Test Methods for Prefilled Syringes

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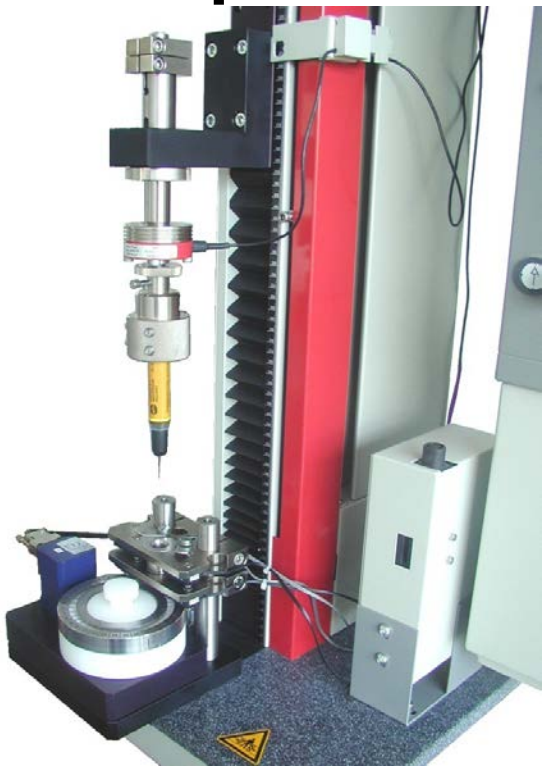
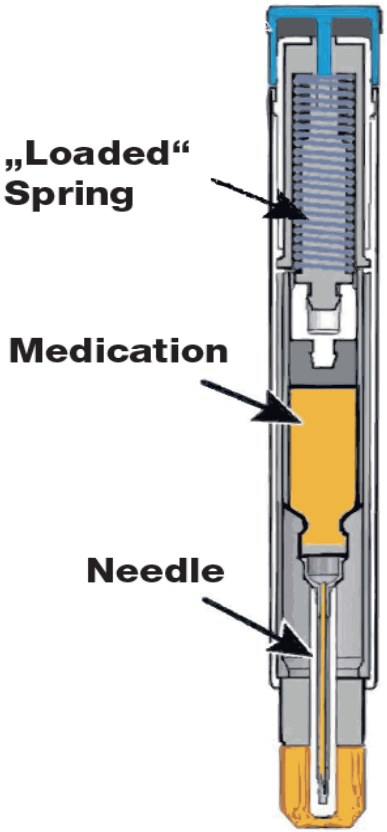
Test Methods for Prefilled Syringes

- **Requirements of the use in devices**



Test assembly

Liquid collecting station



Regulatory References for Finished Pre-filled Syringes in Delivery Devices

ISO 11608-3

Needle Based Injection Systems (NIS)

for medical use

Part 3: Finished containers

ISO 11608-3 / Second edition 2012-10-01 (TC 84)

ISO 11608-5

Needle Based Injection Systems (NIS)

for medical use

Part 5: Automated functions

Regulatory References for Delivery Devices

Regulatory Reference: 11608-1 (NIS)

System Designation

- **Multi Dose / Single Dose container**
- **Replaceable / Integrated non replaceable container**

- **Multi Dose: fixed or variable**
- **Single Dose: entire / portion of deliverable volume**

- **Test Matrix and Test Methods:**
  - **Dose accuracy / last dose accuracy / free fall / conditioning / cyclical / vibration**

Pre-filled Container in NIS TM

Regulatory Reference: 11608-3 (NIS)

Requirements (Syringes)

- **Freedom from leakage**
- **Plunger force**
- **Dimensions**

→ pre-requirement is an identified compatible NIS

Pre-filled Container in NIS TM

Regulatory Reference: 11608-3 (NIS)

Requirements

- **Coring (fragmentation)**
- **Particulates**
- **Dose accuracy / Deliverable volume**
- **Freedom from damage**

→ pre-requirement is an identified compatible NIS

Freedom from leakage TM

Principle

Check if container is tight by applying an axial force via a plunger rod

Procedure

Apply axial pressure: $F = 0.64 N/mm^2 \times (\text{inner diameter})^2$

Hold for 1 min

Interpretation of Results

No leakage visible around front end and back end of container

Plunger force TM

Principle

Check plunger force on open container

Procedure

Use universal tensile and compression machine with recommended test speed of 50mm/min

Record force versus displacement curve

Interpretation of Results

Compare results with pre-defined specification

Dimensions TM

Principle

Check critical dimensions (e.g. plunger insertion depth)

Procedure

Check length of end of FF to back end of plunger

Check length from needle tip to back end of plunger

Check length from tip of septum to back end of plunger

Interpretation of Results

Compare results with pre-defined specification

Coring (Fragmentation) TM

Principle

Check if rubber particles are present after rubber penetration

Procedure

Use NIS system as described in Instruction of Use

Flush lumen of needle after penetration onto a filter

Inspect for rubber particles

Interpretation of Results

Shall not exceed more than 6 fragments / 100 punctures

Particulates TM

Principle

Check for particulate contamination

Procedure

Inspect under normal or corrected-to-normal vision

Interpretation of Results

Shall be essentially free of particulates or droplets (lubrification) on the outside or inside surfaces

Dose accuracy / Deliverable volume TM

Principle

Check dose accuracy assessment matrix in ISO 11608-1

Procedure

Follow informative Annex A / Annex B of ISO 11608-1

Interpretation of Results

Compare results with pre-defined specification

Freedom of damage TM

Principle

Free fall in vertical and horizontal orientation

Procedure

Follow sample preparation and drop orientation as described in section 10.5 of ISO 11608-1

Drop height = 1m

Test surface is a smooth, hard rigid steel (3mm) backed by wood (>10mm)

Interpretation of Results

Compare results with pre-defined specification (breakage)

Workshop: Test Methods for Pre-filled Systems

ISO 11608-5
Needle Based Injection Systems (NIS) for medical use
Part 5: Automated functions

Customizable Testing Modules:

- Special low pressure grips
- Integrated high-precision scale
- Activation forces
- Sensor Needle length with removal last drop
- Sensor Ejection Time
- Sound detection via microphone
- Camera for needle tip/fluid stream recording

Workshop: Test Methods for Pre-filled

Workshop: Test Methods for Pre-filled Systems

Additional testing for use in delivery devices

E N D

Acknowledgements