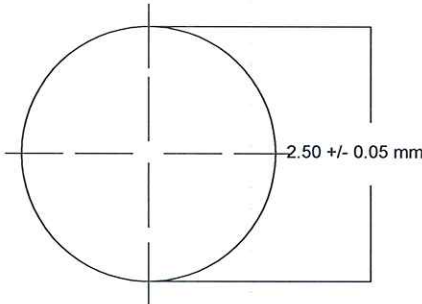
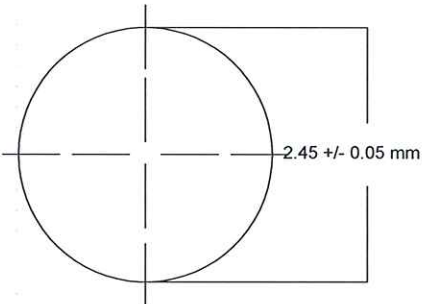
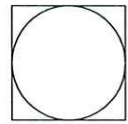
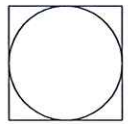
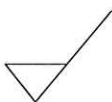
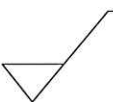


Glass Beads Type I Glass for Pharmaceutical Industry as mixing beads in insulin cartridges


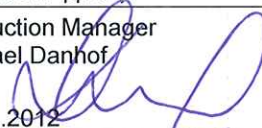
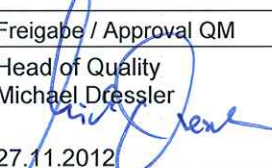
Chemical/Technical Parameter

Pharmaceutical Data	Glass Beads are in accordance with the current versions of Pharmacopoeia Ph.Eur., USP and JP	
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 for the elements Pb, Cd, Hg, Cr-VI is below 100 ppm
Chemical Resistance according DIN methods (tested on beads)	Hydrolytic Class HGB 1 (DIN ISO 719) Acid Class S1 (DIN 12116) Alcaline Class A2 (DIN ISO 695)	
Specific Weight	2,23 kg/dm ³	2,23 kg/dm ³
Diameter (further diameter by request)	2,50 mm Ø 	2,45 mm Ø 
Ø-Tolerance	+/- 0,05 mm	+/- 0,05 mm
Sphericity	0,1 mm  Ovality max. 0,1 mm	0,1 mm  Ovality max. 0,1 mm
Roughness	 Ra < 0,03 µm	 Ra < 0,03 µm

① 100 % Quality Control by optical inspection system
in clean room ISO 8 / Grade D (GMP)

② Final Control - Specification of potential faults (List of Defects)

Criteria of Defects	Inspection Equipment	Inspection Scope	Tolerance Acceptance
Diameter: Beads outside tolerance 2,50 mm (min. 2,45 mm / max. 2,55 mm) 2,45 mm (min. 2,40 mm / max. 2,50 mm)	Inspector Diameter check with calibrated Micrometer	ISO 2859-1 Special Inspect. S3 AQL table 2-A sample size: 50 beads per Lot	AQL = 0,25 Approval: 0 beads / Blocked: ≥ 1 beads
Faults inside the glass bead: stones, nodes and air bubbles (> 0,20 mm)	Inspector Visual final control with help of lighted magnifier	ISO 2859-1 General Inspect. Level II AQL table 2-A sample size: 1250 beads per Lot	AQL = 0,4 Approval: ≤ 10 beads/ Blocked: ≥ 11 beads
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)	Inspector Visual final control with help of lighted magnifier	ISO 2859-1 General Inspect. Level II AQL table 2-A sample size: 1250 beads per Lot	AQL = 0,4 Approval: ≤ 10 beads/ Blocked: ≥ 11 beads
Typ I Glass (hydrolytic resistance of powdered glass)	Pharmacopoeia Test made by Dorfner Analysezentrum	200 gr. beads (taken from sorting in clean room)	Results of glass grain tests are conform to current limits of Ph.Eur, USP and JP

Ersteller / Authoring/Implementer	Freigabe / Approval	Freigabe / Approval QM	Gültig ab / valid from
Quality Manager, Reinhold Schneider 26.11.2012 	Production Manager Michael Danhof 27.11.2012 	Head of Quality Michael Dressler 27.11.2012 	03.12.2012