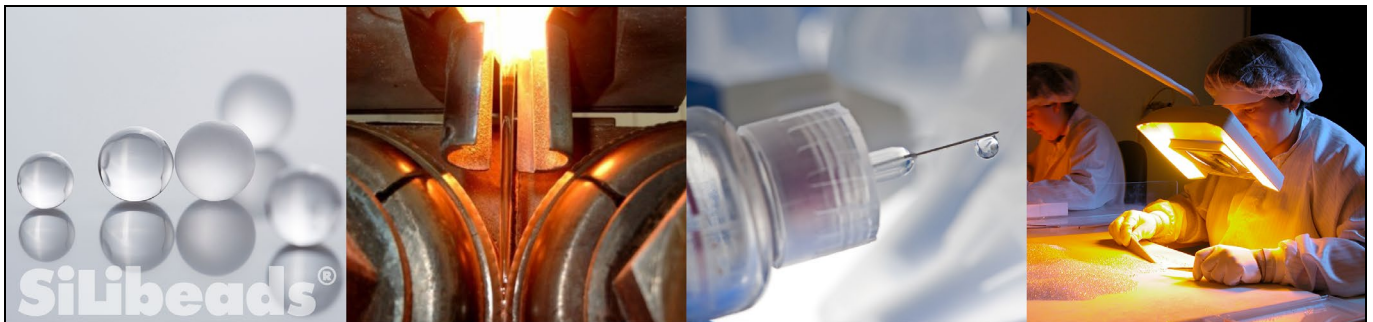




**SiLibeads® Type P PHARMA RTS**

Version: 2019-12-12 V4



**Chemical/Technical Parameter**

**Article:** Glass Beads Borosilicate Type I Glass RTS (Ready to Sterilize)  
 2.50 mm +/- 0.05 mm polished  
 Article No. 55-02500-90RTS

**Type of glass and applied regulations:** Glass Beads are in accordance with the current versions of Pharmacopoeia Ph. Eur., USP and JP

**Cleaning Process and applied regulations:**

**Water Quality**  
 Water for Injections (WFI) in accordance with the European Pharmacopoeia (Ph. Eur. Monograph 0169)

**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).

**Chemical Composition** (main components in approx. weight %):

SiO <sub>2</sub>	81 %
B <sub>2</sub> O <sub>3</sub>	13 %
Na <sub>2</sub> O + K <sub>2</sub> O	4 %
Al <sub>2</sub> O <sub>3</sub>	2 %

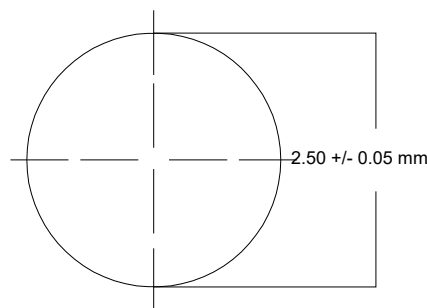
The heavy metal content (Pb, Cd, Hg, Cr-VI) is below 100 ppm

**Chemical Resistance according DIN methods:**

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

**Density:** 2.23 kg/dm<sup>3</sup>

**Diameter:** 2.50 mm Ø



**Ø-Tolerance:** +/- 0.05 mm

**Surface roughness:** Sa < 0.111 µm

**Glass Beads for Medicinal Applications RTS**  
**Technical Specification**



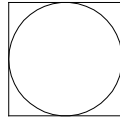
*The German spirit of quality since 1854*



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**Sphericity:** 0.1 mm



Ovality max.  
0.1 mm

**Quantity per kg:** ≈ 54,800 pcs.

**Inspection Strategy:**

- ① 100 % Quality Control by a permanent validated optical inspection systems in clean room class 7 (EN ISO 14644) / Grade C (GMP)
- ② Final inspection by attributes in accordance to DIN ISO 2859-1

Criteria	inspection equipment	scope of inspection	AQL
<b>Diameter: beads out of specification Tolerance</b> 2.45 – 2.55 mm	Inspector (Measuring of diameter with calibrated Micrometer)	ISO 2859-1 Special Inspection S3 AQL table 2-A, Code H Amount: 50 pcs. per Lot-Number	<b>MINOR</b> AQL = 2.5 accepted 3 beads / rejected ≥ 4 beads
<b>Wrong Beads:</b> (e.g. coloured or matt beads)	Inspector (visual final control with lighted magnifier)	ISO 2859-1 General Inspect. Level II AQL table 2-A; Code Q Amount: 1,250 pcs. per Lot-Number	<b>CRITICAL</b> AQL = 0.010 accepted 0 beads / rejected ≥ 1 bead(s)
<b>Broken beads</b> (also half beads or broken twins)			<b>CRITICAL</b> AQL = 0.010 accepted 0 beads / rejected ≥ 1 bead(s)
<b>Hair or hair like fibers</b>			<b>CRITICAL</b> AQL = 0.010 accepted 0 hair/fibres / rejected ≥ 1 hair/fibres
<b>Cosmetical defects</b> (dents, scratches, cracks, holes, cullets) <b>+ Foreign material</b> (fixed spot) on the glass bead surface <b>Size area ≥ 0.05 mm<sup>2</sup></b> (Diameter/Diagonal ≥ 0.25 mm)			<b>MAJOR</b> AQL = 0.40 accepted ≤ 10 beads / rejected ≥ 11 beads

Packaging has to be defined by/with the customer.

Shelf Life:	Sigmund Lindner recommends a shelf life of maximum 1 year for the glass beads packed in sterilizable bags (packaging made with DuPont Tyvek®).
Storage Conditions:	Dry and at room temperature. Protect from heat and direct sunlight.

Issued by	Released by		Effective date
Reinhold Schneider Quality Manager	Michael Dressler Head of Quality / Product Manager for Pharma and Food Applications		12.12.2019
12.12.2019	12.12.2019		