LOOPS OF PURIFIED WATER (PW) AND WATER FOR INJECTIONS (WFI)

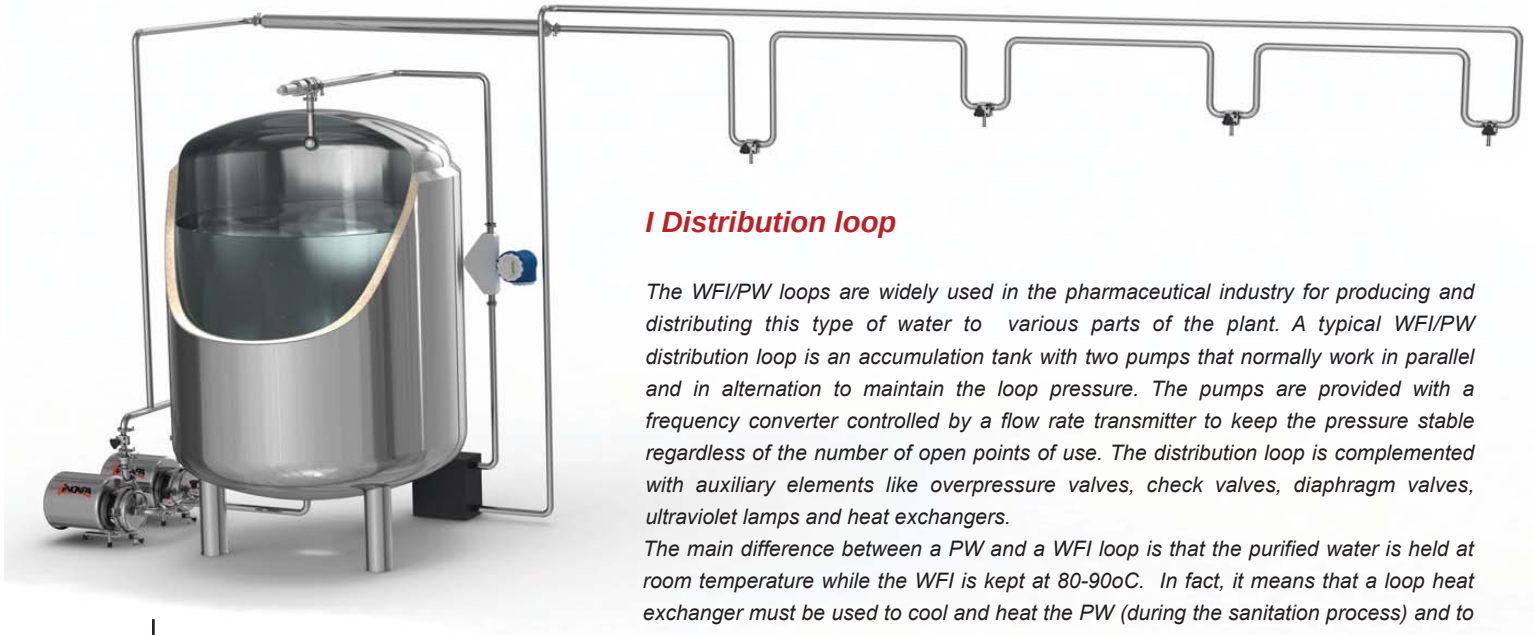
The use of purified water (PW) and water for injection (WFI) in the production processes is very common in the pharmaceutical industry. These systems are represented by two main stages: water production and its storage and distribution. The assembly consisting of a storage tank and a distribution loop is called a purified water (PW) loop or a water for injection (WFI) loop.
The difference between the purified water (PW) and water for injection (WFI) is mainly based on their physical, chemical and microbiological properties. The main differences are briefly described below.

