

1 4040 Examination Method of Luer Conical Fitting of Prefilled Syringes

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

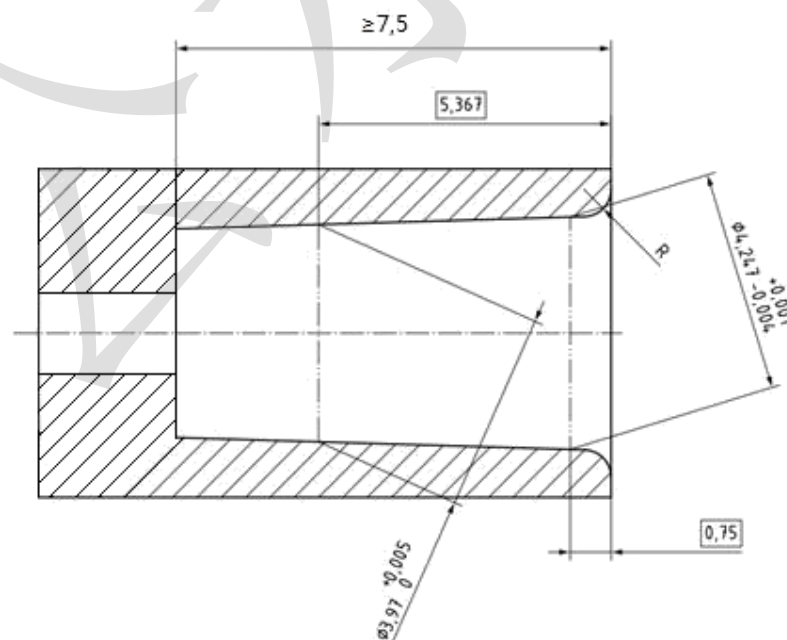
4 Reference connector

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

7 Reference connectors used to test the glass barrel of the prefilled syringe shall be
8 manufactured from semi-rigid materials, and those used to test the plastic barrel shall
9 be manufactured from corrosion-resistant rigid materials with a surface roughness
10 value Ra not exceeding $0.8\mu\text{m}$ on critical surfaces. Semi-rigid material is the material
11 with a modulus of elasticity in flexure or in tension between 60MPa and 3433MPa.
12 Rigid material is the material with a modulus of elasticity in flexure or in tension
13 greater than 3433MPa.

