

Recommended Nylon final filter Operating Procedures

Pall Ultipor[®] N66 (AB*)

Note: The following procedure does not address the safety issues related to the handling of hot alkali and other hazardous solutions. This procedure does not address regulatory nor cleaning validation issues that may arise as the result of using this procedure.

Install pressure gauges upstream and downstream of the filter housing.
Pressure should be monitored during filtration and water flushes.
Recommended filter change out is at 25-30 psid.

Integrity Test

Perform as per integrity test procedure document after sterilization.
Ensure that filters are water wet, housing is drained, and upstream valves are closed.

Filtration

1. Connect all hoses to appropriate connections for forward flow.
2. Open housing vent.
3. Initiate product flow at a low flow rate (<0.5x process).
4. Close housing vent after housing is filled and air is removed.
5. Increase flow rate to process flow rate.
6. Continue product filtration until the batch is complete or differential pressure reaches set maximum.

Water flush

1. Open valves and vent on the filter housing.
2. Attach water to outlet of the filter housing and allow ambient temperature water to flow in the forward direction to drain at up to 1.5 times the process flow rate.
3. Close housing vent after housing is filled and air is removed
4. Run cold water for 10 minutes or until the outlet is clear.
5. Slowly increase the water temperature to 120°F over 10 minutes.
6. Run 120°F water for 10 minutes.
7. Optional: Hold 120°F water in housing for 10 minutes.
8. Slowly decrease the water temperature to ambient over 10 minutes.
9. Stop water flow.

Short term storage

Overnight

1. Cold water flush as per above procedure.
2. Counter pressure with carbon dioxide or nitrogen (~5 psi).
3. Sterilize as per standard procedures in the morning prior to filtration.

3 days-1 week

1. Fill filter housing with 200 ppm sodium metabisulphite.
2. Allow to stand for up to 3 days to 1 week.
3. Drain sodium metabisulphite from filter housing.
4. Sterilize filters prior to filtration.

Long term storage

1. Sterilize filters by chosen method.
2. Drain and seal housing assembly.
3. Counter pressurize with carbon dioxide or nitrogen.
4. Filter assembly may stand indefinitely under these conditions.
5. Sterilize filters prior to filtration.

“Sterilization”

Hot water

1. Connect water source to inlet and outlet to drain.
2. Open valves and vent to housing
3. Flow water in the forward direction
4. Slowly increase water temperature until it reaches 185°F at the coldest point. Maximum differential pressure at 185°F is 14.5 psid.
5. Maintain flow at 185°F for 20 minutes. Flow through all vents and sample ports.
6. Slowly decrease water temperature to process temperature.
7. Proceed to integrity test.