I Purified water (PW)

A typical purified water system consists of various stages, each one is designed for further purification of water. The first step is known as "pretreatment" and the aim of is to modify the supplied water quality until it is suitable for final treatment. The following processes are performed at this stage: control over fouling, elimination of particles and turbidity; control over rust and elimination of water hardness and of metals; control over corrosion and degradation; elimination of organic materials and microbiological impurities; and also control over microbial growth and elimination of the applied chemical agents. The next step is known as "final treatment" and mostly consists of passing the pretreated water through the reverse osmosis modules (other systems available: ultrafiltration, electro-deionisation, distillation according to the requirements). Before its storage, the treated water is passed through a UV lamp to reduce the microbial load.

I Water for injection (WFI)

Water for injection has the highest purity possible and it is sterile. It is mainly used as a medium in the preparation of injection solutions and must therefore have the highest level of chemical purity and must be completely sterile.
For some applications, sterilising filtration is acceptable (microfiltration through 0.22 µm filters) as a way of obtaining sterile solutions, in the case of WFI, distillation is the only accepted method. Industrially, WFI is obtained by means of condensing clean steam coming from a generator supplied with purified water (PW). WFI is condensed and is generally kept at 80 - 90 °C to maintain its properties.



I Distribution loop

The WFI/PW loops are widely used in the pharmaceutical industry for producing and distributing this type of water to various parts of the plant. A typical WFI/PW distribution loop is an accumulation tank with two pumps that normally work in parallel and in alternation to maintain the loop pressure. The pumps are provided with a frequency converter controlled by a flow rate transmitter to keep the pressure stable regardless of the number of open points of use. The distribution loop is complemented with auxiliary elements like overpressure valves, check valves, diaphragm valves, ultraviolet lamps and heat exchangers.
The main difference between a PW and a WFI loop is that the purified water is held at room temperature while the WFI is kept at 80-90oC. In fact, it means that a loop heat exchanger must be used to cool and heat the PW (during the sanitation process) and to heat and maintain the temperature of the WFI.
Another important difference is that the WFI loops must be provided with cooled points of use to cool the water before use.

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I Common application problems

As mentioned before, the most common problem of the loops is the maintenance of the physical, chemical and microbiological properties of the PW/WFI. For this reason, the design of the installation must be completely cleanable, drainable and its components must be capable of resisting the rigorous sanitation/sterilisation processes.

I Solution by INOXPA

INOXPA offers the following components for the PW/WFI distribution loops: centrifugal pump, regulating diaphragm and point of use valves, check valves, overflow valves that comply with the highest requirements of hygiene in the pharmaceutical industry. Loops can be totally automated with SCADA systems and also validated.

I Description of the solution

The centrifugal pump is the PROLAC SWFI model with clamp connections and sanitary SiC/TungC/EPDM mechanical seal (standard version). An optional double mechanical seal (SiC/TungC - SiC/TungC) is available with a barrier of the process water. The pump is completely drainable and all parts in contact with the product are manufactured in AISI 316L. Surface finish: Ra < 0.5 µm.
There is a possibility of offering an assembly of two pumps completely connected, with diaphragm and check valves, mounted in parallel on one baseplate can be offered.

Manually or pneumatically actuated diaphragm valves are intended for use in hygienic and aseptic processes in the pharmaceutical industry.
Furthermore, this valve type is valid for controlling or regulating flow rate and for work on close/open duties.
The unique "V" shape of the body is different from the "W" profile of the traditional diaphragm valves. Thus the valve has excellent flow characteristics in comparison with other designs. Additional benefits are better cleanability, excellent performance on products with particulates and less cavitation on flow control applications.

The function of the NDL diaphragm valve intended for points of use is to close only one product discharge outlet of the main line, and standard diaphragm valves close the whole line.
The design of this valve type reduces the dead leg to minimum. This condition is preferred by standards like ASME BPE in the pharmaceutical industry. The valve body is machined from a block of stainless steel, it is completely drainable, all parts in contact with the product are manufactured in AISI 316L. Surface finish: Ra < 0.5 µm. Standard diaphragm: EPDM (components in accordance with FDA177.2600).

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Check valves are fitted to the discharge outlets of each of the pumps mounted in parallel in order to prevent the water from recirculating through the other pump. This valve allows a low flow rate so that the water in this area does not remain stagnant.