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

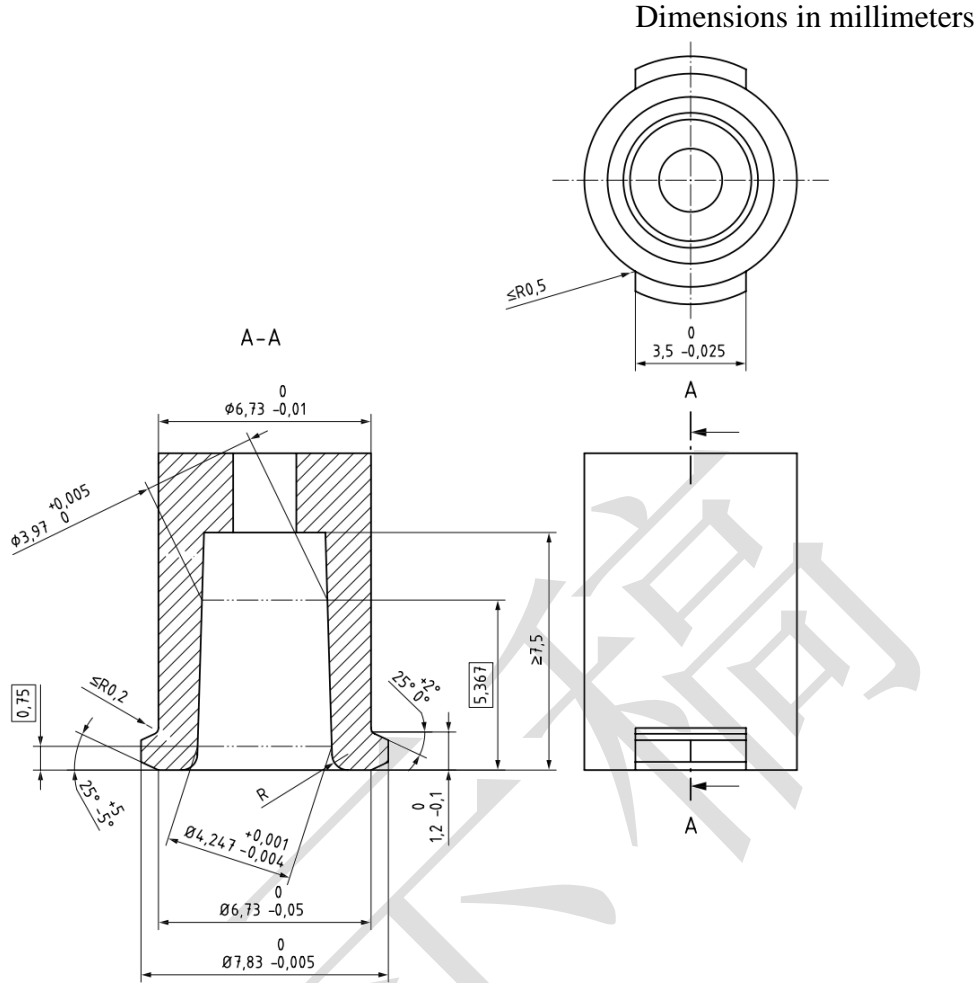
19 Dimensions in millimeters



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

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

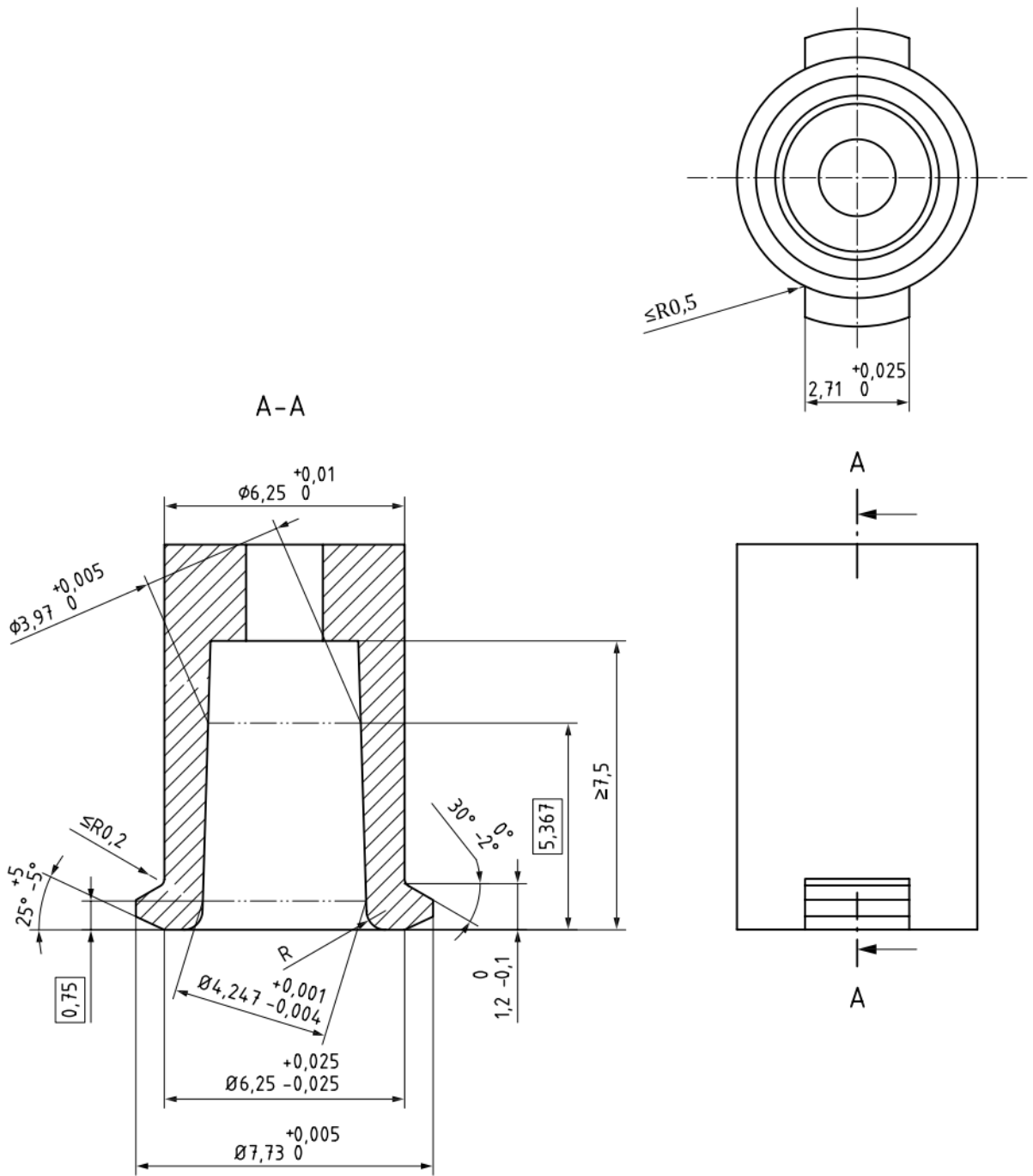
22 Note2: Conical taper 0.06:1.



