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| \_\_\_\_\_  \_\_\_\_\_ | \_\_\_\_\_  \_\_\_\_\_ | **1. PRODUCTION FERMENTATION**  1.1. Equipment code  1.2. Previously used for  1.3. Refer equipment log for cleanliness  1.4. Cleanliness visually checked by  1.5. Area certified  **2. CALIBRATION OF pH AND DO2 PROBES :** 2.1. CALIBRATION OF 1st pH PROBE ANDDO2 PROBE2.1.1. Calibrate the pH probe using buffer 7.00 2.1.2. Calibrate the pH probe using buffer 4.01    2.1.3. Confirm calibration by checking the pH using    2.1.4. Calibrate the DO2 probe 2.2. CALIBRATION OF 2nd pH PROBE ANDDO2 PROBE2.2.1. Calibrate the pH probe using buffer 7.00 2.2.2. Calibrate the pH probe using buffer 4.01    2.2.3. Confirm calibration by checking the pH using    2.2.4. Calibrate the DO2 probe  2.3. Fix the 1st and 2nd pH probes in the designated port  2.4. Fix the 1st and 2nd DO2 probes in the designated port | F104 - A / B / C / D  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Clean / Not clean  Clean / Not clean  pH\_\_\_\_\_\_\_\_  pH\_\_\_\_\_\_\_\_  pH\_\_\_\_\_\_\_\_  pH\_\_\_\_\_\_\_\_  pH\_\_\_\_\_\_\_\_  pH\_\_\_\_\_\_\_\_ | \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ | \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ |

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| **3. LEAKAGE TEST** | | | | | | | \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ | \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ |
| 3.1. Replace the rubber septa of the inoculation ports with new ones.  3.2. Replace the vessel isolation actuated valve on the related RM solution feed  lines with manual valve. | | | | Yes NA | | |
| 3.3. Charge XX Kg of Potable water into the fermenter: \_\_\_\_\_\_\_\_\_\_\_ Kg A.R.No.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | |
| 3.4. Set the Air flow to YY Nm3/hr  3.5. Pressurize the fermenter to ZZ bar.  3.6. Start the leakage check. | | | Process value \_\_\_\_\_\_\_\_\_\_\_ Nm3/hr  process value \_\_\_\_\_\_\_\_\_\_\_ bar | | | |
| **Note 4:** All unions connected to the vessel and all vessel isolation valves should be checked for leakage. Soap solution should be sprayed on the unions using spray bottle. If there is a leakage, bubble formation will occur, if not, it is confirmed that there is no leakage. Valve leakage (valve passing) is confirmed by holding water in a beaker beneath the open drain valve, which is next to vessel isolation valve (tip of the drain line is immersed in the water). If there is a leakage bubble formation will occur, if not, it is confirmed that there is no leakage in the vessel isolation valve.  **3.7. LEAKAGE CHECK RESULT**  **Note 5: ‘**P’ represents PASS, ‘F’ represents FAIL.  **Note 6:** For any leakage, inform the maintenance personnel about leakage. After rectification, restart the test. If there is a leakage in harvesting valve, level transmitter or Bottom flange, drain the water and inform the maintenance personnel about leakage. After rectification, charge potable water then restart the test and enter the result in the below column. | | | | | | | | |
| **Details** | **Test -1** | **Test-2/NA** | | | **Test-3/NA** | **Test -4/NA** | | |
| 3.7.1. Charge XX Kg of potable  water. | NA | \_\_\_\_\_\_\_\_\_ Kg/NA  A.R.No.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_Kg/NA  A.R.No.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_Kg/NA  A.R.No.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.2. Test start time and Date | \_\_\_\_\_\_\_\_\_ hrs  Date\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ hrs  Date\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_ hrs  Date\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ hrs  Date\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.3. Diaphragm of Harvesting  valve. | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Done by : | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Checked by : | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

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| **Details** | | **Test -1** | | | **Test-2/NA** | | **Test-3/NA** | | | **Test -4/NA** | | |
