Electro Steam™
Food Safety Division

Steam Applications in the Pharmaceutical and Nutraceutical Industries

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Water is a key component of virtually every pharmaceutical and nutraceutical operation due to its role in the generation of steam. Industry professionals utilize steam for a variety of functions, including sterilizing processing and handling equipment, regulating humidity, and distilling and extracting active compounds.

However, to fulfill these process functions, the pharmaceutical and nutraceutical industries require high purity water and steam that meets their standards for safe and clean use. Clean steam generators provide an easy and affordable solution for this need.

Applications of Steam

Steam finds use in a variety of applications in the pharmaceutical and nutraceutical industries, including:

- **Steam cleaning.** Also referred to as sterilize-in-place and steam-in-place (SIP) processes, steam cleaning sanitizes manufacturing and assembling equipment to a high standard between production runs to remove trace residues and microbiological contaminations. With clean steam, processing facilities can sanitize a wide range of equipment, including autoclaves, centrifuges, condensers, continuous processing equipment, crystallizers, distillation and extraction columns, dryers and dryer pipes, filters, freeze dryers, packaging, and reactors.
- **Humidity control.** Steam generators allow industry professionals to control the humidity levels within cleanrooms for applications that need to maintain precise environmental conditions.
- **Steam distillation, extraction, and other processes.** Steam is used in production processes, such as distillation and extraction, that facilitate the formulation and production of pharmaceutical or nutraceutical products.
- **Clean water production.** Pure steam generators produce high purity water suitable for dilution of compounds used for injection.

- **Energy generation.** Steam serves as an energy source in heat exchange operations, especially in non-critical heat exchanges and exchanges regulated under the FDA's Current Good Manufacturing Practice (cGMP) standards.

To handle these functions and more on-site, industrial facilities employ electric steam generators to maintain a reliable source of steam.

Clean Steam vs. Utility Steam

Steam used in pharmaceutical and nutraceutical processes is classified into one of three categories—utility (or plant) steam, chemical-free steam, and clean (or pure) steam. These classifications are based on the quality of the steam, which is defined by the intended use and regulated by industry standards and pharmacopeias (i.e., an official publication that lists medicines and an overview of each product). For example, in 2006, the United States Pharmacopeia (USP) set the definition for pure steam as steam with water-for-injection (WFI) quality condensate.

Good manufacturing practices establish what type of steam may be used for various processes, such as:

- Non-critical HVAC functions, such as providing heating and cooling to a plant's front lobby or break room, can use utility steam.
- Non-critical and cGMP heat exchanges can use plant steam but often use pure steam.
- Sterilization processes and critical production steps generally require pure steam.

While in the previous section, we listed some of the most common uses of steam, below we provide an overview of which type of steam is required for each application.

Sterilize in Place or Steam in Place (SIP)

Pharmaceutical and nutraceutical production lines require sanitization between each use to minimize the risk of cross-contamination and trace ingredients in future batches. Sterilize-in-place and steam-in-place processes typically feature in a facility's sanitation routine. Following the clean-in-place (CIP) process, steam cleaners sterilize the entire biopharmaceutical production train in a facility. It's a timed process that uses clean steam made from USP purified water to adequately sanitize the equipment between production stages and halt the growth of microbiological contaminants.

ISO 13408-5:2006 states the requirements for SIP processes used to clean manufacturing equipment for sterile healthcare products and sets guidelines regarding control, operation, qualifications, and validation. The processes must inject steam into the components to heat them to a minimum temperature of 250°F and maintain the temperature for at least 30 minutes. Temperature sensors validate the operation and notify site managers of a SIP failure and if additional SIP operations are required.

There are two main ways to generate pure steam for SIP and other pharmaceutical and nutraceutical applications—clean steam generators and water purification systems. Although clean steam generators can directly produce pure steam, they primarily feature in larger water purification systems as support equipment.

Steam Humidification

Pharmaceutical and nutraceutical facilities employ steam to regulate humidity levels in both cleanrooms and non-critical HVAC systems. The use of clean steam in cleanrooms mitigates the risk of product contamination, while utility steam is used in areas that lack direct contact with the products.

Steam Distillation and Other Proprietary Formulation Processes

In many pharmaceutical and nutraceutical production processes—including parenteral and non-parenteral dosage form applications—steam directly interacts with active pharmaceutical ingredients (APIs) to produce the final substances. Specific applications include:

- Separating fatty acids from mixtures through steam distillation
- Extracting and refining organic compounds
- Providing heat in distillation, extraction, and formulation stages

For these sterile and high-purity applications, the use of a clean steam generator is required.

Production of Water-for-Injection (WFI)

Water-for-injection (WFI) is the condensate standard by which regulatory bodies define pure steam. Water that meets WFI standards is safe to use for diluting intravenous drug, making it the ideal measure for water or steam used in pharmaceutical production and sanitation.

Although small- and medium-sized facilities can use electrical steam generators to produce pure steam that meets the WFI standard, larger facilities typically employ water purification systems for this purpose. In these instances, electric steam generators are used to sanitize the purification equipment.

Energy Source for Non-Critical and cGMP Heat Exchanges

Heat exchangers and process heat systems employ steam as a consistent and controllable energy source. The FDA also identifies steam as current good manufacturing practice (cGMP) regulation for human pharmaceutical manufacturing applications.

Contact Electro-Steam for Clean Steam Generators

The pharmaceutical and nutraceutical industries use steam to facilitate the production of high-quality products that comply with industry standards and FDA regulations. To meet these high safety and quality standards, they typically require clean (or pure) steam for their operations.

At Electro-Steam, we offer a variety of clean steam generators designed for use in pharmaceutical, biotechnical, and laboratory applications. Our generator range includes:

- "Benchtop" low-pressure LG Series
- LB Series equipment (for larger facilities and more robust performance)
- Customized designs for specialty applications

About Us

We are a “Customer Service First” based industry-leading, Made in America OEM manufacturer of electric steam generators. Since 1952, Electro-Steam has provided our partners with the highest quality electric-fired miniature boilers in the USA. Electro-Steam has tens of thousands of units in use across the globe and just as many satisfied customers. Each one of our steam generators is built to ASME code, inspected by an independent licensed inspector, and registered with the National Board of Boiler and Pressure Vessel Inspectors as required by US law. Electro-Steam’s Steam Generators are available in many configurations for many industries and applications.

Contact Us **Resource Library**

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