

Summary of the most commonly used test methods

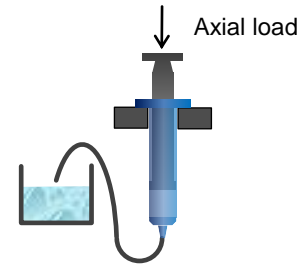
Part 11 – Prefilled syringes (ISO 11040)

Finished prefilled syringes are tested according to ISO 11040-8. A detailed description of the tests can be found in ISO 11040-4, ISO 7668-1 and ISO 80369.

ISO 11040-8

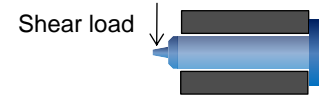
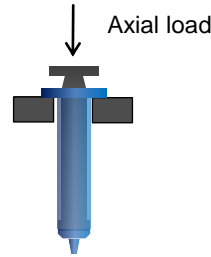
Glide force test:

- 6.2: Break loose and extrusion forces (see also [ISO 11040-4, Annex E](#))



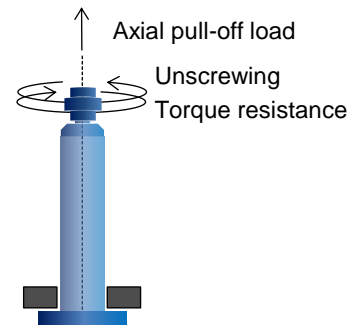
Test methods for syringe barrels:

- 6.3: Burst resistance (see also [ISO 11040-4, Annex G.2](#))
- 6.4: Flange break resistance (see also [ISO 11040-4: C.1](#))
- 6.4: Luer cone break resistance (see also [ISO 11040-4: C.2](#))



Closure system forces and torques:

- 6.5: Luer lock adaptor collar pull-off force (see also [ISO 11040-4, Annex G.3](#))
- 6.5: Luer lock adaptor collar torque resistance (see also [ISO 11040-4, Annex G.4](#))
- 6.5: Luer lock rigid tip cap unscrewing torque (see also [ISO 11040-4, Annex G.5](#))
- 6.5: Pull-off force of the tip cap or the needle shield (see also [ISO 11040-4, Annex G.6](#))



Connectivity with fluid path connectors:

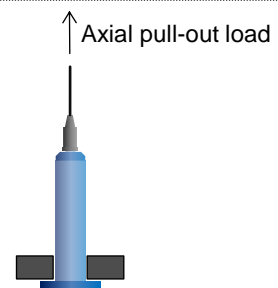
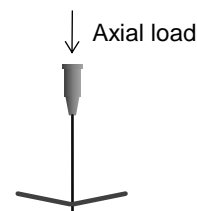
- 6.6: various, see [ISO 80369-20](#)

Residual volume:

- 6.7: Residual volume (see [ISO 7886-1](#))

Test methods for needles:

- 6.8: Needle penetration test (see also [ISO 11040-4, Annex F](#))
- 6.9: Needle pull-out force (see also [ISO 11040-4, Annex G.1](#))



Leakage tests:

- 6.11: Liquid leakage beyond plunger (see [ISO 7886-1](#))
- Closure system liquid leakage (see [ISO 11040-4, Annex G.2](#))

For further information also regarding additional test methods not covered by this summary please contact:

SpineServ GmbH & Co. KG, Soefflinger Strasse 100, 89077 Ulm, Germany
 Phone: +49 (0)731 175 6788
 mail@spineserv.de
 www.spineserv.de