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Diploma in Pharmacy 1st Year
Pharmaceutics
Experiment
To demonstrate the particulate matter monitoring of sterile injections as per the monographs.

Aim:

To demonstrate the particulate matter monitoring of sterile injections as per the monographs.

Reference :

‘ Dr. Gupta G.D , Dr. Sharma Shailish , Dr. Sharma Neelam’ “Practical Manual of Pharmaceutics” Published by Nirali Prakashan, Page no 191 – 193

Apparatus and Materials Required :

Membrane filter, microscopically. 10000 particles/container of size and sterile injection

Theory :

The presence of particulate matter in a solution to be administered intravenously is considered harmful. Till now limited data has been procured related to the extent of damage caused by these particulate matter, although Garvan and Gunner have shown in 1964 that particles of rubber, insoluble chemical, lint and other foreign chemicals can produce emboli in the vital organs of animal and man. Particulate matter in infusion fluids causes infusion phlebitis.

Erythrocytes have a diameter of 4.Sum, thus particles of more than Sum size should form the basis of evaluation. By using Tyndall effect for analysis, particles of 10um size can be viewed.

Procedure

The methods employed for particulate matter monitoring are as follows:

1) **Visual Inspection :** The U.S.P has specified that each final container of an injection should be visually inspected and those having visible particles should be discarded. Thus, all the products from the production line undergo separate inspection under good light and against black and white background. Visual inspection however has some drawbacks like particle size limitation (that can be seen with naked eyes), the visual opinion may vary from inspector to inspector as their emotional state, eyes strains, fatigue and other personal factors may affect the evaluation.
2) **Microscopic Method :** Particles of size smaller than 50um cannot be detected by visual inspection. Thus, a microscopic method has been developed by the U.S.P. for detecting large volumes of intravenous solutions. This method has a limit of not more than 50 particles/ml of size 10um and large and not more than 5 particles/ml of size 25µm and large. In this method, a measured volume of sample solution is filtered through a membrane filter under aseptic conditions and then the particles on the surface of the filter are counted microscopically using oblique light at 40x and 100x magnification.
3) **Shadow Cast Method :** The US.P. has established standards for small-volume parenteral meant for intravenous administration, using an electronic instrument which measures particle size by mode of a shadow cast by the particles, as it passes through high-intensity light beams.

   The prescribed limits are not more than 10000 particles/container of size 2 10µm and not more than 1000 particles/container of size ≥ 25µm. These specifications were laid on the assumption that five products can be added to a IL bottle of a large-volume parenteral and they should

not contribute to more than the overall limits of particles prescribed for large-volume parenteral.

4) **Electronic Particle Counter :** Some other methods are also available for determining the presence of particulate matter. Many electronic particle counters are available, which utilise the principle of light scattering for counting particles in a liquid sample.
5) **Thermocouple Conductivity Method :** Some instruments, e.g., the Coulter Counter are available for counting and sizing particles by measuring the resistance effect between two electrodes when the particle passes between them.

All of these methods require aseptic preparation techniques to achieve accuracy in counting and sizing the practices present in solution, and not those introduced accidentally during sample preparation or testing procedure. These procedures are also quite destructive, and can be performed using only those samples withdrawn from a production lot.

Result :

The particulate matter monitoring of sterile injections as per the monographs was studied.