Tech Sheet #S 604

Overview of Sanitary Utility Systems-Steam Grades

All pharmaceutical plants run essentially as two separate plants when considering utility systems. The industrial or "dirty" side utility system is used for infrastructure applications such as steam for building heat, water for plant maintenance and equipment washdowns, and air systems for pneumatic devices and instrumentation/control. These systems will closely resemble those seen in non-sanitary utility systems.

The pharmaceutical or "clean" side utility system is used for the actual production of the product, and although it may be functionally identical (example: steam for heating equipment or product), the pharmaceutical side will be separate from the industrial side and will be of entirely different construction. This tech sheet will explore the specifics of pharmaceutical or "clean" side utility systems.

Generating steam for utility services is a convenient way to introduce energy to processes. Steam can be broken into the following four steam grades based on its intended use.

Plant steam – This grade of steam is the lowest grade of steam and is suitable for all applications other than those requiring further filtering or sanitation. Plant steam utilized throughout life science facilities on systems and processes is never in direct contact with sanitary processes. It generally contains additives to protect the boiler and pipes from scaling and corrosion.

Filtered steam – This grade of steam is commonly referred to as culinary as it is suitable for the food and beverage industry. This grade is simply plant steam that has been filtered, typically by passing through a stainless-steel filter of five microns. "Accepted Practices for a Method of Producing Culinary Steam, Number 609-03" is published by 3-A and is the recognized minimum sanitary (hygienic) requirement for producing Culinary Steam that comes into direct contact with food products, other comestibles, or product contact surfaces (all surfaces in contact with culinary steam).

Filtered/culinary grade steam is utilized for all applications where the steam touches the food product, in sterilization, and on surfaces where steam and food touch. Application examples include:

- injection in milk pasteurization, soups, and sauces
- creating vacuums in food packaging

- humidification in bread proofing and finishing
- can and bottle sterilization
- SIP/CIP processes.

Clean steam – This grade of steam is suitable for the pharmaceutical industry and is considered the highest grade of steam. The steam is produced from purified water in a devoted clean steam generator, which is utilizing plant steam. Clean steam can be commonly specified wherever culinary steam is required. The clean version, however, is produced with a controlled water source, such as reverse osmosis, in a secondary clean steam generator without the use of water chemicals and any possibility of boiler carryover. In this manner, the quality of steam and condensate touching food is maintained.

Pure steam – This grade of steam is suitable for the pharmaceutical industry. Pure steam's quality and purity are greater than that required for food and beverage applications. Pure steam is generated by vaporization in a separate pure single and multiple effect distillation steam generator from purified water. The condensate of USP Pure is equivalent to water for injection (WFI). There is often a steam dryness stipulation of 0.9 from the generator. Pure steam applications include the production of WFI, direct injection, sterilizers, steam in place (SIP)/CIP) processes, and humidification.

It should be noted that the terms "clean and pure" steam can sometimes be used interchangeably so clarification must be sought to fully understand the end-user requirements and specifications to ensure the appropriate grade of steam is supplied and suitable for its intended use.

Distribution

Once the desired quality of steam is generated, it must be distributed. The steam headers should be designed to minimize condensate formation. Furthermore, any condensate present within the header shall be drainable. This can be accomplished by having piping run at a slight slope as well as sanitary steam traps at the end of each header branch, at intermediate points in a straight run, at the lowest point of a vertical riser, and any place where condensate could collect. The formed condensate should be routed to drip legs where sanitary thermostatic steam traps are located. Thermostatic steam traps have the ability to discharge air as well as condensate. Non-free draining steam traps are not recommended.

Throughout the distribution, piping system flow and pressure control, regulators are a critical component. Regulators are placed where the inlet is on the bottom, so the collected condensate is drainable. Regulators should be placed throughout the distribution system where needed. Weir style diaphragm valves are often found at sterile boundary points of the aseptic system and commonly throughout the system for both flow metering and shutoff control.

Steam at 250°F (121°C) is the most common operating temperature as it eliminates micro-organisms and their spores. Other operating pressures and temperature are sometimes used depending on the specific application. In pure steam applications sampling is recommended to

ensure that the media quality is compliant with relevant standards. Sample coolers provide a sterile and convenient method of cooling the media so that specimen can be taken for analysis.

Summary

The two sides of the pharmaceutical steam system are very different in terms of use and application. Preparing the steam and associated pipe work is an extremely important and detailed process. The clean and pure sides of pharmaceutical steam systems require separate and distinctly different steam generation components and distribution lines to ensure steam is suitable and sterile at the point of use. It is imperative that when discussing the required level of steam grade and quality, end-users and specialty steam product manufacturers confirm what is defined as clean or pure steam. This will ensure that, when designed and installed per the manufacturer's recommendations, clean and pure steam systems will provide reliable and consistently high-quality steam for the application.