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1.0 Purpose

This procedure explains the use and maintenance of Mobile Steam Samplers that are used for obtaining condensed-steam samples from pure-steam or clean-steam sources.

2.0 Scope

This procedure applies to Biopharmaceutical Development Program (BDP) personnel who will be performing this procedure [REDACTED].

3.0 Authority and Responsibility

3.1 The Director, Technical Operations, Late Process Sciences, and the Director, Process Analytics\Quality Control (PA\QC), Biopharmaceutical Development Program (BDP) have the authority to define this procedure.

3.2 Biopharmaceutical Quality Assurance (BQA) is responsible for assignment of this procedure and for review of results for accuracy.

3.3 Biopharmaceutical Manufacturing personnel or designated personnel will perform this procedure.

3.4 BQA is responsible for quality oversight of this operation.

4.0 Equipment

- 4.1 Sanitary heat exchanger with tri-clamp connections for product flow path.
- 4.2 WK-500 LAUDA Water Circulation Bath with Cooler.
- 4.3 Dedicated flexible inlet and outlet tubing for condensing water use.
- 4.4 High-pressure, smooth-bore steam-collection flex line dedicated to use with pure- and clean-steam utilities.
- 4.5 Adequate water source (potable/non-potable) for cooling (ex. process-chilled water).
- 4.6 3/4" Tri-clamps, BDP PN 21026 or BDP-approved equivalent.
- 4.7 3/4" Tri-clamp sanitary gaskets, 3/4" in EPDM, TFE or Tefsteel, BDP PN 20956, 20957, 21246 or BDP-approved equivalent.

5.0 Procedure

- 5.1 Operation using an external water source for condensing steam.
 - 5.1.1 Attach the flexible inlet tubing to the lower connection or inlet on the sanitary heat exchanger.
 - 5.1.2 Attach the flexible outlet tubing to the upper connection or outlet on the sanitary heat exchanger.
 - 5.1.3 Attach the other end of the inlet tubing to a water source capable of cooling the sanitary heat exchanger and condensing the steam. Suitable sources include potable water, non-potable water, and chilled water.
 - 5.1.4 Place the other end of the outlet tubing into an adequate drain or connect to a return line if using a chilled water system.
 - 5.1.5 Attach the dedicated high-pressure steam flex line to the clean- or pure-steam inlet valve on the sanitary heat exchanger using 3/4" sanitary gaskets and clamps.
 - 5.1.6 Attach the opposite end of the steam flex line to the clean- or pure-steam outlet valve using 3/4" sanitary gaskets and clamps.
 - 5.1.7 Slowly, open the water source to the sanitary heat exchanger.
 - 5.1.8 Place a collection vessel under the sample collection outlet.
 - 5.1.9 Slowly, open the clean- or pure-steam supply valve to allow steam to enter the sanitary heat exchanger. Steam will enter sanitary heat exchanger causing any condensate in the sanitary heat exchanger to be forced out of the collection tubing.
 - 5.1.10 The flow of water should condense the steam entering the sanitary heat exchanger resulting in a suitable flow of steam condensate.



