IACUC Guidelines for Sterile Preparation of Injectable Compounds

Last Review:4/2022
Revision History:

Note: The syringe, filter and receiving container are all sterile. Also, while not necessary, doing the procedure in a biosafety hood is recommended to improve sterile transfer.

Procedures:

1. If you have a limited amount of sample – draw a small amount of air (about 1 ml) into a sterile syringe before filling with the sample solution. This air is used to purge the filter at the end ensuring the minimum sample left in the filter.
2. Load the sample into the syringe. Note the visible air pocket ready to purge the filter.
3. Attach the sterile filter securely with a twisting motion. Filters with nominal pore size of 0.2 micron are typical for sterilizing applications (but 0.1 and 0.45 are also common). With a luer slip syringe, this is about one quarter turn as the filter is pushed on. If the syringe has a luer lock (as in this example), fix it firmly but do not over-tighten.
4. Hold the assembled syringe and the filter vertically to wet the membrane evenly. This prevents air blocks and promotes high flow rates as the sample is spread evenly over the membrane surface. The actual physical design of the syringe filter will have a big bearing on the possible flow-rate through the filter.
5. Press the syringe plunger gently to express the sample through the filter. If the back pressure ever increases significantly, change the filter as it may have plugged. Avoid pressing excessively as this could cause the filter housing to burst.
6. Push the air through the filter to purge the housing and membrane and recover the maximum amount of sample.
7. In all steps, use aseptic technique.

NOTE: There are many manufacturers of syringe filters (e.g., Fisher) so PI's should be able to find the membrane material to fit their needs. They may cost about $2.00 each and are single use. If there is concern about filter hold up of the active substance it could be confirmed by any analytical method suitable for the active substance (UV/Vis, MS, Elisa) whereby the concentrations in the pre-and post-filtered substance are compared.

Sterility is required in addition to pharmaceutical grade (note that pharmaceutical grade does not necessarily mean sterile) for anything that is injected unless a scientific justification is provided to the IACUC and approved.