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| Standard Operating Procedure Materials Preparation for GTAW in Pharmaceutical | SOP No. 5.004 |
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DCR No.: 10007
Revision No.:7

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- 1 Purpose
 - 1.1 To establish a standard preparation procedure of piping materials for orbital/automatic and manual gas tungsten arc welding (GTAW).
- 2 Scope
 - 2.1 This procedure applies to high-purity stainless steel and tool hookup assemblies.
- 3 Responsibility
 - 3.1 Therma general foreman (GF) shall manage the welders and verify compliance with this procedure.
 - 3.2 The welders who have been certified under SOP 7.009 (GTAW Welder Performance Qualification) shall be responsible for performing procedures listed below.
- 4 Procedures
 - 4.1 Prepare materials in an area protected against airborne contamination.
 - 4.2 Select materials for use from the "Approved Material" storage area. Verify the materials have been approved by the Quality Control Examiner (QCE) using procedures described in SOP 7.002 (Quality Control Examination for Pharmaceutical Material). General Note: Welder shall use latex or lint free cotton gloves when handling approved material.
 - 4.2.1 Cut the required tubing by using a cutter dedicated to stainless steel tubing.
 - 4.2.2 Label the tubing heat number on the piece which is cut from the main tube length. Ensure that all pieces are labeled with the original heat number.
 - 4.2.3 Recap and return all unused tubing to the "Approved Material" storage area.

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- 4.3 Use a tube squaring machine specifically designed to provide a square end (squareness tolerance should be less than 10% of wall thickness).
- 4.4 Use a stainless steel or titanium carbide deburring tool to remove all burrs.
- 4.5 Use lint-free cloth and 90% isopropyl alcohol in water to remove cutting chips from inside pipe. Completely clean both pieces to be welded 1-1/2 inches back from weld area.
- 4.6 Make final examination of interior for scratches or other surface defects.
- 4.7 For valves and instrumentation with low melting point materials, remove these items to protect against damage.
- 4.8 If material is not ready for fabrication, cap off all openings of the material with appropriated plastic end protection as example "Caplug" that is manufactured by Protective Industries, Inc.

5 Review and Approval

- 5.1 No approval is necessary.

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Document Approval


 Field Operations Manager

3-6-12
 Date


 Process Systems Manager

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 Date


 Engineering Manager

3/06/12
 Date


 Quality Assurance Manager

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 Date

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