24 Fig.2 Reference connector for leakage, separation from screwing and stress cracking
25 test of Luer lock connector
26

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

Dimensions in millimeters



30

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

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

35 Environmental test conditions

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

38 1. Positive-pressure liquid leakage test**39 Instruments**

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

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

43 Pressure gage, measuring the applied pressure with a minimum accuracy of 0.3%

44 Timer, with an accuracy of ± 1 s.

45 Examination method

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

48 b) For a Luer non-locking connector, assemble by applying an axial force of
49 between 26.5N and 27.5N for 5s to 6s while rotating the connector under test
50 to a torque of between 0.08N·m and 0.10N·m or a rotation not exceeding
51 90°.

52 c) For a Luer lock connector, assemble by applying an axial force of between
53 26.5N and 27.5N for 5s to 6s while rotating the connector under test to a
54 torque of between 0.08N·m and 0.12N·m.

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

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

61 Result determination

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

63 2. Stress cracking test**64 Instruments**

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

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

68 Pressure gage, measuring the applied pressure with a minimum accuracy of 0.3%

69 Timer, with an accuracy of ± 1 s.

70 **Examination method**

- 71 a) Dry the sample and the reference connector.
- 72 b) For a Luer non-locking connector, assemble by applying an axial force of
73 between 26.5N and 27.5N for 5s to 6s while rotating the connector under test
74 to a torque of between 0.08N·m and 0.10N·m or a rotation not exceeding
75 90°.
- 76 c) For a Luer lock connector, assemble by applying an axial force of between
77 26.5N and 27.5N for 5s to 6s while rotating the connector under test to a
78 torque of between 0.08N·m and 0.12N·m.
- 79 d) Leave the sample and reference connector assembled for not less than 48h.
- 80 e) Inspect visually, then do the positive-pressure liquid leakage test.

81 **Result determination**

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

84 **3. Resistance to separation from axial load test**

85 **Instruments**

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

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

89 Timer, with an accuracy of ± 1 s.

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

91 **Examination method**

- 92 a) Dry the sample and the reference connector.
- 93 b) For a Luer non-locking connector, assemble by applying an axial force of
94 between 26.5N and 27.5N for 5s to 6s while rotating the connector under test
95 to a torque of between 0.08N·m and 0.10N·m or a rotation not exceeding
96 90°.
- 97 c) For a Luer lock connector, assemble by applying an axial force of between
98 26.5N and 27.5N for 5s to 6s while rotating the connector under test to a
99 torque of between 0.08N·m and 0.12N·m.
- 100 d) Apply an axial force in a direction away from the test fixture at a rate of
101 approximately 10N/s. For Luer non-locking connector, the axial force is
102 between 23N and 25N. For Luer lock connector, the axial force is between
103 32N and 35N. Hold the axial force for 10s to 15s. Do not apply any

104 supplementary force in other directions.

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

107 **Result determination**

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

110 **4. Resistance to separation from unscrewing test (only applicable to Luer** 111 **lock connector)**

112 **Instruments**

113 Reference connector, see Fig.2.

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

116 Timer, with an accuracy of ± 1 s.

117 Loading device, which can apply a torque between $0.018\text{N}\cdot\text{m}$ and $0.020\text{N}\cdot\text{m}$.

118 **Examination method**

119 a) Dry the sample and the reference connector.

120 b) Assemble the sample and the reference connector by applying an axial force
121 of between 26.5N and 27.5N for 5s to 6s while rotating the connector under
122 test to a torque of between $0.08\text{N}\cdot\text{m}$ and $0.12\text{N}\cdot\text{m}$

123 c) Apply an unscrewing torque between $0.018\text{N}\cdot\text{m}$ and $0.020\text{N}\cdot\text{m}$ over a hold
124 period between 10s and 15s.

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

127 **Result determination**

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

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

131 **Instruments**

132 Reference connector, see Fig.3.

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

135 Timer, with an accuracy of ± 1 s.

136 Loading device, which can apply a torque between $0.15\text{N}\cdot\text{m}$ and $0.17\text{N}\cdot\text{m}$.

137 **Examination method**

- 138 a) Dry the sample and the reference connector.
- 139 b) Assemble the sample and the reference connector by applying an axial force
140 of between 26.5N and 27.5N for 5s to 6s while rotating the connector under
141 test to a torque of between 0.08N·m and 0.12N·m.
- 142 c) Apply a screwing torque between 0.15N·m and 0.17N·m over a hold period
143 between 5s and 10s. Do not apply any supplementary force or torque in other
144 directions.
- 145 d) Inspect whether the threads or lugs of the reference connector have not
146 completely extended past the threads or lugs of the connector under test.

147 **Result determination**

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

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