

# Specification - Pharmaceutical Beads

Data file: C4 Technical Specification for Pharmaceutical Beads 2010-02-08 V3



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

### Chemical/Technical Parameter

<b>Pharmaceutical Datas</b>	Glass Beads are in accordance with the current version of Pharmacopoeia Ph.Eur., USP and JP	
<b>Chemical Composition – Main Components</b> (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 for the elements Pb, Cd, Hg, Cr-VI is below 100 ppm
<b>Chemical Resistance according to DIN methods</b>	Hydrolytic Class HGB 1 Acid Class S 1 Alcaline Class A 1	ISO 719 DIN 12116 ISO 695
<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)	2,50 mm Ø	2,45 mm Ø
<b>Ø-Tolerance</b>	+/- 0,05 mm	+/- 0,05 mm
<b>Roundness-Tolerance</b>	0,1 mm	0,1 mm
<b>Surface</b>	polished	polished
<b>Roughness</b>	Rz ≤ 2,0 µm	Rz ≤ 2,0 µm

**Quality Control (100 % Control) by automatically sorting system / Clean Room Class 100.000**

### Specification of potential faults / List of Defects

Criteria of Defects	Inspection Equipment	Inspection Scope	Tolerance Accept
<b>Diameter:</b> Beads outside diameter tolerance 2,50 mm (min. 2,45 mm / max. 2,55 mm) 2,45 mm (min. 2,40 mm / max. 2,50 mm)	Inspector (Measuring of diameter with calibrated <b>Micrometer</b> )	ISO 2859-1 Special Inspection 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 (> 0,1 mm)	Inspector (visual final control with <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, culllets) + <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 <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>Amalgamated beads</b> (inseparable block, „8 shape“ 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)	Limit Ph.Eur: 1.0 ml Condition: 0.02 m HCl per 10.0 gr. of glass
Authoring/Implementer Quality Manager, Reinhold Schneider 03.02.2010 <i>Scheid</i>	Approval Technical Manager, Dr. Ralf-Peter Hitzschke 04.02.2010 <i>Dr. Hitzschke</i>	Approval Head of Quality + Innovation, Michael Dressler 04.02.2010 <i>M. Dressler</i>	valid from 08.02.2010