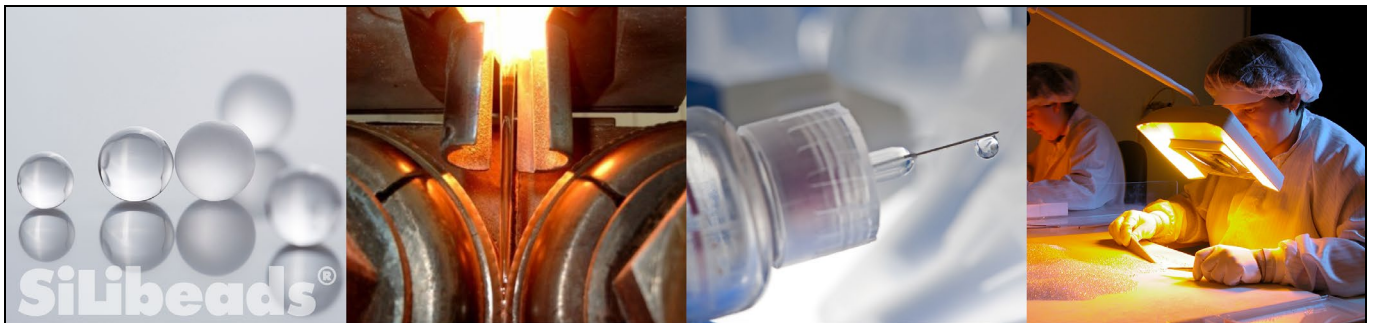




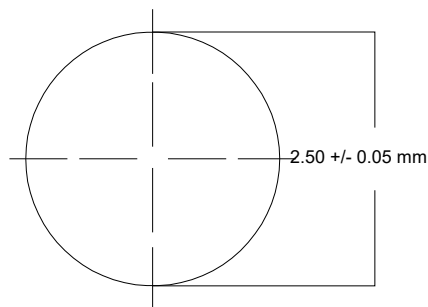
**SiLibeads® Type P PHARMA**

Version: 2019-12-12 V14

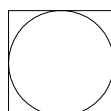


**Chemical/Technical Parameter**

|   |  |                     |
|---|--|---------------------|
| <b>Article:</b>   | Glass Beads Borosilicate Type I Glass<br>2.50 mm +/- 0.05 mm polished<br>Article No. 55-02500-90   |                     |
| <b>Type of glass beads and applied regulations:</b>                   | Glass Beads are in accordance with the current versions of Pharmacopoeia Ph. Eur., USP and JP      |                     |
| <b>Registrations:</b>   | U.S. FDA Drug Master File Number 15588<br>China CFDA Registration Number B20180001251              |                     |
| <b>Final washing:</b>   | Final washing is done with drinking water in accordance with the German Drinking Water Regulation. |                     |
| <b>Chemical Composition</b><br>(main components 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 (Pb, Cd, Hg, Cr-VI) is below 100 ppm                                       |                     |
| <b>Chemical Resistance according DIN methods:</b>                     | Hydrolytic Resistance  | HGA 1 (DIN ISO 720) |
|   | Acid Class   | S1 (DIN 12116)      |
|   | Alkaline Class   | A2 (DIN ISO 695)    |
| <b>Density:</b>   | 2.23 kg/dm <sup>3</sup>  |                     |
| <b>Diameter:</b>  | 2.50 mm Ø  |                     |



|                     |             |
|---------------------|-------------|
| <b>Ø-Tolerance:</b> | +/- 0.05 mm |
| <b>Sphericity:</b>  | 0.1 mm      |



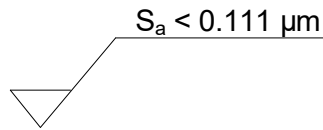
Ovality max.  
0.1 mm



**SiLibeads® Type P PHARMA**

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**Surface roughness:**



**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   |
|---|---|---|---|
| <b>Diameter: beads out of specification Tolerance</b><br>2.45 – 2.55 mm   | Inspector<br>(Measuring of diameter with calibrated Micrometer) | ISO 2859-1<br>Special Inspection S3<br>AQL table 2-A, Code H<br>Amount: 50 pcs. per Lot-Number        | <b>MINOR</b> AQL = 2.5<br>accepted 3 beads /<br>rejected ≥ 4 beads                  |
| <b>Wrong Beads:</b><br>(e.g. coloured or matt beads)  | Inspector<br>(visual final control with lighted magnifier)      | ISO 2859-1<br>General Inspect. Level II<br>AQL table 2-A; Code Q<br>Amount: 1,250 pcs. per Lot-Number | <b>CRITICAL</b> AQL = 0.010<br>accepted 0 beads /<br>rejected ≥ 1 bead(s)           |
| <b>Broken beads</b><br>(also half beads or broken twins)  |   |   | <b>CRITICAL</b> AQL = 0.010<br>accepted 0 beads /<br>rejected ≥ 1 bead(s)           |
| <b>Hair or hair like fibers</b>   |   |   | <b>CRITICAL</b> AQL = 0.010<br>accepted 0 hair/fibres /<br>rejected ≥ 1 hair/fibres |
| <b>Cosmetical defects</b><br>(dents, scratches, cracks, holes, cullets)<br><b>+ Foreign material</b><br>(fixed spot) on the glass bead surface<br><b>Size area ≥ 0.05 mm<sup>2</sup></b><br>(Diameter/Diagonal ≥ 0.25 mm) |   |   | <b>MAJOR</b> AQL = 0.40<br>accepted ≤ 10 beads /<br>rejected ≥ 11 beads             |

Standard-Packaging of beads: Plastic-bags á 5 kg, packed in carton boxes

|                     |  |
|---------------------|--|
| Shelf Life:         | Sigmund Lindner recommends a shelf life of maximum 3 years for the glass beads.                      |
| Storage conditions: | - temperature from 2 °C to 30 °C<br>- humidity not more than 65 %<br>- storage in original packaging |

|                                       |   |  |                |
|---------------------------------------|---|--|----------------|
| Issued by                             | Released by   |  | Effective date |
| Reinhold Schneider<br>Quality Manager | Michael Dressler<br>Head of Quality / Product Manager<br>for Pharma and Food Applications |  | 12.12.2019     |
| 12.12.2019                            | 12.12.2019  |  |                |