

Translated English of Chinese Standard: YBB00112004-2015

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National Drug Packing Container (Material) Standard

YBB 00112004-2015

Assemblages for prefilled syringes (with stainless-steel needles)

预封装注射器组合件（带注射针）

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Assemblages for prefilled syringes (with stainless-steel needles)

This standard applies to prefilled syringe assemblages (with stainless-steel needles). The assemblage consists of a glass needle, a rubber piston, a stainless-steel needle, a needle cap, and a putter.

[Appearance] TAKE appropriate amount of this product; MAKE direct visual inspection against the product in a bright place in natural light. The glass needle tube sleeve shall be free from cracks or fractures AND the curling shall be free from deformation; the cone and curling shall be free from cracks or breakage; the needle tube external surface shall be free from spots, stains, or scratches; there shall be no printing defects which may affect normal use; the needle shall be free from separation, reversing, or obstruction; AND the needle and needle cap shall be free from separation.

[Glass needle tube] It shall meet the requirements for the borosilicate glass needle tube which is used for the prefilled syringe (YBB00062004-2015).

[Rubber piston] It shall meet the requirements for the chlorinated butyl rubber piston (YBB00072004-2015) or the brominated butyl rubber piston (YBB00082004-2015) which is used for the prefilled syringe.

[Stainless-steel injection needle] It shall meet the requirements for the stainless-steel injection needle (YBB00092004-2015) which is used for the prefilled syringe.

[Needle cap] It shall meet the requirements of the polyisoprene rubber needle cap which is used for the prefilled syringe (YBB00102004-2015).

[Connection force between needle and needle seat] TAKE appropriate amount of this product; FIX the syringe onto the test machine; at the rate of 100 mm/min $\pm$ 5 mm/min AND the tensile force not less than 22 N, PERFORM the syringe pull test. There shall be no loosening or separation between the stainless-steel needle and the needle seat of the glass needle tube.

[Needle cap pull out force] TAKE appropriate amount of this product; FIX the needle cap and the syringe tube onto the upper and lower fixtures of the test machine; the test rate is 100 mm/min $\pm$ 5 mm/min. The pull-out force of the needle cap shall be 4.0 ~ 45.0 N.

[Fit between piston and putter] (only for threaded pistons) TAKE appropriate amount of this product; CONNECT the putter and the piston; INSERT the piston totally into the prefilled syringe which had been lubricated by the silicon oil and filled with half water; EMPTY the air; CAP the syringe needle; slowly WITHDRAW about 3 mm backwards. The putter shall be kept stable AND not be separated from the piston.

[Piston lubrication] Take appropriate amount of this product; INSERT the piston into the syringe tube which had been lubricated by silicone oil; USE the putter to push the piston into the entire syringe tube. The putter piston shall be moved smoothly AND free from sudden pause.

Connection force between needle and needle seat	S-2	2.5
Pull out force of needle cap	S-2	0.65
Piston sliding performance	S-2	6.5
Body sealability	S-2	2.5
Syringe tube residue	S-2	6.5
Indexing capacity accuracy	S-2	2.5

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