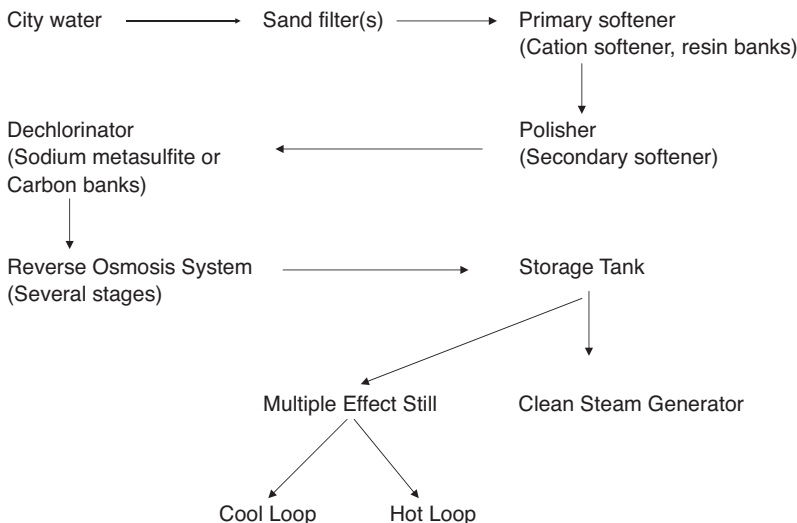


**Table 15-1** Water Monographs in the U.S. Pharmacopeia

Water type	Preparation method	Limit for endotoxins	Comments
Purified water, USP	Distillation ion exchange	None	Pharmaceutical solvent
Water for Injection, USP	Distillation reverse osmosis	0.25 EU/mL	Non-sterile, must use within 24 hr or store < 5°C or > 80°C, used for manufacture of parenteral products going to be sterilized
Sterile Water for Injection, USP	Distillation reverse osmosis	0.25 EU/mL	Single-dose containers same as WFI; also used to reconstitute sterile solids and dilute sterile solutions
Bacteriostatic Water for Injection, USP	Distillation reverse osmosis	0.5 EU/mL	Multiple-dose and single-dose products
Sterile Water for Irrigation, USP	Distillation reverse osmosis	0.25 EU/mL	1 L or larger, wide mouth. Does not meet particulate matter requirements for large volume injections labeled "for irrigation only"
Sterile Water for Inhalation, USP	Distillation reverse osmosis	0.5 EU/mL	Inhalation therapy only
Sterile purified water, USP	Distillation reverse osmosis	None	Used in preparation of non-parenteral compendial dosage forms where sterile form of water is required
Water for hemodialysis, USP	Distillation reverse osmosis	2 EU/mL	Drinking water for patients undergoing hemodialysis. Reduced levels of Al, F, Cl. Bioburden 100 CFU/mL. Not intended for injection

impurities in feed water include bacteria, bacterial endotoxins, particles, electrolytes, organics, colloids, and disinfectants such as chlorine. A distillation system consists of a:

1. Boiler (evaporator) containing feed water (distilland)
2. Source of heat to vaporize the water in the evaporator
3. Headspace above the level of distilland with condensing surfaces for refluxing the vapor, thereby returning nonvolatile impurities to the distilland



**Figure 15-1** WFI system (example of flow from source to end).