RESINTECH INC
INNOVATIONS IN ION EXCHANGE

TECHNICAL DATA SHEET | **PHARMACEUTICAL WATER**

The United States Pharmacopoeia (USP) defines the characteristics of different grades of pharmaceutical waters:

PURIFIED WATER (PW)

This is a general type of pharmaceutical water that can be produced using ion exchange, reverse osmosis, distillation, or other suitable treatment methods. PW must meet chemical and bacterial purity. It is not meant to be used parenterally.

WATER FOR INJECTION (WFI)

WFI must meet the same requirements for PW but must not contain pyrogens. Usually produced from PW with a polishing step of distillation or double pass reverse osmosis.

STERILE WFI

Same as PW with the additional requirement of being sterile and not containing pyrogens. Does not contain any preservatives or chemical additives and is packaged in maximum one liter containers intended for single dose.

BACTERIOSTATIC

Same as Sterile WFI, but contains preservatives that function as anti-microbial agents. Maximum container size of 30 mls is intended for single or multiple doses.

STERILE WATER FOR IRRIGATION

Same as Sterile WFI but can be packaged in containers greater than one liter and must be labeled "For irrigation purposes only, not for injection."

All of the pharmaceutical waters must be prepared from a water that meets or exceeds the Federal EPA Regulations for drinking water. Microbial contamination of ion exchange beds used for pharmaceutical waters is a concern. Sanitization of the beds can be accomplished by several methods including frequent regenerations, UV lights and fine filtration, and chemical sanitation such as sodium hypochlorite or peracetic acid. Hot water recycle at a temperature of 180oF is also a method used today, particularly attractive because it does not add any substances to the water.

Note: Contact ResinTech for sanitization procedures suitable for ion exchange resin beds.

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