| 3.7.4. Bottom flange | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.5. Level transmitter | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.6. 25 mm port 1 | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.7. 25 mm port 2 | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.8. 25 mm port 3 | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.9. 25 mm port 4 | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.10. 25 mm port 5 | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.11. 25 mm port 6 | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.12. Sampling valve | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.13. Man hole lid | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.14. Sight glass | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Done by : | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Checked by : | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **Details** | | **Test -1** | | | **Test-2/NA** | | **Test-3/NA** | | | **Test -4/NA** | | |
| 3.7.15. Steam supply union to  sight glass | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.16. Spare nozzle 1 | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.17. Spare nozzle 2 | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.18. Header E | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.19. Header F | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.20. Header A | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.21. Header B | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.22. Partial Harvest line | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.23. Header C | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.24. Header D | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.25. Transfer line from seed fermenter | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Done by : | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Checked by : | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **Details** | | **Test -1** | | | **Test-2/NA** | | **Test-3/NA** | | | **Test -4/NA** | | |
| 3.7.26. Transfer line from 10kL  fermenters. | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.27. Transfer line from 100L  fermenters. | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.28. Light glass | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.29. Steam supply union to  light glass | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.30. Dip rod sample valve | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.31. Foam sensor | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.32. Header G | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.33. Spare nozzle 4 / NA | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.34. Spare nozzle 5 / NA | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.35. Spare nozzle 6 / NA | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.36. Additional Sparger  line /NA | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Done by : | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Checked by : | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **Details** | | **Test -1** | | | **Test-2/NA** | | **Test-3/NA** | | | **Test -4/NA** | | |
| 3.7.37. Pressure transmitter | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.38. Bursting disc | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.39. CIP Port 1 | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.40. CIP Port 2 | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.41. 19 mm port 1 | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.42. 19 mm port 2 | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.43. 19 mm port 3 | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.44. 19 mm port 4 | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.45. 19 mm dummy port | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.46. Air line  ( After Air fine filter ) | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.47. Exhaust view glass | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Done by : | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Checked by : | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **Details** | | **Test -1** | | | **Test-2/NA** | | **Test-3/NA** | | | **Test -4/NA** | | |
| 3.7.48. Exhaust valve before filter | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.49. Exhaust filter housing  Joints | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.50. Exhaust Filter top clamp | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.51. Exhaust Filter bottom  clamp | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.52. Valve before exhaust  control valve | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.53. Exhaust bypass valve | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.54. Exhaust control valve joint  flanges | | P / F  Rectified by  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | P / F / NA  Rectified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 3.7.55. Test end time and Date | | \_\_\_\_\_\_\_\_\_ hrs  Date\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_ hrs  Date\_\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_\_\_\_ hrs  Date\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_ hrs  Date\_\_\_\_\_\_\_\_\_ | | |
