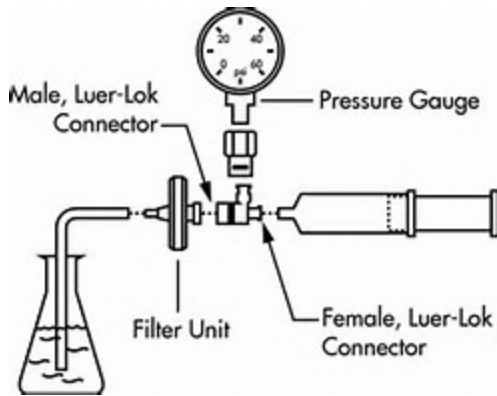


NVBOP – Bubble Point Testing Procedure

- The correct type of filter must be selected for the type of fluid being filtered.
- The size and configuration of filtration devices must accommodate the volume being filtered to permit complete filtration without clogging. Typically a 25mm disk should filter no more than 100ml of solution.
- All filters used for sterilization must be subjected to a filter integrity test (bubble point test) against the filter's bubble point PSI rating.
- Filter integrity testing must be performed immediately after filter use. No release of compounded sterile products may take place until the filter test is complete.
- Passing a bubble point test is NOT used in place of sterility testing.
- Documentation of a passed bubble point test should include the actual PSI that the bubble point was realized as opposed to just documenting "Pass" on a form.
- Documentation of a bubble point test must include the filter manufacturer, lot number, PSI rating from manufacturer, actual bubble point result from test, and person performing the test.
- If a bubble point test is listed as "failed" there must be clear documentation as to how the product and subsequent testing was adjudicated.



Bubble Point Testing Procedure:

- Wet the filter with sterile water.
- Remove the filter from the syringe and attach all equipment per the diagram shown above.
- Utilize a 60ml syringe as shown in the diagram above.
- Starting from zero pressure slowly increase the pressure until a steady stream of bubbles emerges from the end of the tubing. The reading on the pressure gauge at this point is the “bubble point”.
- Record the actual bubble point reading on the appropriate form and document whether or not the filter “passed” the integrity test.
- The facility must have a SOP related to what steps are taken if a filter “fails” the integrity testing procedure.

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.