

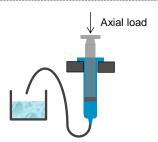
Test Methods for Prefilled syringes - ISO 11040

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

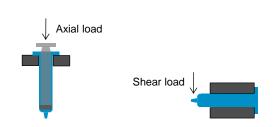
Glide force test

☐ 6.2: Break loose and extrusion forces (see also ISO 11040-8, Annex E)



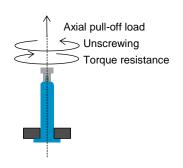
Test methods for syringe barrels

- ☐ 6.3: Burst resistance (see also ISO 11040-4, Annex G.2
- ☐ 6.4: Flange breake resistance (see also ISO 11040-4:C.1)
- □ 6.4: Luer cone breake 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

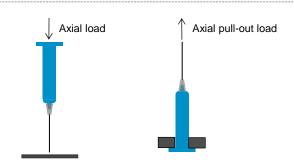
□ 6.6: various, see ISO 80369)

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)