تحضير، تعبئة و تغليف، حلول هندسية
Process, Packaging, Engineering

ORBITAL WELDING PIPING SYSTEM QUALIFICATION

In the pharmaceutical industry the automatic orbital TIG (Tungsten Inert Gas) welding became established to secure reproducibility and high quality which is the most important for the long-term successful operation of the system. The orbital TIG welding process is used to manufacture piping systems supplying processing of different types such as preparation line, purified water (PW), purified steam (PS) and water for injections (WFI).

The orbital welding power supplies have evolved from digital switch machines on which weld parameters set on the front panel of the orbital machine to microprocessor based machines that store weld parameters as programs in memory and the power supply can print a report. The orbital welding point report that consist welding process parameter (welding point number, welder name, date and time, welding current, electrode speed, pulse times and level times), much can be determined by analyzing the weld parameters for example: variations in the voltage may indicate a change in the arc gap (distance between the electrode and weld joint Figure 1) which could be the result of ovality in the weld joint. It could also indicate that the weld joint was not properly prepared and that there is a gap or space present in the weld joint. There are numerous other possible conclusions that could be made regarding different data variations. Without the data, such an analysis would not be possible.

Figure 1

These analysis can be used for welding procedure qualification, the welding qualification is required by the FDA (U.S food and drug administration) to provide full traceability for all materials and procedures used for construction of bioprocessing systems, the FDA seek to determine whether the requirements of three key documents, the cGMP (Current Good Manufacturing Practices), the ASME (American Society of Mechanical Engineers) and the project specifications have been met. The documentation is required to provide the necessary verification that each weld meets the acceptance criteria as defined by the weld specification. In the event there is a problem with a system, such as contamination, the documentation provides a means to go back and review each welded connection as part of the effort to track down and find the source.

The qualification test of orbital welding prior, during and upon to welding work properly identified, the welding report analysis is a part of tests to do to ensure the quality of piping system installation upon the welding work in addition to RVI (Remote Visual Inspection). The camera (Figure 2) used for the RVI gives a good view of the weld root and the tinted area along the weld. Modern devices make it possible to reach welds with a video-camera within 10 m from the inlet opening.The root side shall be inspected from various viewing angles. The image obtained can be enlarged and dimensions of the defect detected can be measured.

Figure 2

Qualified and certified welders are required for welding work for co-ordination and control of welding work knowing well the pharmaceutical equipment. He should also meet all other quality requirements for welding work[1] and follow the designs of piping system as well as the welding maps identify the welding procedure specification (WPS), each welder should weld control test pieces for all the diameters to be welded that particular day. These test pieces (Figure 3) shall be stored and serve as reference specimens for the subsequent assessment of weld quality at the facility.

Figure 3

1 EN 729-3: Quality Requirements for Welding - Fusion welding of metallic materials. Part3: Standard quality requirements

Proper inert gas purging is necessary to prevent the formation of heat tint during welding is critical to maintaining the corrosion resistance of type stainless steel (AISI SS 316L). The amount of color or heat tint produced during welding of stainless steel is proportional to the amount of oxygen and moisture in the purge gas and has a direct bearing on the corrosion resistance of the weldment. The BPE Standard specifies color-free welds on the product contact surface, while some slight bluish or gold color may be permitted in the heat-affected-zone of the weld. The BPE references the color chart[2](Figure 4). Typically discoloration levels higher than sample number 3 have been unacceptable for bioprocess piping systems.

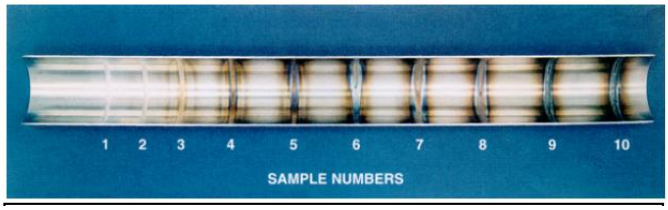

Figure 4

Orbital welding technology and more than that are available by AFAQ, which constantly look up to use the latest technologies to provide the best services to its clients, the tests shown above are a part of what is being applied by AFAQ during the piping system installation to ensure the highest quality standards and to recommendations of the FDA.

Figure 5

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2 in the American Welding Society (AWS) D18.1/D18.2 Specification for Welding of Austenitic Stainless Steel Tube and Pipe Systems