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- 5.1.11 If the discharge from the sanitary heat exchanger is not condensing or is too hot, verify that the flow path for the condensing water and the water flow are adequate. The steam valve may, also, be closed slightly to restrict steam flow.
 - 5.1.12 Disposable gloves must be worn when collecting samples. Flush the minimum volume of steam condensate into the collection vessel before collecting the sample according to **SOP- 22316 – Water Monitoring in BDP GMP Areas** .
 - 5.1.13 Each sample container is to be rinsed out with clean/pure-steam condensate, shaken, and emptied prior to collecting the sample.
 - 5.1.14 After collecting all the necessary steam samples, fully close the clean/pure-steam supply valve to discontinue steam.
 - 5.1.15 The flow of steam condensate being expelled from the sample collection port should discontinue.
 - 5.1.16 Run enough water through the sanitary heat exchanger to cool down the unit and, then, turn off the water supply.
 - 5.1.17 Uncouple the flexible inlet and outlet tubing from the source/return, drain any remaining water from both tubing legs, and roll the tubing for storage.
 - 5.1.18 Uncouple the high-pressure steam flex line and drain any remaining water from the tubing, the clean-steam outlet, and the clean-steam inlet to the sanitary heat exchanger. Wrap the flex line with sterilization wrap and, then, hang it to dry or store it in manner to avoid potential growth of organism.
- 5.2 Operation using the LAUDA WK-500 Water Circulation Cooler (WK-500).
- 5.2.1 The water circulation cooler allows the collection of clean/pure-steam samples in locations where cooling water is not available or in circumstances where it is not convenient. Be aware that the rate of sampling can overwhelm the capacity of the cooler and an operator will need to wait for the circulating fluid to cool sufficiently before collecting additional samples.
 - 5.2.2 Verify connected or connect the corresponding braided inlet and outlet tubing from the WK-500 to the sanitary heat exchanger.
 - 5.2.3 Plug in the WK-500 and turn the unit on.
 - 5.2.4 Monitor the bath-level indicator and add liquid to the filling nozzle to fill the reservoir, as needed. As the system is a closed loop, the liquid does not impact the environment provided that filling or exchange is not performed within classified clean room areas.
 - 5.2.4.1 Tap water is acceptable.
 - 5.2.4.2 If more cooling capacity is desired, use a mixture of glycol–water at a 3:1 ratio.
 - 5.2.4.3 Do not use RO- or WFI-quality water.



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- 5.2.5 Attach the high-pressure steam-collection flex line to the clean-steam inlet valve on the sanitary heat exchanger using 3/4" sanitary gaskets and clamps.
 - 5.2.6 Attach the opposite end of the steam flex line to the clean/pure-steam supply valve using 3/4" sanitary gaskets and clamps.
 - 5.2.7 Place an adequate collection vessel under the sample-collection outlet.
 - 5.2.8 Slowly, open the clean/pure-steam supply to charge the high-pressure steam-collection tubing. Slowly, open the steam-inlet valve on the sanitary heat exchanger, if present, to allow steam to enter the sanitary heat exchanger.
 - 5.2.9 Steam will enter the sanitary heat exchanger forcing any condensate to be forced out of the sample-collection tubing.
 - 5.2.10 Turn on the WK-500.
 - 5.2.11 Disposable gloves must be worn when collecting samples. Flush the minimum volume of steam condensate into the collection vessel before collecting sample according to **SOP- 22316 – Water Monitoring in BDP GMP Areas**.
 - 5.2.12 Each sample container is to be rinsed out with the clean/pure-steam condensate, shaken, and emptied prior to collecting the sample.
 - 5.2.13 After collecting all necessary clean/pure-steam samples, turn off the WK-500 chilled source.
 - 5.2.14 Close the clean/pure-steam supply fully and any secondary valve on the sanitary heat exchanger to discontinue steam.
 - 5.2.15 Unplug the WK-500.
 - 5.2.16 Uncouple the high-pressure steam-collection flex line from the steam inlet and outlet to the sanitary heat exchanger, cover the end of the hose, and hang for storage.

6.0 Maintenance

- 6.1 Routinely check fittings for tightness.
- 6.2 Inspect flex lines and hoses for signs of wear, before use. Replace any worn flex line or hose based on signs of wear. Replace clean/pure-steam flex line based on evidence of interior degradation based on elevated sample results.
- 6.3 The date that clean/pure-steam flex lines are placed into service shall be written or engraved on the lines if the manufacturing date is not part of the factory label.
- 6.4 Gaskets that fall onto unclean surfaces in utility areas shall be discarded and replaced. Do not spray gaskets with disinfectant as this may impact results particularly with respect to elevating TOC results.
- 6.5 Sanitary gaskets will degrade with use. Replace any torn, brittle, or deformed gasket or any gasket that is no longer able to provide a secure seal.