| 3.8. Test result | | P / F | | | P / F / NA | | P / F / NA | | | P / F / NA | | |
| Done by : | | \_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Checked by : | | \_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_\_\_\_\_\_\_ | | | \_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **Note 7:** If there is any leakage observed after the 4th leak test, enter those details in the section 3.9. | | | | | | | | | | | | |
| **3.9. Details of failure and rectification / NA**  Done by : \_\_\_\_\_\_\_\_\_\_\_\_\_ Checked by : \_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | |
| **4. VESSEL PRESSURE TEST -1 (PRESSURE HOLD TEST)** | | | | | | | | | | | | |
| **4.1. CRITERIA:** Pressure drop should not be > 0.2 bar in 10 minutes to pass the test. | | | | | | | | | | | | |
| **Parameter** | **Std.set point** | | | **Actual set point** | | **Process value for Test** | | | **Process value for Test repeat / NA** | | **Done**  **by** | **Checked by** |
| 4.2. Test SP 1 | 000 bar | | |  | |  | | |  | | \_\_\_\_\_ | \_\_\_\_\_ |
| 4.3. Test Time | 10 minutes | | |  | | NA | | | | |
| 4.4. Air flow set Point | YY Nm3/hr | | |  | |  | | |  | |
| 4.5. De-pressurise set point | 0.1 bar | | |  | |  | | |  | |
| 4.6. Test Hysteresis | 0.2 bar | | |  | | NA | | | | |
| 4.7. Confirm the parameters and start the test. | | | | | | | | | | |
| **Details** | | | **Pressure test** | | | | | **Repeat pressure test / NA** | | | | |
| 4.8. Test start Time and Date | | | \_\_\_\_\_\_\_\_\_\_\_\_ hrs  Date\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ hrs  Date\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| 4.9. Test End Time and Date | | | \_\_\_\_\_\_\_\_\_\_\_\_ hrs  Date\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ hrs  Date\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| 4.10. Pressure at the end | | | \_\_\_\_\_\_\_\_\_\_\_\_ bar | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ bar | | | | |
| 4.11. Test result | | | P / F | | | | | P / F / NA | | | | |
| 4.12. Accept the prompt | | | Yes | | | | | Yes / NA | | | | |
| Done by : | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| Checked by : | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| **Note 8:** If there is any leakage observed after the repeat test, enter those details in the section 4.13. | | | | | | | | | | | | |
| **4.13. Details of failure and rectification / NA**  Done by : \_\_\_\_\_\_\_\_\_\_\_\_\_ Checked by : \_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | |

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| \_\_\_\_\_ | \_\_\_\_\_ | 5. ADDITIONAL SPARGER FINE FILTERSTERILISATION / NA (Applicable only for F104-D) **Note 9:** Place the sterilisable grade Air fine filters on the  filter housing.  **Note 10:** Pre-sterilisation of the Air fine- filter should be  done without pressurising the filter by just passing  steam through the filter for 15 to 17 minutes.  5.1. Fix the Air fine filters  5.2. Give YY Nm3/hr set point to Air flow control valve of  additional sparger.  5.3. Start the filter sterilisation  5.4. Pre-sterilisation of the additional sparger fine filter  should be done for 15 to 17 minutes without pressure   |  | | --- | | **5.5. Sterilise the additional sparger fine filter by passing steam and maintain the steam pressure at 1.1 to 1.3 bar for 30 to 35 minutes.** |   **Note 11:** Sterilise the additional sparger fine filter for 30 to 35 minutes. Record the details in the chart provided below. | | | Yes NA  \_\_\_\_\_\_\_ Nm3/hr / NA  Yes NA  \_\_\_\_\_\_\_\_\_\_\_\_bar  \_\_\_\_\_\_\_\_\_\_\_\_ bar | \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ | \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ |
| **5.6. ADDITIONAL SPARGER FINE FILTER STERILISATION CHART / NA** | | | | | |
| Interval | Time | **Pressure (bar)** | | **Done**  **by** | **Checked by** |
| 5.6.1. Initial |  |  | |  |  |
| 5.6.2. After 10 minutes |  |  | |  |  |
| 5.6.3. After 20 minutes |  |  | |  |  |
| 5.6.4.30th to 35th minute |  |  | |  |  |
| 5.6.5. Cool the filter to ambient temperature. | | | |  |  |
