

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

Pharmaceutical Datas	Glass Beads are in accordance with the current version 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 to DIN methods	Hydrolytic Class HGB 1 Acid Class S 1 Alcaline Class A 1	ISO 719 DIN 12116 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
Roundness-Tolerance	0,1 mm	0,1 mm
Surface	polished	polished
Roughness	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
Diameter: 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 Micrometer)	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
Faults inside the glass bead: stones, nodes and air bubbles (> 0,1 mm)	Inspector (visual final control with 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, culllets) + Foreign material (fixed spot) on the glass bead surface Size area ≥ 0,05 mm² (Diameter/Diagonal ≥ 0,25 mm)	Inspector (visual final control with 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
Amalgamated beads (inseparable block, „8 shape“ beads)			
Typ I Glass (hydrolytic resistance of powdered glass)	Pharmacopoeia Test 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