4040 Examination Method of Luer Conical Fitting of Prefilled Syringes

This method is used to examine the fitness of the Luer conical fitting of a prefilled syringe.

Reference connector

Reference connector is the standard connector that fits with the Luer conical fitting of the prefilled syringe during examination.

Reference connectors used to test the glass barrel of the prefilled syringe shall be manufactured from semi-rigid materials, and those used to test the plastic barrel shall be manufactured from corrosion-resistant rigid materials with a surface roughness value Ra not exceeding 0.8μm on critical surfaces. Semi-rigid material is the material with a modulus of elasticity in flexure or in tension between 60MPa and 3433MPa. Rigid material is the material with a modulus of elasticity in flexure or in tension greater than 3433MPa.

Reference connector specified in Fig. 1 is used to test the Luer non-locking connector. Reference connector specified in Fig. 2 is used to test the leakage, separation from screwing, stress cracking of the Luer lock connector. Reference connector specified in Fig. 3 is used to test the separation from axial load, overriding of the Luer lock connector.

Dimensions in millimeters

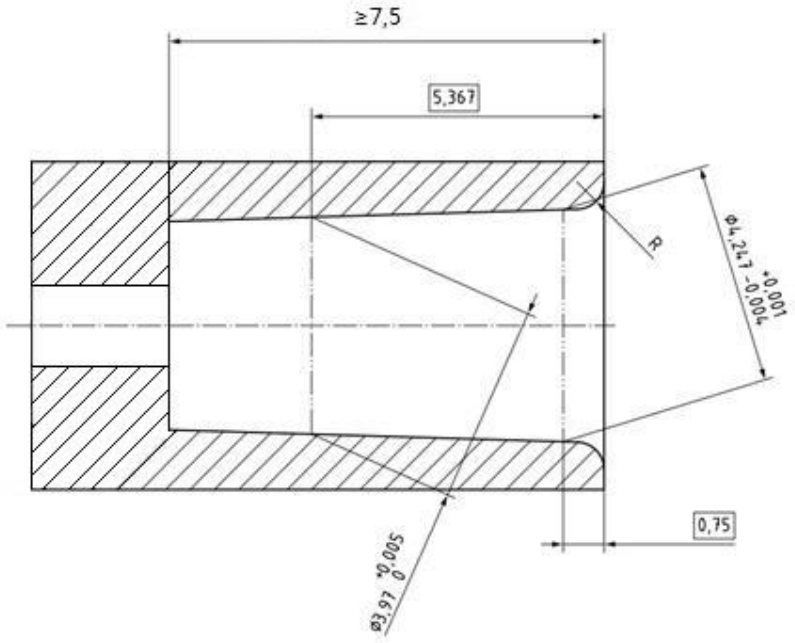

Fig. 1 Reference connector for Luer non-locking connector tests

Note1：R is the radius or chamfer not to exceed 0.5mm.

Note2：Conical taper 0.06:1.