7.0 Documentation

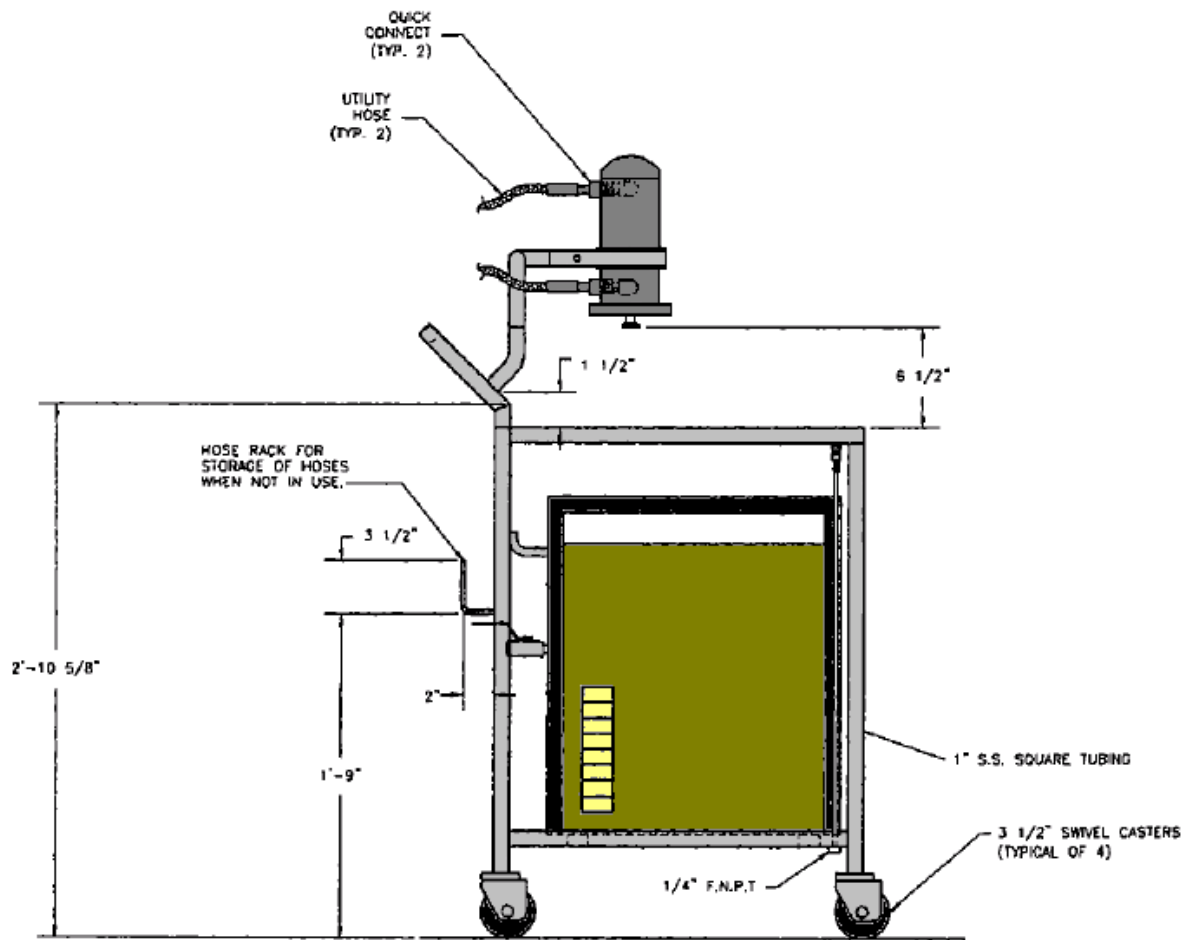
7.1 Record maintenance in the equipment logbook per **SOP 21531 - Equipment Logs.**

8.0 References and Related Documents

SOP 21531 *Equipment Logs.*

SOP 22316 *Water Monitoring in BDP GMP Areas* [REDACTED].

9.0 Schematics of WK-500 with Heat Exchanger (A-500 shown)



10.0 Change Summary

