Parenteral quality control

1. Product potency
2. Volume in container.
4. Pyrogen test.
5. Clarity and particulate analysis.
6. Glass-seal of ampoules “leaker testing”.
Volume in container

Carefully transfer the volume of 1 container (10 ml), 3 containers (3-10 ml) or 5 containers (<3 ml)

Graduated cylinder

Tared beaker
Clarity Testing

By visual inspection of solutions for contaminants such as glass, fibers, floaters and precipitate.

Particulate Analysis

Particulate matter is any mobile, undissolved solids not intended for sterile preparations. Examples include lint, cellulose and cotton fibers, glass, rubber, metals, plastics, undissolved chemicals, rust, diatoms, and dandruff.
Clarity Testing

By visual inspection of solutions for contaminants such as glass, fibers, floaters and precipitate.

Particulate Analysis

By filtration, imaging or coulter counter for micronized particles (cannot be visualized by naked eye)

limits for LVP:

not > 100 particles of 5 μ and larger/ml

not > 1000 particles of 2 μ and larger/ml.
Sterility Testing

To estimate the probability of presence of m.o.

- Direct inoculation
- Membrane filtration

membrane of porosity of 0.45 μm.
Sterility Testing

To estimate the probability of presence of m.o.

- Direct inoculation
  - Thioglycollate medium (for anaerobic)
    - Aqueous solutions without preservative
    - Oily solution + emulsifying agent
    - Solids (dissolved in suitable solvent)
  - Membrane filtration
    - Soybean-casein digest medium (for aerobic)
      - Parenterals with preservative
      - Oily solution (different viscosities)
      - Solids (dissolved)
Sterility Testing

Inactivation of antimicrobial agent

• Filtration & washing of the membrane using saline solution
• Solids are dissolved in suitable solvent before filtration
• Addition of suitable inactivators
• Dilution to a conc. less than the MIC of the antimicrobial
Pyrogen Testing

Rabbit test

The test involves measuring the rise in temperature of rabbits following the IV injection of the tested preparation.
Detect and quantify bacterial endotoxins in injectable pharmaceuticals, biological products, and medical devices.

The critical component of the LAL reagents is derived from blood cells (amebocytes) of the horseshoe crab. It contains the proteins of the blood clotting mechanism.
Pyrogen Testing

There are three principal LAL test methods: the gel-clot method and photometric methods (turbidimetric and chromogenic).

The simplicity and economy of the LAL Test encourages the testing of in-process solutions and raw materials as well as end-product drugs, devices and biologics.
Sealing Verification
(Leaker testing)

Immersion in dye solution (1% methylene blue)
Vacuum for 15 min
Rapid vacuum release
Defective ampoules will contain blue solution
GOOD LUCK