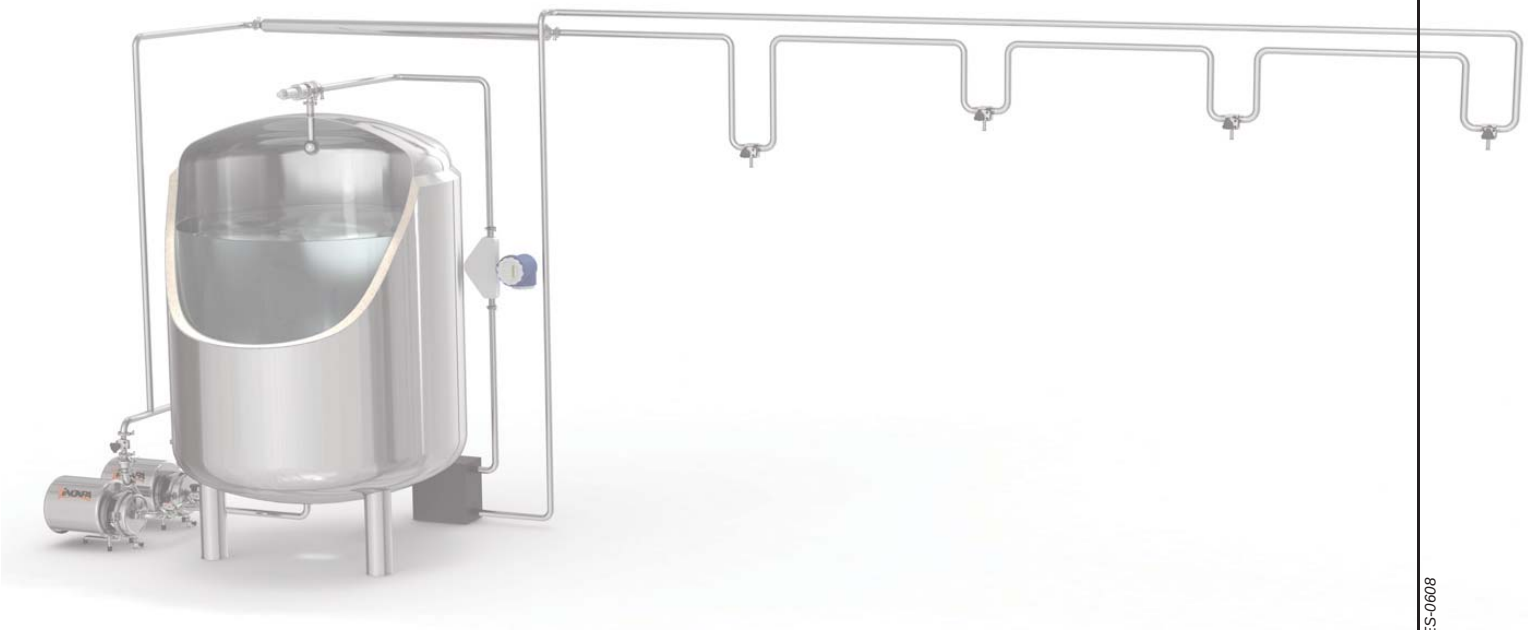
Overflow valves are installed at the end of the line to maintain pressure at the end of the loop. As a result, the points of use in this area are provided with pressure. These valves are also used to prevent pump cavitation by creating a counterpressure during acceleration when the end-of-line flow rate is not sufficient.

INOXPA also supplies fittings (e.g. pipes, bends, Tees, reductions and conventional and cooled points of use, etc.) certified in accordance with BPE standards, suitable for use in purified water loops.

Plate or tubular heat exchangers can also be supplied to heat the loop water. The exchangers are usually tubular or double plate in order to prevent any contamination.

INOXPA offers a wide range of solutions for processes automation applying the most advanced technology. The solutions offered for the pharmaceutical and biotechnological sector are characterised by total automation and meet internationally recognised quality standards such as GAMP, cGMP, USDA, 3A, FDA and Pharmacopoeia.

Documentation necessary for validation/qualification of the control systems and equipment is provided.



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