

Generation Storage and Distribution System for Purified Media



TECNINOX®

*Your partner
in process technology*



Pharmaceutical water is the most widely used ingredient in drug manufacturing

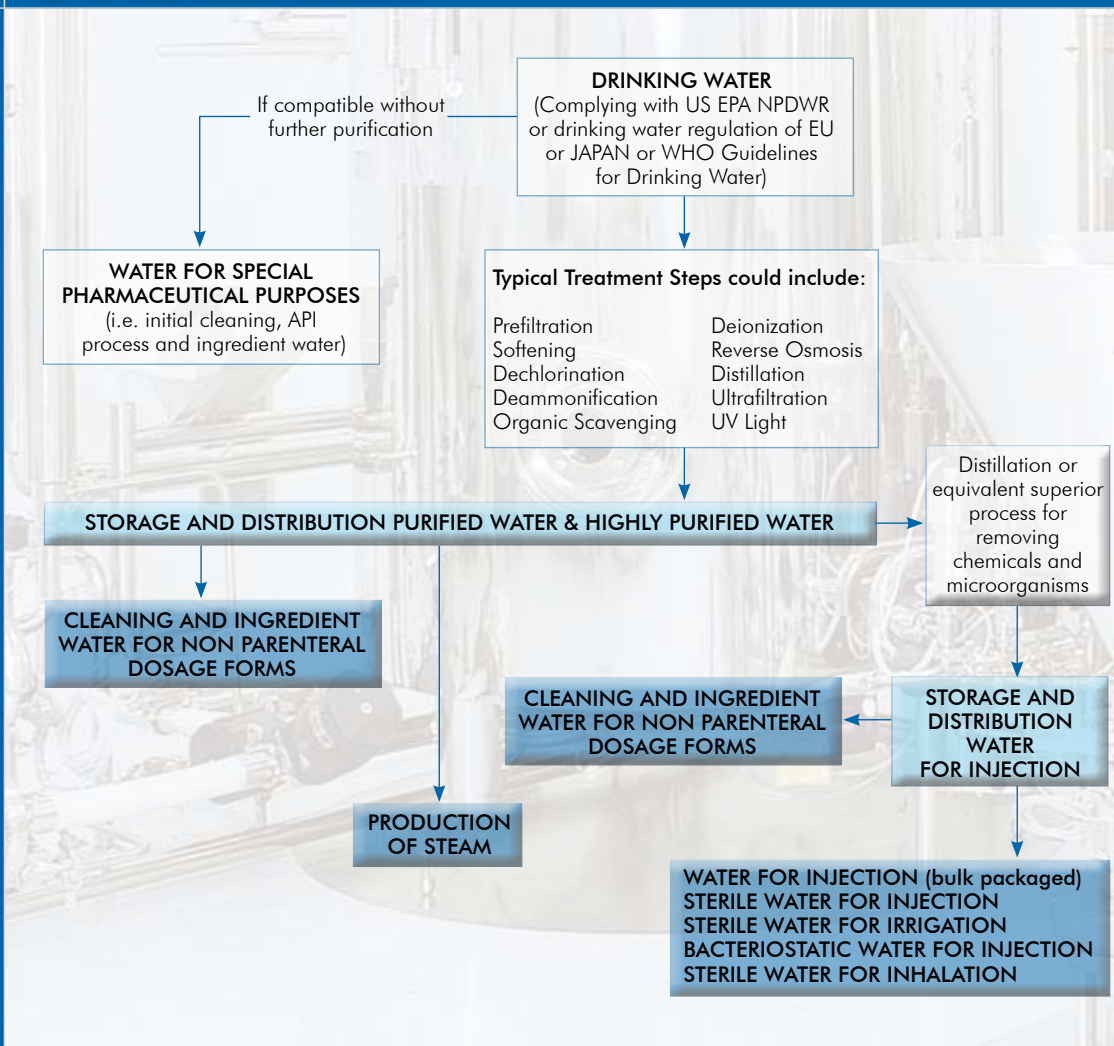
Water is a natural resource vital for the survival of humanity and all species on earth.

Water is much more than just a basic human need. It is an essential, irreplaceable element to ensure life... and is one of the major commodities used by the pharmaceutical industries.

It may be present as an excipient, or used for reconstitution of products, during synthesis, during production of the finished product or as a cleaning agent for rinsing vessels, equipment, packaging material etc.

Different grades of water quality are required depending on the different pharmaceutical uses.

Control of the quality of water, in particular, the microbiological quality, is a major concern and the pharmaceutical industry devotes considerable resource to the development and maintenance of water purification system in the storage and distribution loop.



Load cell



Uses of water in pharmaceutical and biotechnology

- Parenteral
- Ophthalmic
- Cytotoxic preparation
- Haemofiltration haemodiafiltration solution
- Peritoneal dialysis solution
- Irrigation solution
- Nasal/ear preparation
- Cutaneous preparation
- Buffer preparation
- Oral preparation
- Clean in place process