Dimensions in millimeters

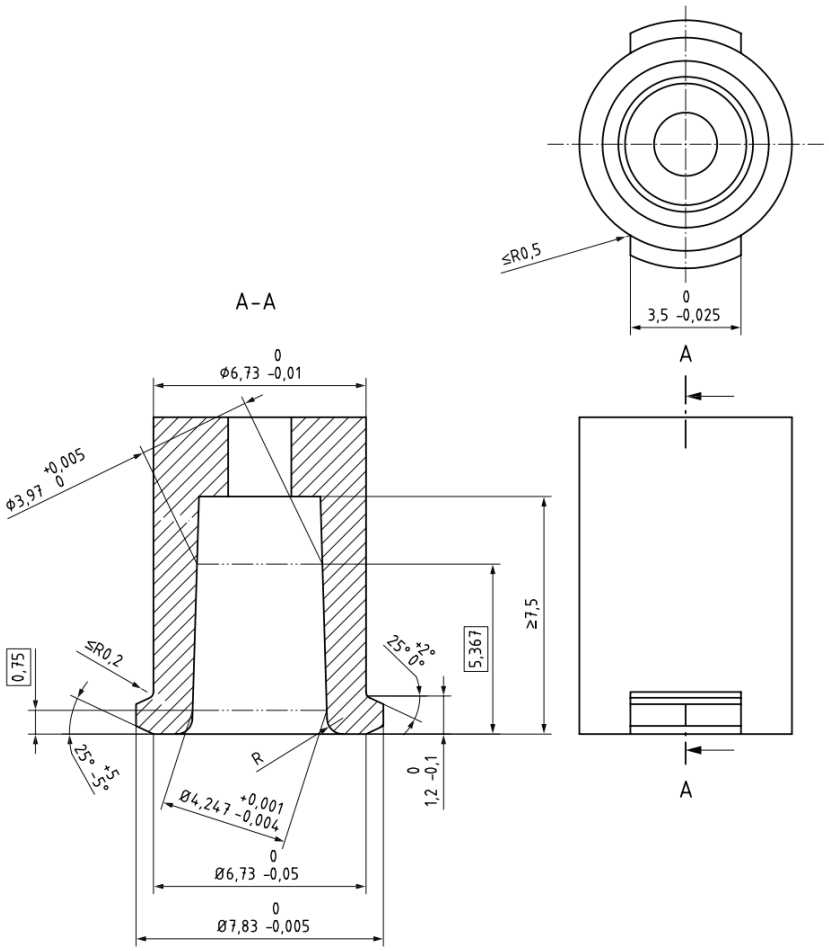

Fig. 2 Reference connector for leakage, separation from screwing and stress cracking test of Luer lock connector

Note：All outside edges of lug or thread form shall have a radius between 0.15mm and 0.20mm. R is the radius or chamfer not to exceed 0.5mm.

