

Liqui-Cel® Membrane Contactors Can Help Meet Pure Steam Requirements in Pharmaceutical Industry

Pure Steam

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 noncondensable gas content allowance. The UK National Health document HTM 2010 and the European Standard EN 285 set limits for noncondensable gasses at 3.5% v/v and moisture content < 5.0%.

The USP does not include a requirement for noncondensable gasses but does state “The level of steam saturation or dryness, and the amount of noncondensable 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 noncondensable gasses and dryness to assure the steam meets or exceeds the required quality.

| 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 (20° C) | 1.1 µS/cm | 1.1 µS/cm |
| Noncondensable Gas | To be determined by application | 3.5% |
| Moisture | To be determined by application | < 5.0% |

Noncondensable 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 noncondensable gasses, such as nitrogen, oxygen and carbon dioxide, will be present in water that comes into contact with the atmosphere.

Any noncondensable gasses present in water that is used to produce steam will carryover with the steam when the water is boiled. These noncondensable gasses 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 gasses 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.

Meeting the Specification

In order to remove the dissolved gas, many steam generators will preheat the feed water. Heating lowers the solubility of dissolved gasses in the water, thereby lowering any noncondensable gas carried over into the steam. However, this process requires that the hot water is 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.

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 1.)

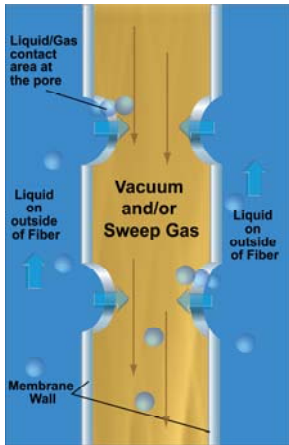


Fig. 1



Operating System by Pharmatec GmbH
A Bosch Packaging Technology Company

For more information and system sizing, please contact your Membrana representative or visit us online at www.Liqui-Cel.com.

| Feature | Benefit |
|----------------------------|-----------------------------------------------------------------------------|
| In-line | 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 |

This product is to be used only by persons familiar with its use. It must be maintained within the stated limitations. All sales are subject to Seller's terms and conditions. Purchaser assumes all responsibility for the suitability and fitness for use as well as for the protection of the environment and for health and safety involving this product. Seller reserves the right to modify this document without prior notice. Check with your representative to verify the latest update. To the best of our knowledge the information contained herein is accurate. However, neither Seller nor any of its affiliates assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of the suitability of any material and whether there is any infringement of patents, trademarks, or copyrights is the sole responsibility of the user. Users of any substance should satisfy themselves by independent investigation that the material can be used safely. We may have described certain hazards, but we cannot guarantee that these are the only hazards that exist.

Liqui-Cel, Celgard, SuperPhobic and MiniModule are registered trademarks of Membrana-Charlotte, A division of Celgard, LLC and nothing herein shall be construed as a recommendation or license to use any information that conflicts with any patent trademark or copyright of Seller or others.

©2009 Membrana - Charlotte A Division of Celgard, LLC

(TB73 12-09)

Membrana - Charlotte
A Division of Celgard, LLC
13800 South Lakes Drive
Charlotte, North Carolina 28273 USA
Phone: (704) 587 8888
Fax: (704) 587 8610

Membrana GmbH
Oehder Strasse 28
42289 Wuppertal
Germany
Phone: +49 202 6099 - 658
Phone: +49 6126 2260 - 41
Fax: +49 202 6099 -750

Japan Office
Shinjuku Mitsui Building, 27F
1-1, Nishishinjuku 2-chome
Shinjuku-ku, Tokyo 163-0427
Japan
Phone: 81 3 5324 3361
Fax: 81 3 5324 3369



ISO 9001
ISO 14001

MEMBRANA
Underlining Performance

www.liqui-cel.com

A **POLYPOR** Company