



Biopharmaceutical Development Program

Standard Operating Procedure

Title: Preventive Maintenance of Process Chromatography Systems

SOP Number: 21543

Revision Number: 01

Supersedes: Revision 00

Effective Date: ~~AUG 26 2014~~

Originator/Date:

Approval/Date:

Approval/Date:

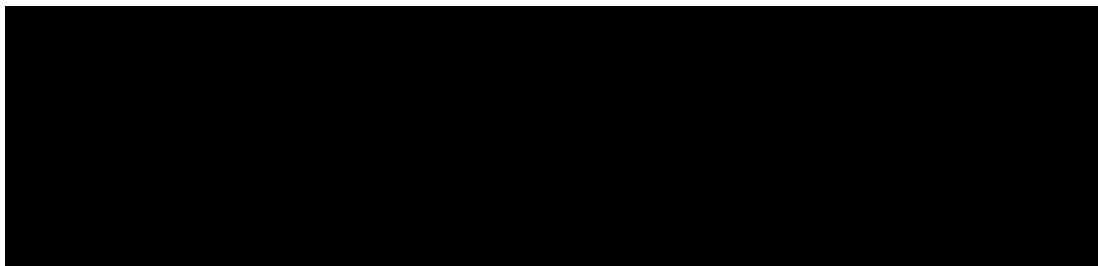


Table of Contents

- 1.0 Purpose
- 2.0 Scope
- 3.0 Authority and Responsibility
- 4.0 Procedure
- 5.0 Documentation
- 6.0 Attachments

1.0 Purpose

This procedure describes Preventive Maintenance (PM) activities required for the various types of process chromatography systems in the BOP. The procedure supplies a means for consistent documentation of maintenance of process chromatography systems.

2.0 Scope

This document pertains to individuals (to include equipment users as well as Facilities, Maintenance, and Engineering personnel) who perform PM on process chromatography systems. This procedure describes **PM** on the chromatography system (pumps, valves, flow paths, detectors, etc.) and excludes the chromatography column(s).

3.0 Authority and Responsibility

- 3.1 The Quality Engineering Validation Manager, Biopharmaceutical Quality Assurance (BOA) has the authority to define this procedure.

- 3.2 BQA is responsible for quality oversight of this procedure.
- 3.3 BDP personnel who use process chromatography skids or Facilities, Maintenance, and Engineering (FME) Department Instrument Shop are responsible for performing routine PM that occurs on an annual or biennial schedule. These tasks are listed in Attachments I through III of this SOP.
- 3.4 The Quality Engineering and Validation Group is responsible for reviewing completed PM worksheets.

4.0 Procedure

- 4.1 Annual or Biennial PM to be completed.
 - 4.1.1 Check with the Area Supervisor and the Master Equipment File (MEF) to see if the unit is under warranty.
 - 4.1.2 If the unit is still under warranty or service contract, **STOP**. Notify the appropriate persons so that the warranty or service contract vendor can be called.
 - 4.1.3 Locate the manufacturer's manual. If available, obtain the service manual.
 - 4.1.4 Make sure that columns have been removed from the system and that there is a safety tag on the unit indicating that it is clean and safe to work on. If columns are still present, **STOP**, and contact the Area Supervisor. Do not proceed until column(s) are removed and the unit has been cleaned.
 - 4.1.5 Review the PM worksheet and verify that the equipment owner has provided the necessary supplies and consumables.
 - 4.1.6 Complete the PM and worksheets as described in Attachments 1 through 3.
 - 4.1.7 Locate the equipment log and record activities in the log as described in **SOP 21531, Equipment/Facility Logs**.
 - 4.1.8 Ensure the unit under test is operational before leaving the area. If the unit is not operational, initiate the appropriate paperwork according to **SOP 21526, Engineering Event Management and Status Placarding**.
 - 4.1.9 Give the completed, original checklist to BQA Documentation (BQAD) to route for signature through the equipment owner and the Quality Engineering and Validation Group.
 - 4.1.10 BQAD places the original paperwork in the Master Equipment File (MEF).

5.0 Documentation

- 5.1 The individual(s) performing this procedure records all pertinent data and comments on the appropriate attachment using Good Documentation Practices.
- 5.2 When the data contains calibration information, the format shall follow **SOP 21508, Equipment Calibration Program**, and calibration data shall be stored according to that SOP.

- 5.3** A copy of all documentation generated during this preventive maintenance, except for calibration, is placed in the MEF.

6.0 Attachments

- 6.1** 6mm AKTA Process Non-User PM Work Sheet, Form 21543-01
- 6.2** ÄKTA™ Pilot User PM Work Sheet, Form 21543-02
- 6.3** ÄKTA™ Explorer and Purifier User PM Work Sheet, Form 21543-03

Attachment 1

NCI-Frederick
Form No.: 21543-01
SOP No.: 21543
Revision 01: AUG 26 2014

6 mm Processor Non-user PM Worksheet
Equipment Number: _____

Complete the checklist in the order given. Indicate completion of each task by entering the technician's initials and date in the column to the right of the task. If the step is not applicable because that equipment or option is not installed, enter "NA". If the step is not completed for any other reason, indicate this in the comments section at the end of the page.