Dimensions in millimeters

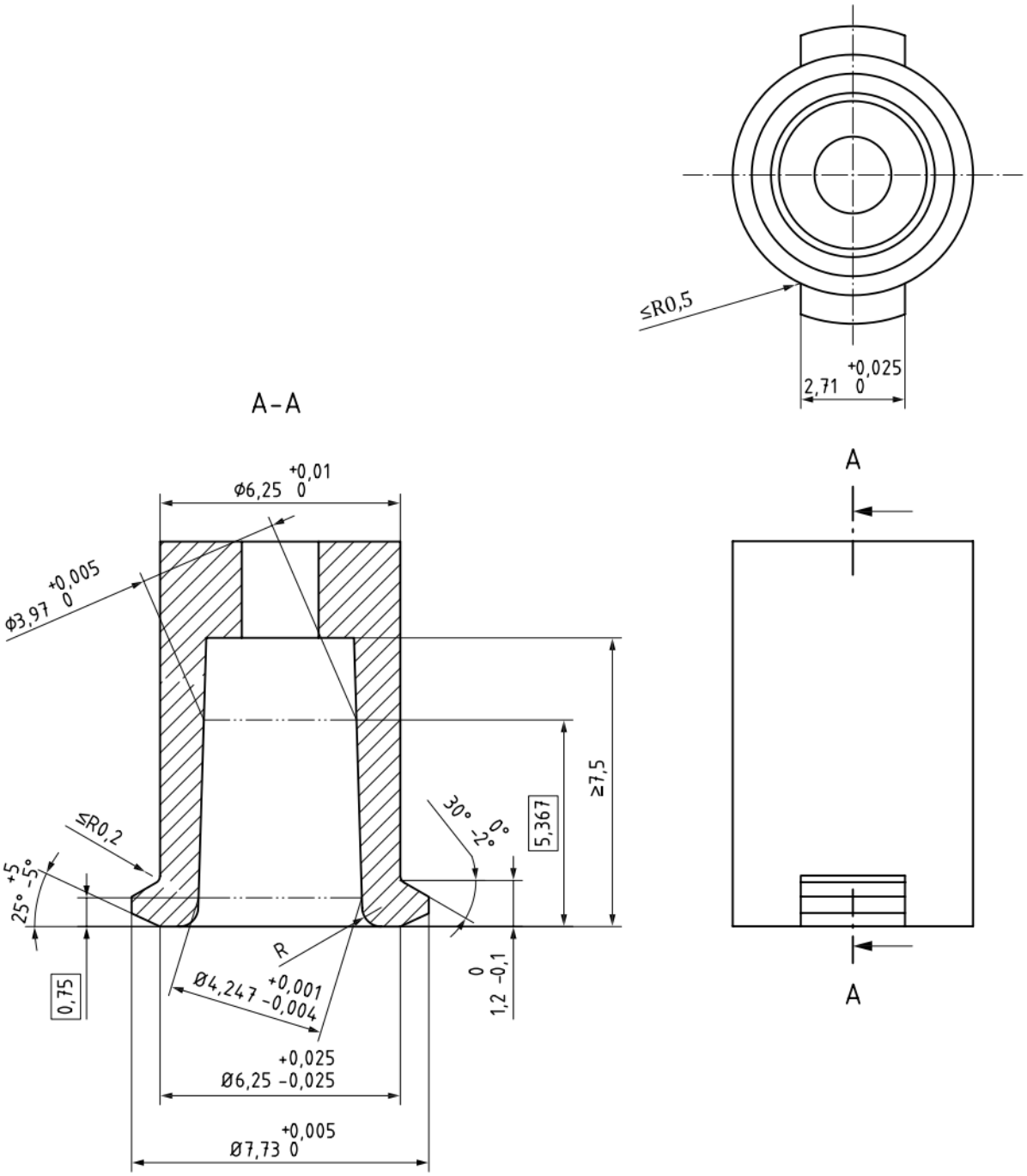

Fig. 3 Reference connector for separation from axial load and overriding test of Luer lock connector

Note：All outside edges of lug or thread form shall have a radius between 0.15mm and 0.20mm. R is the radius or chamfer not to exceed 0.5mm.

Environmental test conditions

Perform tests at a temperature within the range of 15℃ to 30℃ and at a relative humidity between 25% and 65%.

1. Positive-pressure liquid leakage test

Instruments

Reference connector, see Fig.1 or Fig.2.

Assembling device, which can simultaneously apply an axial force and torque to assemble Luer conical fitting and reference connector.

Pressure gage, measuring the applied pressure with a minimum accuracy of 0,3%

Timer, with an accuracy of ±1s.

Examination method

a) Introduce water of about a quarter nominal volume into the prefilled syringe, dry the outside of the connector after exhausting the air in it.

b) For a Luer non-locking connector, assemble by applying an axial force of between 26.5N and 27.5N for 5s to 6s while rotating the connector under test to a torque of between 0.08N·m and 0.10N·m or a rotation not exceeding 90°.

c) For a Luer lock connector, assemble by applying an axial force of between 26.5N and 27.5N for 5s to 6s while rotating the connector under test to a torque of between 0.08N·m and 0.12N·m.

d) With the axis of assembled connector horizontal, position the plunger stopper by the plunger rod to avoid the movement of the plunger stopper by pressurizing.

e) Apply a pressure between 300kPa and 330kPa through the small bore of the reference connector, hold a period of 30s to 35s. Visually inspect the connection.

Result determination

The test is passed if there is no falling drop of water.

2. Stress cracking test

Instruments

Reference connector, see Fig.1 or Fig.2.

Assembling device, which can simultaneously apply an axial force and torque to assemble Luer conical fitting and reference connector.

Pressure gage, measuring the applied pressure with a minimum accuracy of 0,3%

Timer, with an accuracy of ±1s.

