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1.0 Purpose

This Standard Operating Procedure (SOP) describes the methods to prepare and document media and solution preparation and sterilization.

2.0 Scope

This procedure primarily applies to Biopharmaceutical Development Program (BDP) Technical Operations staff preparing and sterilizing various solutions for production use. This procedure does not cover those solutions prepared per **SOP 15100, *Preparing Reagent Solutions***.

3.0 Authority and Responsibility

3.1 The Technical Operations Manufacturing Lead, BDP has the authority to define this procedure.

3.2 BDP Manufacturing Managers are responsible for training personnel in this procedure and for documenting this training to Biopharmaceutical Quality Assurance (BQA).

3.3 BDP Technical Operations personnel are responsible for the implementation of this procedure.

3.4 BQA is responsible for quality oversight of this procedure.

4.0 Medium and Solutions Preparation

4.1 The project-specific Master Production Record (MPR) describes specific medium formulations.

4.2 Use requisite raw materials weighed per **SOP 21500, *General Policies and Procedures for Balances***.

4.3 Batch medium and solutions in containers prepped per **SOP 19104, *Labware Preparation and Cleaning***, and the MPR.

4.4 Use WFI to mark the total volume on the batching container if gradations are not present. Label the container with the medium/solution name, initials, and date. Account for displacement in volume caused by stir bars by adding the stir bar before filling.

4.5 Begin preparation with approximately 50% of the requisite amount of WFI in the container.

4.6 Mix using a stir bar and stir plate or other mixer, such as an overhead mixer. Follow the MPR if the mixing technique is specified.

4.7 Add each component to the liquid one at a time. Wait until each component has dissolved before adding the next. Add components in the order listed on the MPR.

4.8 Continue to mix the solution until all components are dissolved. Quantum suffice (QS) to final volume with WFI.

4.9 Proceed with sterilization if required per section 5.0.

4.10 If sterilization is not required, add the production lot number, expiration date and volume to the container label.

5.0 Sterilization of Media, Solutions and Antifoam

NOTE: Solutions that are autoclavable may be filter-sterilized. However, solutions designated for filter sterilization **may not** be autoclaved.

5.1 Autoclaving

5.1.1 Confirm caps are not screwed down tightly or container is outfitted with a vent device.

5.1.2 Tank addition valves, if present, should be autoclaved in the open position with the open end covered with sterilization wrap.

5.1.3 Choose a liquid autoclave cycle with the appropriate dwell time as indicated by the MPR or autoclave SOP.

5.1.4 Indicate that the solution has been autoclaved and include the expiration date on the label.

5.1.5 Store the autoclaved material per section 6.0 or as specified by the MPR.

5.2 Filter Sterilization

NOTE: Filter sterilization requires the use of a final pore size ≤ 0.2µm. It is recommended but not required that filter sterilization be performed within a BSC. Follow MPR for specific process details.

5.2.1 Prepare BSC per **SOP 19102, *Routine Use and Disinfection of Biological Safety Cabinets, Incubators, Shakers, Centrifuges, and Bioreactors***, for making aseptic manipulations to assembly.

5.2.2 Open or confirm open the filtration pathway. Confirm the addition pathway (if present) is closed.

5.2.3 Using a peristaltic pump located on the inlet side of the filter, pump the solution through the filter. (Pump and non-sterile solution may be located outside the BSC.)

5.2.4 When the filtration is complete, reconfigure the tubing pathway as required.

5.2.5 Indicate that the solution has been sterile filtered and include the expiration date and production lot number on the label.

5.2.6 Retain the filter unit for integrity testing per ***SOP 12240, Testing Filters with the Sartocheck 5 Integrity Test System***.

5.2.7 Store the filtrate per section 6.0 or as specified by the MPR.

6.0 Sterilization, Expiration, and Storage Guidelines

Solution Type	Method of Sterilization	Expiration Date	Storage
Antibiotics (All)	Filter	24 hours from time of preparation	2-8ºC
IPTG	Filter	24 hours from time of preparation	2-8ºC
Trace Metals	NA (Batched with Media)	One month from date of preparation	2-8ºC
Medium and Feed Solutions	Filter or Autoclave	One month from date of preparation	Room Temperature
Heat-labile Nutrient Supplements	Filter	One month from date of preparation	2-8ºC
Antifoam	Filter or Autoclave	One month from date of preparation	Room Temperature
WFI	Filter	One year from date of preparation while sealed, one day once opened; refer to SOP 19001.	Room Temperature

7.0 Documentation

7.1 Document the Solution Preparation and Sterilization in the Batch Production Record (BPR), validation protocol, or laboratory notebook.

7.2 If solution is to be retained for future use, verify the storage container is labeled with the following information.

- Solution Name
- Concentration/Formulation
- Date Prepared
- Sterilization method (if applicable)
- Expiration (see Section 6.0)
- Prepared By:
- Verified By:
- Solution Lot Number

8.0 References and Related Documents

SOP 15100 *Preparing Reagent Solutions*

SOP 12240 *Testing Filters with the Sartocheck 5 Integrity Test System*

SOP 19001 *Guidelines for Use of Water in production Processes Used in the Biopharmaceutical Development Program*

SOP 19104 *Labware Preparation and Cleaning*

SOP 19102 *Routine Use and Disinfection of Biological Safety Cabinets, Incubators, Shakers, Centrifuges, and Bioreactors*

SOP 21500 *General Policies and Procedures for Balances*

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