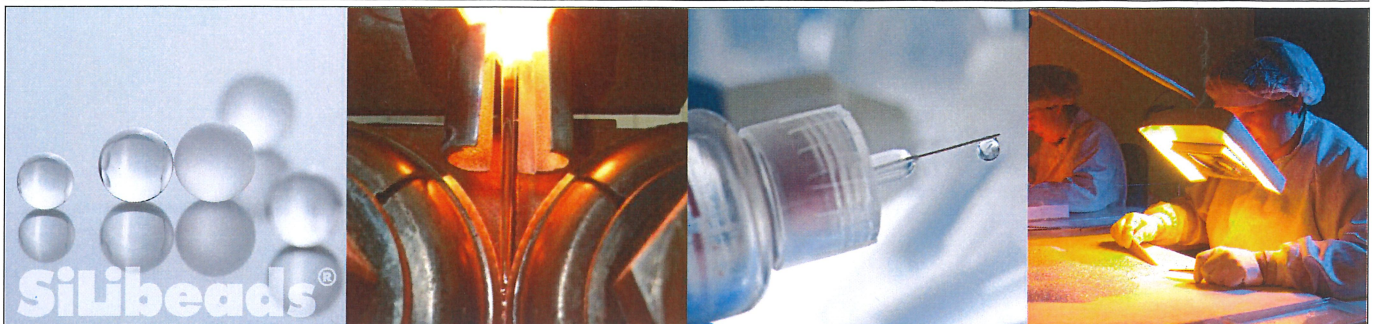


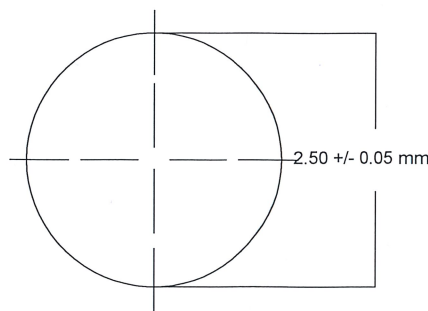
SiLibeads[®] Type P PHARMA RTS

Version: 2020-08-21 V6



Chemical/Technical Parameter

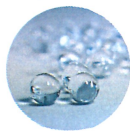
Article:	Glass Beads Borosilicate Type I Glass RTS (Ready to Sterilize) 2.50 mm +/- 0.05 mm polished Article No. 55-02500-90RTS	
Type of glass and applied regulations:	Glass Beads are in accordance with the current versions of Pharmacopoeia Ph. Eur., USP and JP	
Cleaning Process and applied regulations:	<p>Water Quality Water for Injections (WFI) in accordance with the European Pharmacopoeia (Ph. Eur. Monograph 0169) and USP requirements.</p> <p>Washer Washer meets GMP, GAMP and FDA 21 CFR Part 11 requirements.</p> <p>Cleanroom Cleanroom conditions ISO 7 in accordance with DIN EN ISO 14644; Grade C (GMP).</p>	
Chemical Composition (main components in approx. weight %):	SiO ₂	81 %
	B ₂ O ₃	13 %
	Na ₂ O + K ₂ O	4 %
	Al ₂ O ₃	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 ³	
Diameter:	2.50 mm Ø	



Ø-Tolerance: +/- 0.05 mm

Surface roughness: $S_a < 0.111 \mu\text{m}$

Glass Beads for Medicinal Applications RTS
Technical Specification



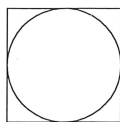
The German spirit of quality since 1854



SiLibeads® Type P PHARMA RTS

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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
Diameter: beads out of specification Tolerance 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	MINOR AQL = 2.5 accepted 3 beads / rejected ≥ 4 beads
Wrong Beads: (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	CRITICAL AQL = 0.010 accepted 0 beads / rejected ≥ 1 bead(s)
Broken beads (also half beads or broken twins)			CRITICAL AQL = 0.010 accepted 0 beads / rejected ≥ 1 bead(s)
Hair or hair like fibers			CRITICAL AQL = 0.010 accepted 0 hair/fibres / rejected ≥ 1 hair/fibres
Cosmetical defects (dents, scratches, cracks, holes, cullets) + Foreign material (fixed spot) on the glass bead surface Size area ≥ 0.05 mm² (Diameter/Diagonal ≥ 0.25 mm)			MAJOR AQL = 0.40 accepted ≤ 10 beads / rejected ≥ 11 beads

Packaging in sterilisable bags (made with DuPont Tyvek®) has to be specified by/with the customer.

Shelf Life: From the date forth of washing/packaging Sigmund Lindner recommends a shelf life of maximum 3 years for the glass beads packed in sterilisable bags (packaging made with DuPont Tyvek®).

Storage Conditions: In original packaging. Dry and at room temperature. Protect from heat and direct sunlight.

Issued by	Released by	Effective date
Marius Amschler Quality Assurance <i>Marius Amschler</i> 21.08.2020	Michael Dressler Head of Quality / Product Manager for Pharma and Food Applications <i>M. Dressler</i> 21.08.2020	21.08.2020