Examination method

a) Dry the sample and the reference connector.

b) For a Luer non-locking connector, assemble by applying an axial force of between 26.5N and 27.5N for 5s to 6s while rotating the connector under test to a torque of between 0.08N·m and 0.10N·m or a rotation not exceeding 90°.

c) For a Luer lock connector, assemble by applying an axial force of between 26.5N and 27.5N for 5s to 6s while rotating the connector under test to a torque of between 0.08N·m and 0.12N·m.

d) Leave the sample and reference connector assembled for not less than 48h.

e) Inspect visually, then do the positive-pressure liquid leakage test.

Result determination

The test is passed if there is no visible cracks in the sample connector and positive-pressure liquid leakage test has passed

3. Resistance to separation from axial load test

Instruments

Reference connector, see Fig.1 or Fig.3.

Assembling device, which can simultaneously apply an axial force and torque to assemble Luer conical fitting and reference connector.

Timer, with an accuracy of ±1s.

Loading device，which can apply at least 35N axial separation force

Examination method

a) Dry the sample and the reference connector.

b) For a Luer non-locking connector, assemble by applying an axial force of between 26.5N and 27.5N for 5s to 6s while rotating the connector under test to a torque of between 0.08N·m and 0.10N·m or a rotation not exceeding 90°.

c) For a Luer lock connector, assemble by applying an axial force of between 26.5N and 27.5N for 5s to 6s while rotating the connector under test to a torque of between 0.08N·m and 0.12N·m.

d) Apply an axial force in a direction away from the test fixture at a rate of approximately 10N/s. For Luer non-locking connector, the axial force is between 23N and 25N. For Luer lock connector, the axial force is between 32N and 35N. Hold the axial force for 10s to 15s. Do not apply any supplementary force in other directions.

e) Inspect whether the connectors have completely detached at the interface between the connectors.

Result determination

The test is passed if the connectors have not completely detached at the interface between the connectors.

4. Resistance to separation from unscrewing test (only applicable to Luer lock connector)

Instruments

Reference connector, see Fig. 2.

Assembling device, which can simultaneously apply an axial force and torque to assemble Luer conical fitting and reference connector.

Timer, with an accuracy of ±1s.

Loading device，which can apply a torque between 0.018N·m and 0.020N·m.

Examination method

a) Dry the sample and the reference connector.

b) Assemble the sample and the reference connector by applying an axial force of between 26.5N and 27.5N for 5s to 6s while rotating the connector under test to a torque of between 0.08N·m and 0.12N·m

c) Apply an unscrewing torque between 0.018N·m and 0.020N·m over a hold period between 10s and 15s.

d) Inspect whether the connectors have completely detached at the interface between the connectors.

Result determination

The test is passed if the connectors have not completely separated at the interface between the connectors.

5. Resistance to overriding test (only applicable to Luer lock connector)

Instruments

Reference connector, see Fig.3.

Assembling device, which can simultaneously apply an axial force and torque to assemble Luer conical fitting and reference connector.

Timer, with an accuracy of ±1s.

Loading device，which can apply a torque between 0.15N•m and 0.17N•m.

Examination method

a) Dry the sample and the reference connector.

b) Assemble the sample and the reference connector by applying an axial force of between 26.5N and 27.5N for 5s to 6s while rotating the connector under test to a torque of between 0.08N·m and 0.12N·m.

c) Apply a screwing torque between 0.15N·m and 0.17N·m over a hold period between 5s and 10s. Do not apply any supplementary force or torque in other directions.

d) Inspect whether the threads or lugs of the reference connector have not completely extended past the threads or lugs of the connector under test.

Result determination

The test is passed if the threads or lugs of the reference connector have not completely extended past the threads or lugs of the connector under test.

参与单位：江苏省医疗器械检验所、山东威高普瑞医药包装有限公司、山东省药用玻璃有限公司、宁波正力药品包装有限公司、山东永聚医药科技有限公司、肖特药品包装（浙江）有限公司、碧迪医疗器械（上海）有限公司