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| \_\_\_\_\_ | \_\_\_\_\_ | | 6. MEDIA PREPARATION **Note 12:** Media solution should be prepared in A1 block and the same is transferred to respective equipment in A2 block. The media preparation details are recorded in the respective BMR of A1 Block.   |  | | --- | | **6.1. Batch size** |   6.2. Receive media solution from A1 Block to the fermenter in A2 Block. Simultaneously switchʻONʼ agitator of the fermenter and set the RPM to YY ± Y  6.3.Total Qty. (XX Kg) of Product media solution  transferred from A1 Block.  6.3.1. A1 Block Media Preparation Batch No.  **7. Vessel pressure test – 2**  **7.1. CRITERIA:** Pressure drop should not be > 0.2 bar in  10 minutes to pass the test. | | | | | | | | | | | | |  | | --- | | **XX Kg** |   RPM \_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_Kg  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ | | \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ | |
| **Parameters** | | | | | **Std. set point** | | | | | **Actual set point** | **Process value for Test** | | | | | | | **Process value for Test repeat / NA** |
| 7.2. Test Pressure | | | | | 1.8 bar | | | | |  |  | | | | | | |  |
| 7.3. Test Time | | | | | 10 minutes | | | | |  | NA | | | | | | | |
| 7.4. Air flow set point | | | | | YY Nm3/ hr | | | | |  |  | | | | | | |  |
| 7.5. De-pressurise set point | | | | | 0.1 bar | | | | |  |  | | | | | | |  |
| 7.6. Test Hysteresis | | | | | 0.2 bar | | | | |  | NA | | | | | | | |
| 7.7. Confirm the parameters and start the test | | | | | | | | | | | | | | | | | | |
| **Details** | | | | | | | | **Pressure test** | | | | | | | | | **Repeat pressure test / NA** | | | | | |
| 7.8. Test start time and Date | | | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ hrs  Date\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ hrs  Date\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |
| 7.9. Test End Time and Date | | | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ hrs  Date\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ hrs  Date\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |
| 7.10. Pressure at the end | | | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ bar | | | | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ bar | | | | | |
| 7.11. Test result | | | | | | | | P / F | | | | | | | | | P / F / NA | | | | | |
| 7.12. Accept the prompt | | | | | | | | Yes | | | | | | | | | Yes / NA | | | | | |
| Done by : | | | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |
| Checked by : | | | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |
| **Note 13:** If pressure test fails inform the maintenance personnel about the leakage. After rectification repeat the test.  **Note 14:** If there is any leakage observed after the repeat test, enter those details in the section 7.13. | | | | | | | | | | | | | | | | | | | | | | |
| **7.13. Details of failure and rectification / NA**  Done by : \_\_\_\_\_\_\_\_\_\_\_\_\_ Checked by : \_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | | | | | | |
| **8. MEDIA STERILISATION AND COOLING** | | | | | | | | | | | | | | | | | | | | | | |
| 8.1. Set the recipe parameters. | | | | | | | | | | | | | | | | | | | | | | |
| **Parameters** | | | | | | | **Std. set point** | | | | | | **Actual set point** | | | | | | | \_\_\_\_\_  \_\_\_\_\_ | | \_\_\_\_\_  \_\_\_\_\_ |
| 8.2. Heating 1 SP | | | | | | | H1 °C | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_°C | | | | | | |
| 8.3. Heating 2 SP | | | | | | | H2 °C | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_°C | | | | | | |
| 8.4. Sterilisation time | | | | | | | 10 minutes | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ minutes | | | | | | |
| |  | | --- | | **8.5. Sterilisation holding temperature and pressure** | | | | | | | | |  | | --- | | **Temperature 120-135 °C**  **Pressure 1.1 – 1.3 bar** | | | | | | | Temperature \_\_\_\_\_\_\_\_\_\_\_\_°C  Pressure \_\_\_\_\_\_\_\_\_\_\_\_bar | | | | | | |
| 8.6. Heating hysteresis | | | | | | | H1 ° C | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_°C | | | | | | |
| 8.7. Exhaust close temperature | | | | | | | T1 ° C | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ °C | | | | | | |
| 8.8. Back pressure SP | | | | | | | ZZ – ZZ bar | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ bar | | | | | | |
| 8.9. Air flow SP | | | | | | | YY ± YY Nm3/ hr | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ Nm3/ hr | | | | | | |
| 8.10. Air pressure set point | | | | | | | ZZ – ZZ | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ bar | | | | | | |
| 8.11. Cooling 1 SP | | | | | | | C1 – C1 °C | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ °C | | | | | | |
| 8.12. Cooling 2 SP | | | | | | | C2 °C | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_°C | | | | | | |
| 8.13. Filter checked | | | | | | | Yes | | | | | | Yes | | | | | | |
