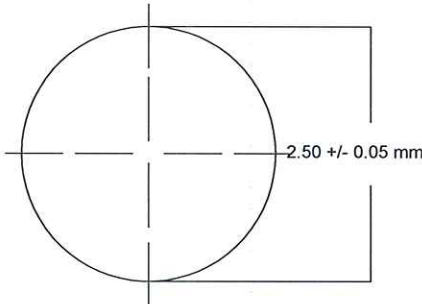
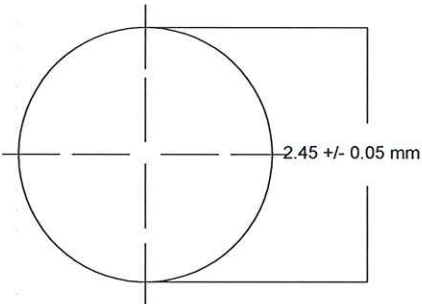
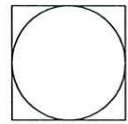
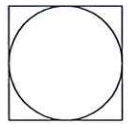
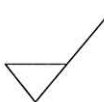
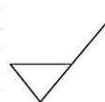


## Glass Beads Type I Glass for Pharmaceutical Industry as mixing beads in insulin cartridges



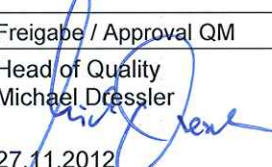
### Chemical/Technical Parameter

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

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
<b>Diameter:</b> 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 <b>Micrometer</b>	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
<b>Faults inside the glass bead:</b> stones, nodes and air bubbles (> 0,20 mm)	Inspector  Visual final control with help of <b>lighted magnifier</b>	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
<b>Cosmetical defects</b> (dents, scratches, cracks, holes, cullets) + <b>Foreign material</b> (fixed spot) <b>on the glass bead surface</b>  <b>Size area ≥ 0,05 mm<sup>2</sup></b> (Diameter/Diagonal ≥ 0,25 mm)	Inspector  Visual final control with help of <b>lighted magnifier</b>	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
<b>Typ I Glass</b> (hydrolytic resistance of powdered glass)	<b>Pharmacopoeia Test</b> 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