**SPU-KO-14-0092-01**

**Vials for injection from tubular transparent glass type FLP-10**

**Quality control according to the manufacturer's specification**

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| **№** | **Control parameters** | **Methods** | **Test methods** | **Acceptance criteria** |
| 1 | Application |  |  | For packaging, storage or transportation of medicines |
| 2 | Name of quality indicators  2.2.Indelible dirt and glass dust  2.3.Geometric dimensions:  2.3.1. Body diameter d1, mm  2.3.2 Outer diameter of the corolla d2, mm  2.3.3 Inner diameter of the throat d4, mm  2.3.4. The outer diameter of the throat d3, mm  2.3.5 Total height, h1  2.3.6. Corolla height, h3  2.3.7. throat height, h4  2.3.8. Body wall thickness, S1  2.3.9. bottom wall thickness, S2  2.3.10Bottom concavity  2.4deviation of the vertical axis,мм  2.5. annealing quality  2.6. water resistance of the inner surface  2.7. Acceptance level of quality,% | Visual  Visual  Measurement of linear dimensions | Standard operating procedures – SOP-KO-14-102  SOP-KO-14-102  SOP-KO-14-141  YBB00192003  YBB00162003  YBB00242003, ISO4802-1-2009 | The surface should be transparent and smooth without visible glass defects and cracks.  The shape of the edge (flange), the neck of the shoulders and the bottom should comply to the drawing  The smooth leading edge should be free of glass folds, surface roughness, rolling, cracks of gas bubbles  There should be no glass folds or cracks on the neck under the edge.  The hangers should smoothly go into a smooth body of the bottle without folds of glass.  The vials should be free of scratches, cracks, capillary bubbles and grains of sand with a diameter of more than 0.5 mm.  The bottom of the bottle is concave, perpendicular to the bottle, ensures the stability of the bottle without vertical deviations.  The bottom surface should be free of gas bubbles.  The absence of small impurities or the outer surface of the bottles (glass particles, dust, soot). The absence of extraneous inclusions in the glass, as well as mechanical contamination.  Compliance with the values shown in the manufacturer's drawing  22,7±0,35  19,8+0,3/-0,4  12,9±0,3  Not more than 16,2  55±0,70  4,0+0,3/-0,5  8,5±0,5  1,1±0,05  min 0,7  max 1,0  not more 1,2  the difference in the course of the rays is no more than 40nm/ mm  according to the manufacturer's certificate for HCB class: no more than 1.6 ml of 0.01M hydrochloric acid solution per 100 ml of a solution  at least 95% |
| 3 | Sampling |  | in accordance with the standard operating procedure SO-KO-14-057 |  |
| 4 | Sample volumes |  |  | for testing - a laboratory sample of 100 pcs, for a bookmark in the archive - a control sample of 100 pcs. |
| 5 | Packaging |  |  | Vials in the amount of 1395 pcs, packed in cardboard boxes and wrapped with shrinkable PE film |