

Pre-conditioning and Hot Water Sanitization of Reverse Osmosis Membrane for Medical Water Production

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Abstract : Water is a critical commodity in the healthcare and medical field. The utility of medical-grade water spans from washing surgical equipment, drug preparation to the key element of life-saving therapy such as hydrotherapy and hemodialysis for patients. A properly treated medical water reduces the bioburden load and mitigates the risk of infection, ensuring patient safety. However, any compromised condition during the production of medical-grade water can create a favorable environment for microbial growth putting patient safety at high risk. Therefore, proper upstream treatment of the medical water is essential before its application in healthcare, pharma and medical space. Reverse Osmosis (RO) is one of the most preferred treatments within healthcare industries and is recommended by all International Pharmacopeias to achieve the quality level demanded by global regulatory bodies. The RO process can remove up to 99.5% of constituents from feed water sources, eliminating bacteria, proteins and particles sizes of 100 Dalton and above. The combination of RO with other downstream water treatment technologies such as Electrodeionization and Ultrafiltration meet the quality requirements of various pharmacopeia monographs to produce highly purified water or water for injection for medical use. In the reverse osmosis process, the water from a liquid with a high concentration of dissolved solids is forced to flow through an especially engineered semi-permeable membrane to the low concentration side, resulting in high-quality grade water. However, these specially engineered RO membranes need to be sanitized either chemically or at high temperatures at regular intervals to keep the bio-burden at the minimum required level. In this paper, we talk about Dupont's FilmTec Heat Sanitizable Reverse Osmosis membrane (HSRO) for the production of medical-grade water. An HSRO element must be pre-conditioned prior to initial use by exposure to hot water (80°C-85°C) for its stable performance and to meet the manufacturer's specifications. Without pre-conditioning, the membrane will show variations in feed pressure operations and salt rejection. The paper will discuss the critical variables of pre-conditioning steps that can affect the overall performance of the HSRO membrane and demonstrate the data to support the need for pre-conditioning of HSRO elements. Our preliminary data suggests that there can be up to 35 % reduction in flow due to initial heat treatment, which also positively affects the increase in salt rejection. The paper will go into detail about the fundamental understanding of the performance change of HSRO after the pre-conditioning step and its effect on the quality of medical water produced. The paper will also discuss another critical point, "regular hot water sanitization" of these HSRO membranes. Regular hot water sanitization (at 80°C-85°C) is necessary to keep the membrane bioburden free; however, it can negatively impact the performance of the membrane over time. We will demonstrate several data points on hot water sanitization using FilmTec HSRO elements and challenge its robustness to produce quality medical water. The last part of this paper will discuss the construction details of the FilmTec HSRO membrane and features that make it suitable to pre-condition and sanitize at high temperatures.

Keywords : heat sanitizable reverse osmosis, HSRO, medical water, hemodialysis water, water for Injection, pre-conditioning, heat sanitization

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