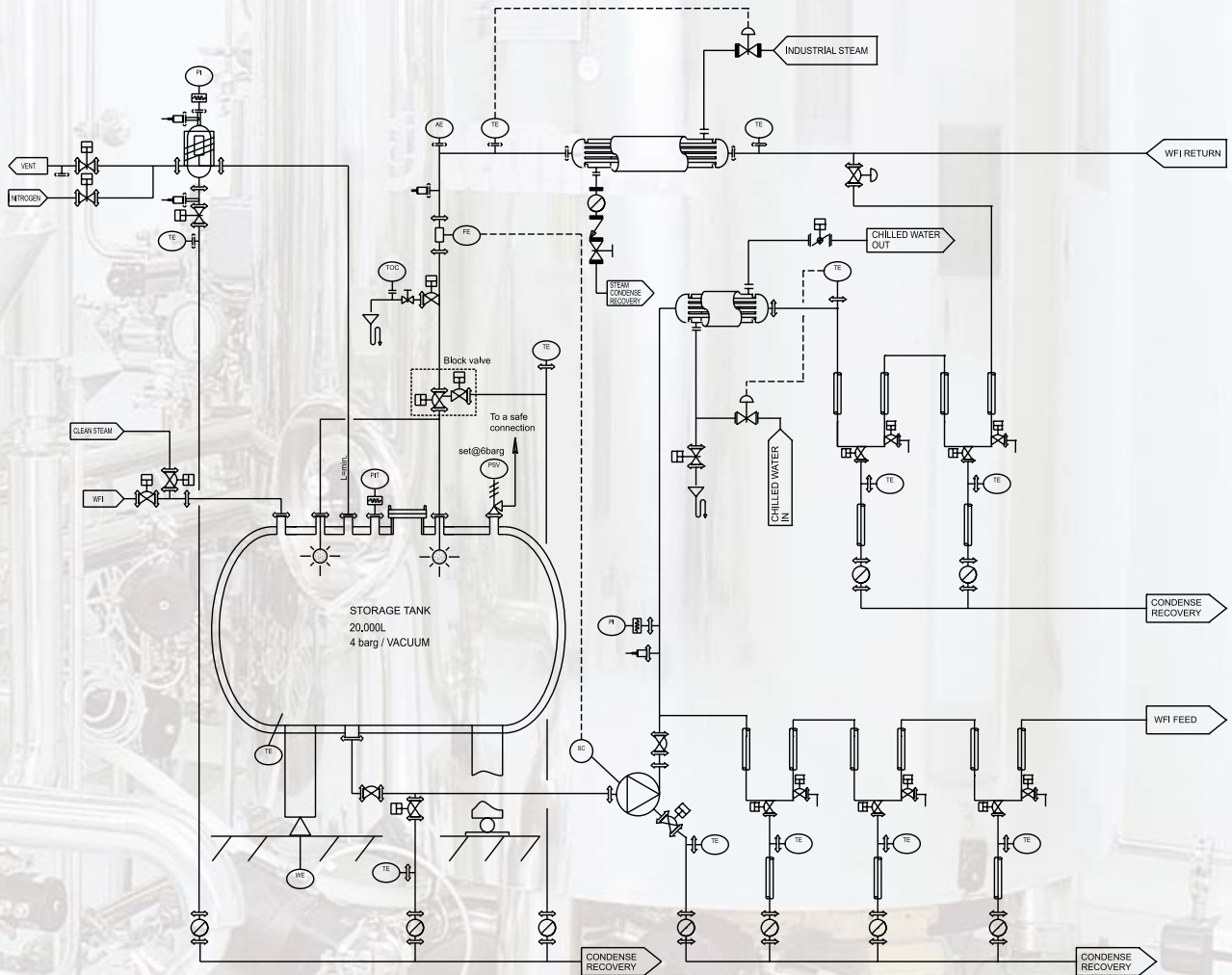


WFI - Storage tank

Storage and Distribution system

TECNinox has a great experience in design, supply, installation and validation of purified water, WFI distribution system. Storage tanks and distribution pipework systems are potential sources of contamination, particularly from bacteria. Good design practice and proper maintenance regimes are needed to minimize problems. Various methods can be used to avoid quality degradation during storage and distribution of the highly water system.

TECNinox high purity systems are designed in accordance with cGMP guidelines and comply with international codes and regulations governing medicinal product manufacture referred to in various regional Pharmacopeia as, for example USP, EP, and JP. These regulation specify standard of purity for a number of waters including Purified Water, highly Purified Water and Water for Injection.



Key criterias for Purified Water (PW) – (HPW) & Water for Injection (WFI) loops

- No stagnant conditions and areas of low flow rate.
- Temperature control.
- Proper slope of the pipeline to ensure drainability.
- Stainless steel surface finish with appropriate roughness in order to avoid nutrient and biofilm accumulation.
- No deadlegs area.
- Periodic sanitisation or sterilisation of the storage tank and loop.
- Storage tank protected with 0.2 micron hydrophobic vent filter.
- Sufficient instrumentation and monitoring equipments.



Recirculation pump

Automation

We are able to supply the plant with any type of operating control you require: starting from local instrumentation with manual control, up to DCS or SCADA fully integrated system.

Temperature, conductivity, flow, TOC are considered our windows to the process, and by utilizing instrumentation in conjunction with process control, we can keep the difference between measured and desired values of variables.

The control system is designed according to the GAMP and if required 21CFR part11 compliant.

WFI - Buffer storage and distribution skid for a small plant



Generation
Storage and
Distribution
System for
Purified Media



Blood Plasma



Syrup and
Suspension



Cream
Gel
Suppository



Vaccines



Cytotoxic
Anticancer



Parenteral
Formulation
Compounding



Biotech
Modules
Superskid



Insuline



TECNinox

TECNinox S.r.l. - Via Emilia, 89/A - 43015 Noceto - Loc. Sanguinaro (PR)

Tel.: +39 0521 825324 - Fax: +39 0521 825257

www.tecninox.it - info@tecninox.it