the importance of water purification in pharmaceuticals manufacturing

SUEZ

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Purified water is essential in a wide range of pharmaceuticals manufacturing applications, with varying degrees of purity required for different purposes.

While routine processes such as Cleaning-in-place (CIP) may demand a relatively low level of purification, for other applications, including analytical experimentation and testing in the laboratory, it is absolutely critical that the highest level of water purity is achieved, using highly advanced water purification technology.

Water is perhaps the most commonly found raw material in pharmaceutical manufacturing, being used in product development, testing and analysis, for product make-up, cleaning production machinery and, in the form of steam, for autoclave feeds, indirect/direct heating of raw materials during the manufacturing process and for CIP duties.

In each case, water drawn from a mains supply, borehole or local groundwater source cannot be used in its raw form, as it will include a wide range of contaminants that will affect the quality, consistency or even safety of the finished product. These contaminants range from organic and suspended matter in surface water to high levels of dissolved minerals in groundwater.

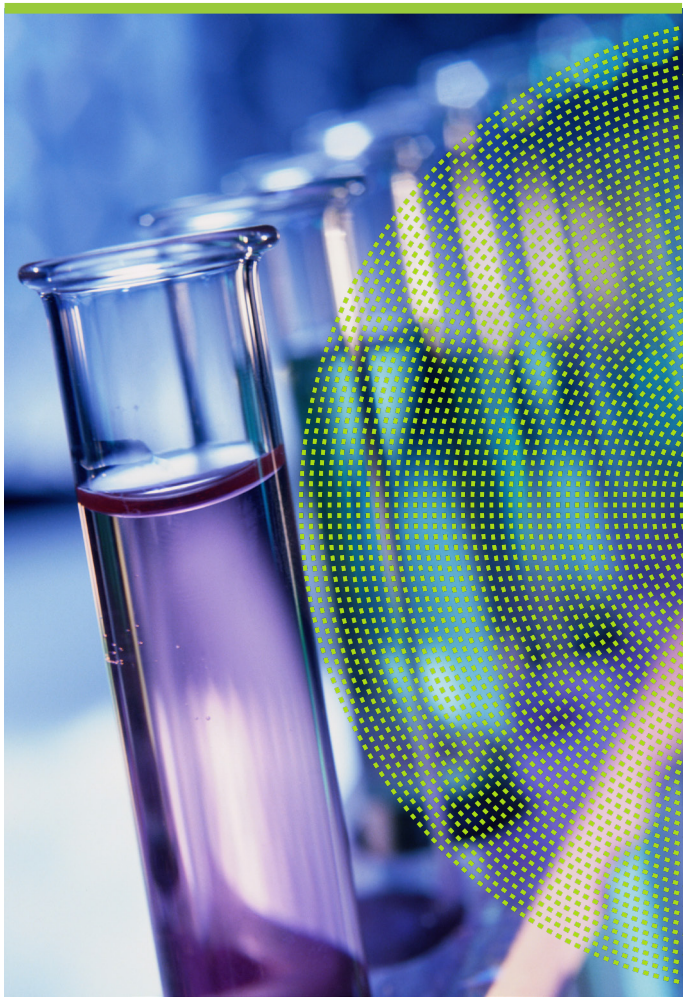
The fact that the successful production of high value pharmaceutical products depends on the quality and consistency of raw materials means that reliable control of water purity is critical. In turn, this depends on correctly specifying the appropriate equipment, which requires an understanding of the quality of the source water.

Water chemistry

In essence, the chemistry of the water supply will depend on the geology of the surrounding catchment area, local environmental conditions and the choice of source between ground and surface waters. In each case, supplies can generally be categorised as soft water/high organics or high hardness/low organics.

Areas with soft water and high organics are typically those where supplies are taken from a surface source such as a reservoir or river, and where the underlying geology is impervious to the percolation of rainwater.

This results in a supply with low levels of dissolved minerals and in particular hardness salts of Calcium and Magnesium but often with perceptible colour and high dissolved organic materials.



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The nature of supplies drawn from surface sources can vary greatly and be subject to short term seasonal changes, extreme weather conditions and the life cycle of many types of flora that might bloom for only a few months of the year; cyanobacteria, or blue/green algae, being a typical example, which can be difficult for conventional purification systems to eliminate.

Maintaining consistent quality has also recently been affected by the issue of increased rainfall, which results in demands on water authorities to put in place additional treatment programmes to deal with the massive fluctuations in abstracted water quality.

The variable condition of water supplies under these conditions and in areas of high risk can therefore make the design of raw water treatment systems more complicated, as they generally need to be based on the anticipated worst case conditions and will almost certainly require pre-treatment, including processes such as conventional media filtration to reduce seasonal levels of suspended and dissolved solids.