Task Number	Task Description	Completed By/Date
1	Record Software Version (Build): Unicorn: _____	
2	Check equipment logbook and exclude maintenance on recently serviced items. Indicate this situation in the comments section at the end of the document.	
3	Perform a general visual inspection of the system.	
4	Flush the system completely with WFI, cycling through each possible flow path.	
5	Perform the PM tasks .	
6	Flush the system completely with WFI, cycling through each possible flow path.	
7	Record PM activities in equipment log.	
8	Affix PM sticker to system.	

Comments:

Note: Components need not be replaced if replacement has already occurred at or before the required frequency as a result of production campaign change-over activities.

Task Item	Action	Frequency	Comments	Completed By/Date
Pumps	Inspect and Replace as Required Oil Level Check Valves Seals Leaks Rust	Biennial		
Valves	Inspect and Replace as Required Feedback Switch	Biennial		
UV Monitor	Inspect and Record hours of use in Comment Section Lamp	Biennial (Replace at 8000 hours)		
Conductivity Monitor	Inspect and Replace as Required Flow Cell Sensor	Biennial		
Air Sensors	Inspect and Verify all Functions	Biennial		

Equipment Owner Accepted By/Date: _____

Quality Engineering and
Validation Accepted By/Date: _____

Attachment 2

NCI-Frederick
Form No.: 21543-02
SOP No.: 21543
Revision 01: AUG 26 2014

ÄKTA™ Pilot Non-user PM Worksheet

Equipment Number: 80060 or LCCC-009-A

Complete the checklist in the order given. Indicate completion of each task by entering the technician's initials and date in the column to the right of the task. If the step is not applicable because that equipment or option is not installed, enter "NA". If the step is not completed for any other reason, indicate this in the Comments section at the end of the page.

Task Number	Task Description	Completed By/Date
1	Record Software Version: Unicorn: _____	
2	Check equipment logbook and exclude maintenance on recently serviced items. Indicate this situation in the Comments section at the end of the document.	
3	Perform a general visual inspection of the system.	
4	Flush the system completely with WFI, cycling through each possible flow path.	
5	Perform the PM.	
6	Flush the system completely with WFI, cycling through each possible flow path.	
7	Record PM activities in equipment log.	
8	Affix PM sticker to system.	

Comments:

Note: Components need not be replaced if replacement has already occurred at or before the required frequency as a result of production campaign change-over activities.

Task Item	Action	Frequency	Comments	Completed By/Date
Pumps (P907 and P908)	Inspect and Replace as Required Piston Inlet and Outlet Check Valves Rinsing System Check Valve Replace O-rings	Biennial		
Valves	Inspect and Replace as Required	Biennial		
UV Monitor	Inspect and Replace as Required (Record hours of use in Comment section.) Flow Cell - O-rings Lamp	Biennial (Replace at 4000 hours)		
Conductivity Monitor	Inspect and Replace as Required Flow Cell	Biennial		
Air Trap	Inspect and Replace as Required O-ring in vent connector	Biennial		

Equipment Owner Accepted By/Date: _____

Quality Engineering and
Validation Accepted By/Date: _____

Attachment 3

NCI-Frederick
Form No.: 21543-03
SOP No.: 21543
Revision 01: AUG 26 2014

ÄKTA™ Explorer and Purifier Non-user PM Worksheet

Equipment Number: _____

Complete the checklist in the order given. Indicate completion of each task by entering the technician's initials and date in the column to the right of the task. If the step is not applicable because that equipment or option is not installed, enter "NA". If the step is not completed for any other reason, indicate this in the Comments section at the end of the page.

Task Number	Task Description	Completed By/Date
1	Record Software Version Unicorn: _____	
2	Check equipment logbook and exclude maintenance on recently serviced items. Indicate this situation in the Comments section at the end of the document.	
3	Perform a general visual inspection of the system.	
4	Flush the system completely with WFI, cycling through each possible flow path.	
5	Perform the PM tasks listed.	
6	Flush the system completely with WFI, cycling through each possible flow path.	
7	Record PM activities in equipment log.	
8	Affix PM sticker to system.	

Comments:

NOTE: Components need not be replaced if replacement has already occurred at or before the required frequency as a result of production campaign change-over activities.

Task Item	Action	Frequency	Comments	Completed By/Date
Pumps (P901 and P903)	Inspect/Clean/Replace as Required Input Manifold Piston Inlet and Outlet Check Valves Purge Valve Inner and Outer Outlet Manifolds Mixer Chamber Rinsing Tubing and Check Valve Replace/Rebuild Pump Seals Pump Rinse Membranes	Biennial		
Valves	Inspect and Replace as Required Valve- Distribution Plates Valve- Channel Plates	Biennial		
Tubing	Inspect and Replace as Required Capillary Tubing Finger tight Fittings	Biennial		
UV Monitor	Inspect and Record hours of use in Comment Section. Lamp	Biennial (replace at 4000 hours)		
Conductivity Monitor	Inspect and Replace as Required Flow Cell	Biennial		

Equipment Owner Accepted By/Date: _____

Quality Engineering and Validation Accepted By/Date: _____