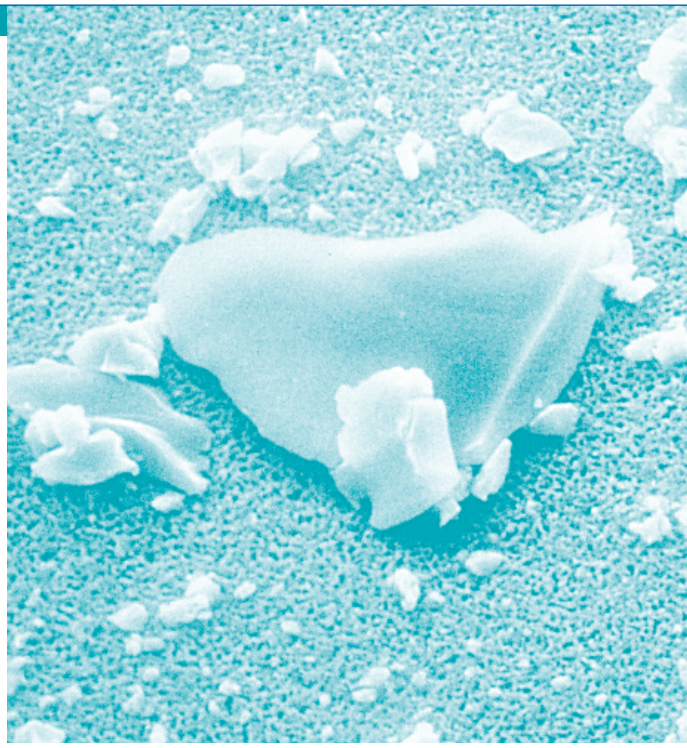
PALL Medical

clinical update



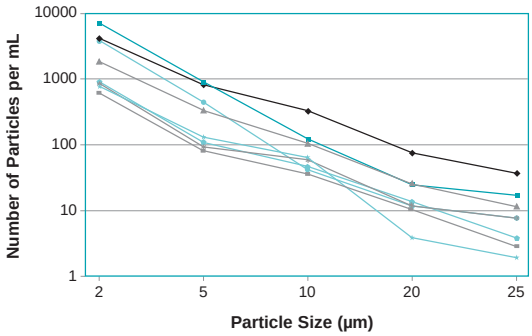
Pharmacy Filtration: Critical Protection for Providers and Patients

*Filtration. Separation. Solution.*SM

Clinical Problem

Particles are present in IV solutions

Glass, rubber, metal, plastic, drug precipitates and other particles are routinely present in IV solutions as inadvertent byproducts of manufacturing. Particles can also be introduced into solutions during extemporaneous compounding prior to administration. The largest contribution is attributed to small volume parenterals.[1]



Particle Counts Obtained on Large Volume Parenterals[2]

Infused particles can result in serious complications

Products introduced into the venous system travel through increasingly larger diameter vessels until reaching the heart, after which the vessels decrease in size to the minute capillary beds of the pulmonary system. Pulmonary capillaries are approximately 6 to 9 µm in diameter, just large enough for a single red blood cell to pass. Rigid particles, equal to or greater than 6 µm in size, can become trapped in the vascular bed, occluding capillaries, and can cause multiple pulmonary infarctions.[3] Foreign particles can also produce emboli in the capillaries of other vital organs, and phlebitis at the infusion site.

A collaborative study conducted by the Pharmaceutical Manufacturers Association described size-dependent localization of particles in different rat organs after intravenous injection of varying quantities and sizes of latex particles.[4]

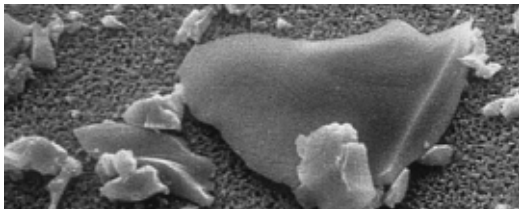
Particle Size	End-Organ Particle Localization
40 µm	Lung and heart tissue 13 of 18 animals died within 5 minutes of injection
10 µm	Lung primarily; also kidney Liver, spleen, heart, and brain
4 µm	Lung, liver, and spleen

