Industrial filtration

Liqui-Cel membrane contactors can help meet pure steam requirements in pharmaceutical industry

The problem

Pure steam is used in sterilization chambers as a common method to sterilize pharmaceutical products, such as equipment parts, instruments, containers and materials for sterile environments. Although regional Pharmacopeias in Europe, Canada, Japan, India and China have minor differences in limits and measurement techniques, they each have similar specifications on pure steam sterilization and Water for Injection (WFI).

The US Pharmacopeia (USP) defines pure steam as steam that meets the criteria for WFI when condensed. The European and British Pharmacopeias have similar standards with additional specifications for dryness and the noncondensible gas content allowance. The UK National Health document HTM 2010 and the European Standard EN 285 set limits for noncondensible gases at 3.5% v/v and moisture content <5.0%.

The USP does not include a requirement for noncondensible gases but does state, “The level of steam saturation or dryness, and the amount of noncondensible gases are to be determined by the pure steam application.” This places the responsibility of producing the proper quality of steam for a particular application on the user. In many cases pure steam generators adopt the European and British pharmacopeia requirements for noncondensible gases and dryness to assure the steam meets or exceeds the required quality.



Figure 1. Thermo Scientific™ Liqui-Cel™ Membrane Contactors

Table 1. Specifications

Specification	Pure steam	HTM 2010/EDN 285
pH	5–7	5–7
TOC	<500 ppb	<500 ppb
Total bacteria	≤10 CFU/100 ml, pathogen free	≤10 CFU/100 ml, pathogen free
Endotoxin	≤0.5 EU/ml	≤0.5 EU/ml
Conductivity 68°F (20°C)	1.1 µS/cm	1.1 µS/cm
Noncondensible gas	To be determined by application	3.5%
Moisture		<5.0%

Noncondensible gas

Whenever water and gas come into contact, gas has the tendency to dissolve into the water. The amount of gas that dissolves into the water is governed by Henry's Law, which dictates that the amount of gas dissolved into a liquid is proportional to the partial pressure of the gas.

The partial pressure value of the gas is dependent on temperature and atmospheric pressure. Henry's Law shows us that noncondensible gases, such as nitrogen, oxygen and carbon dioxide, will be present in water that comes into contact with the atmosphere.

Any noncondensible gases present in water that is used to produce steam will carryover with the steam when the water is boiled. These noncondensible gases mixed into the steam decreases the steam temperature at a given pressure. This reduces the sterilizer's ability to properly transfer the required heat to sterilize its contents, so the removal of dissolved gases is a necessary step in the steam generation process.

Conductivity

The conductivity specification for WFI water is 1.1 µS/cm. Dissolved carbon dioxide can contribute to the conductivity of water. Carbon dioxide will freely pass through an RO membrane and dissociate in the permeate water to increase the conductivity.

The solution

In order to remove the dissolved gas, many steam generators will preheat the feed water. Heating lowers the solubility of dissolved gases in the water, thereby lowering any noncondensible gas carried over into the steam. However, this process requires that the hot water be stored to allow time for the gas to be released. This process is energy intensive.

Carbon dioxide removal is often done using a double pass RO with pH adjustment. This requires a higher initial investment and operating cost.

The process

Thermo Scientific™ Liqui-Cel™ Membrane Contactors offer a reliable, in-line solution that is far more economical for removing dissolved gas. The feedwater enters the membrane contactor on the outside (shellside) of the microporous hollow fiber. Since the hollow fiber is a hydrophobic membrane, water cannot pass through the small pores in the membrane wall. However, the dissolved gases will pass through the pores to the inside (lumenside) of the hollow fiber and exit the lumenside port.

A vacuum is applied to the lumenside of the hollow fiber. By lowering the gas pressure in contact with water a driving force is generated to remove the dissolved gas from the water (see Figure 2).

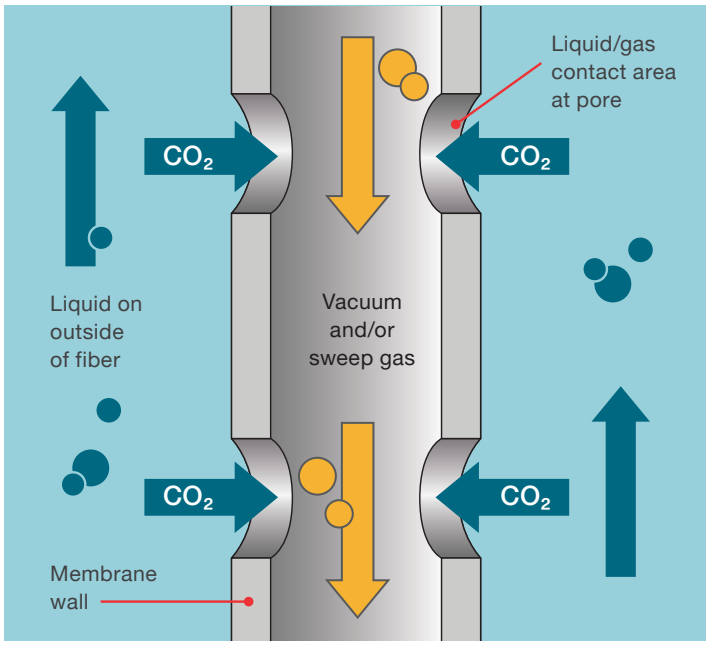


Figure 2. Dissolved gas is removed from water using a Thermo Scientific™ Liqui-Cel™ Membrane Contactor



Figure 3. Operating System by Syntegon Technology (formerly Pharmatec GmbH, a Bosch Packaging Technology Company)

The result

Table 2. Thermo Scientific™ Liqui-Cel™ Membrane Contactor features and benefits

Feature	Benefit
Inline	No need for storage tank to allow time for gas to be removed from hot water
Operates under vacuum only	No need to preheat the water—energy savings
Compact	Can fit on existing racks
FDA listed materials	Easily validated

Application engineering

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