By comparison, water drawn from boreholes and aquifers in regions with chalk sub-strata, have a relatively stable chemistry that is easier to treat and predict. In these areas, acidic rainwater will percolate through the chalk. This effectively filters out any dissolved organics and particulates, but also causes the water to absorb high concentrations of minerals, in particular Calcium, Magnesium and Sodium salts, which can significantly impact on the water treatment system design for example in preventing scaling due to high levels of water hardness. The depth of most boreholes means that water supplies are generally protected from the influences of seasonal rainfall, temperature and biological activity and so the design of any water treatment system becomes more straightforward.

Quality control

Clearly, following the appropriate quality standards is a prerequisite to successful manufacturing. A practical starting point is the guidelines for Good Manufacturing Practices (GMP) issued by the US Food and Drug Administration (FDA), which state the following:

'You should determine whether:

- The water used as a pharmaceutical ingredient is used as-is (i.e., directly from the tap) or if it has been treated before being used (i.e., has it been treated by such means as deionization, distillation, or reverse osmosis)
- There are established procedures for ensuring that the water used as a pharmaceutical ingredient
- Is of a defined quality
- Is not affected by materials used in the water
- Is being tested or monitored regularly to verify that it meets applicable chemical, physical, and microbiological quality; and
- The entire system for supplying water used as a pharmaceutical ingredient is set up to avoid stagnation and risks of contamination (This system should be routinely cleaned and sanitised according to an appropriate Standard Operating Procedure (SOP) that ensures no biofilm build-up.)'

Beyond this, there may be specific quality standards and validation requirements that need to be followed, depending on the nature of the product and of your particular organisation.

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Producing purified water

The wide variations in the chemistry of water supplies can complicate the task of conditioning raw water to remove all minerals, chlorine, bacteria and other pathogens and suspended solids. In particular, the specification and installation of purification systems should be carried out in partnership with a specialised supplier with the detailed knowledge to ensure that systems are correctly designed to maximise removal and flow rates maintain consistency, while optimising long term operating costs, with minimum water and energy consumption.

For many smaller manufacturers of pharmaceuticals the use of distilled water, purchased by the litre, may be a viable and safe option. However, for most of the pharmaceuticals sector, even in product development and laboratory testing, distilled water is unlikely to meet the required level of purity or cost.

For laboratories or low volume production environments, dedicated bench-top or floor standing water purification systems offer an ideal solution. These typically require just a connection to mains water and power supplies, so are quick to set up and easy to operate. They can produce high purity water – if required, up to the theoretical maximum of 18.2MΩ.cm – at volumes ranging from a few litres per day to several hundred.

Each system is self-contained and can integrate a number of water purification technologies in a single unit; for example, pre-treatment, reverse osmosis, UV irradiation, ion exchange or electro-deionisation (EDI), and sub-micron filtration. Control is normally via a front mounted LCD touch screen display, providing details such as water quality, temperature and flow rates, with visual and audible alarms and the ability to export operating data via a USB or networked connection.

Depending on the application, higher volume production operations essentially use scaled up versions of the smaller water purification systems described above, perhaps supplemented by systems such as sand and multi-media filters, for eliminating particulates, or activated carbon adsorption systems for the removal of organic contaminants and chlorine compounds that can affect colour, taste and odour. Reverse osmosis is used for the bulk of the removal of ionic or dissolved mineral contaminants. In addition, ion exchange

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technology in the form of either ion-exchange resins or Electro-deionisation (EDI) is often used to polish the purified water up to compliant levels, with UV and bacterial filtration commonly being added to maintain microbiological integrity.

Reverse osmosis (RO) is one of the most commonly used technologies and incorporates specialised semipermeable membranes through which pressurised feed water is passed to remove inorganic ions and dissolved organic contaminants. This process enables up to 98% of the dissolved minerals and salts contained in the raw water supply to be rejected, together with organic compounds and bacteria.

The latest low energy, high flux RO systems incorporate spiral wound elements constructed from polyamide-thin film composites. These elements are manufactured using advanced adhesive techniques, which significantly enhance membrane surface area available for purification, without compromising the mechanical or chemical properties of the membrane.

This construction produces high flow rates yet at far lower feed pressures, up to 50% less compared to traditional high rejection RO elements, with the bonus of greater resistance to fouling and reduced pressure drop. It also enables operating life to be extended and results in smaller RO plant due to reduction in the number of membrane elements needed to achieve desired flow rates, thereby cutting capital and maintenance costs still further.

Choice and quality

The wide choice of modern purification technologies available from leading suppliers such as SUEZ now gives pharmaceuticals manufacturers a wide range of options to ensure that the output quality and consistency of often variable raw water sources matches the specific demands of each application. These technologies also allow the characteristics of each water source to be standardised globally, while meeting hygiene and safety standards and minimising water and energy consumption.

Please contact us to discuss your applications or start up requirements; we can advise on water quality and quantity and ensure your water supply meets all current legislation. Our advice is free of charge, and we will be happy to undertake free site surveys if required.

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Contact

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