Furthermore, pathological studies in Europe have shown that particles that are too small to block even the smallest blood vessel can irritate blood vessel lining and act as a condensation nuclei for clot formation. Post-mortem studies of patients given unfiltered infusions revealed the presence of very small particles associated with thrombi in the lung and in large granulomata.[5]

Patient Protection

Parenteral solutions must be sterile and free of particulate before delivery

The preparation of pharmaceutical solutions in hospitals, home care, infusion clinics, and long-term care facilities often requires filtration to remove viable and non-viable particulate matter to make solutions clear or sterile. To remove large particles from solutions, a membrane filter with a rated pore size of 5 µm or higher is required. Sterilization requires a filter with a rated pore size of 0.2 µm or smaller. Many facilities also choose to use end-line filters at the point of infusion to remove sub-micron particles, including those contributed by the infusion system.

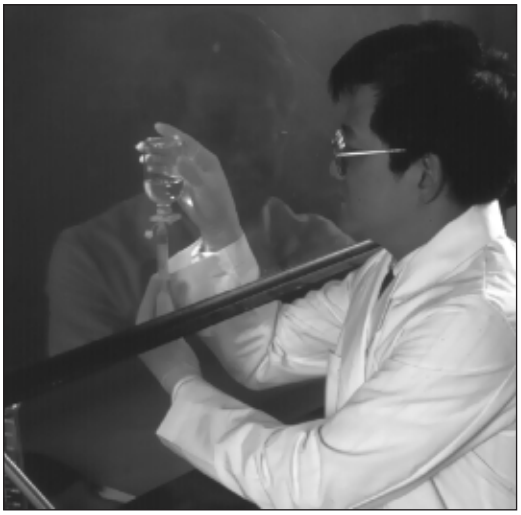


Provider Protection

Reconstitution of cytotoxic drugs poses risks to health care providers

For health care pharmacy professionals, improving patient outcomes begins with safe and effective preparation of pharmaceutical solutions. Reconstitution of sterile cytotoxic drugs involves procedures to protect patients and health care workers during handling, dispensing, and administration of drugs.

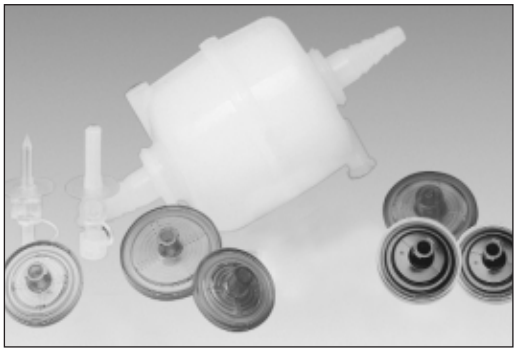
Health care workers may be at risk while preparing or administering antineoplastic injections, including exposure to cytotoxic or hazardous drug aerosols during drug reconstitution, or during the withdrawal of drugs from rubber-sealed vials. This exposure can result in skin and eye irritation and has the potential for cumulative damage to liver, kidneys, and chromosomes of health care workers.[6]



Filtration Solution

Pall Medical Introduces *PharmAssure* - Filtration and Venting Products Specifically Designed for the Health Care Pharmacy

The *PharmAssure* family of filtration products offers a complete range of products for the pharmacy and clinical wards to ensure the quality and safety of compounded products. Additionally, vented vial access devices protect pharmacy professionals and nurses from the hazards associated with exposure to cytotoxic or hazardous drugs from the preparation or administration of antineoplastic products.



Summary

- Particles are present in all IV solutions.
- Infused particles can result in serious complications.
- Parenteral solutions must be sterile and free of particulates before delivery.
- Reconstitution of cytotoxic drugs poses risks to health care providers.
- *PharmAssure* is a complete line of filtration and venting products specifically designed for the health care pharmacy.

References

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