| 8.14. Confirm the parameters and start sterilisation.    8.15. Media sterilisation start time \_\_\_\_\_\_\_\_\_\_\_\_ hours 8.15.1. Date : \_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | | | |
| \_\_\_\_\_  \_\_\_\_\_ | | \_\_\_\_\_  \_\_\_\_\_ | | **8.16. AIR FINE FILTER STERILISATION**  **Note 15:** Pre-sterilisation of the Air fine filter should be done  without pressurising the filter by just passing  steam through the filter for 15 to 17 minutes.  8.16.1.Start the filter sterilisation  8.16.2.Pre-sterilisation of the Air fine filter should be done for  15 to 17 minutes without pressure.   |  | | --- | | **8.16.3. Sterilise the Air fine filter by passing steam and maintaining the steam pressure at 1.1 to 1.3 bar for 30 to 35 minutes** |   **Note 16:** Sterilisation of the Air fine filter done for 30 to 35 minutes. Record the details in the chart provided below. | | | | | | | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ bar  \_\_\_\_\_\_\_\_\_\_\_\_ bar | | | | \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ | | \_\_\_\_\_  \_\_\_\_\_ |
| **8.16.4. AIR FINE FILTER STERILISATION CHART** | | | | | | | | | | | | | | | | | | |
| Interval | | | | | Time | | | | | Pressure (bar) | | | | | **Done**  **by** | | **Checked by** | |
| 8.16.4.1. Initial | | | | |  | | | | |  | | | | |  | |  | |
| 8.16.4.2. After 10 minutes | | | | |  | | | | |  | | | | |  | |  | |
| 8.16.4.3. After 20 minutes | | | | |  | | | | |  | | | | |  | |  | |
| 8.16.4.4. 30th to 35th minute | | | | |  | | | | |  | | | | |  | |  | |
| 8.16.5. Accept the prompt for completion of sterilisation  8.16.6. Cool the filter to ambient temperature  8.16.7. Accept the prompt for completion of cooling | | | | | | | | | | |  | | | | \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ | | \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ | |
| **Note 17:** Ensure that the exhaust valve is closed when the media sterilisation temperature reaches H1° C.  **Note 18:** Once temperature reaches H1 °C send steam through additional sparger continuously (for F104-D).  8.17. Open the vessel isolation valves on G Header line, Edenor feed line and L-Leucine feed line once the  temperature reaches H1°C. | | | | | | | | | | | | | | | | | | | \_\_\_\_\_ | | \_\_\_\_\_ | |
| **Parameters** | | | | | | **Process value** | | | | | | **Attaining time** | | | | | | |
| 8.18. Heating 1 SP (H1 – H1 °C) | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ °C | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ hrs | | | | | | |
| 8.19. Heating 2 SP (H2±1 °C) | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_°C | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_ hrs | | | | | | |
| 8.20. Sterilisation time  (ST – ST minutes) | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_minutes | | | | | | From\_\_\_\_\_\_\_ hrs To\_\_\_\_\_\_\_ hrs | | | | | | |

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| 8.21.Sterilisation  Holding  temperature  and pressure | **Interval** | **Time** | | | **Temperature (°C)** | **Pressure (bar)** | | **Done**  **by** | | **Checked by** | |
| Initial |  | | |  |  | |  | |  | |
| After10 minutes |  | | |  |  | |  | |  | |
| After 20 minutes |  | | |  |  | |  | |  | |
| After 30 minutes |  | | |  |  | |  | |  | |
| After 40 minutes |  | | |  |  | |  | |  | |
| After 50 minutes |  | | |  |  | |  | |  | |
| End |  | | |  |  | |  | |  | |
| **8.22. CHECK POINTS DURING STERILISATION (Tick in the appropriate box)**  **Note 19:** During sterilisation holding, following points to be checked for the temperature using thermo melt pen of range 121°C.  **Note 20:** When media cooling sequence is started, close steam and send Air through the additional sparger (only for F104-D). | | | | | | | | | | | |
| 8.22.1. Air sparger lines | | |  | 8.22.16. Header A | | |  | | \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ | | \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ |
| 8.22.2. Air bypass lines | | |  | 8.22.17. Header B | | |  | |
| 8.22.3. Steam supply line to light glass | | |  | 8.22.18. Header C | | |  | |
| 8.22.4. Steam supply line to sight glass | | |  | 8.22.19. Header D | | |  | |
| 8.22.5. Partial harvest line | | |  | 8.22.20. Header E | | |  | |
| 8.22.6. Transfer line from 10kL fermenter | | |  | 8.22.21. Header F | | |  | |
| 8.22.7. Transfer line from 1kL fermenter | | |  | 8.22.22. Header G | | |  | |
| 8.22.8. Exhaust Filter housing | | |  | 8.22.23. Spare nozzle 1 | | |  | |
| 8.22.9. Exhaust Filter drain line | | |  | 8.22.24. Spare nozzle 2 | | |  | |
| 8.22.10. Exhaust line | | |  | 8.22.25. Transfer line from 100L Fermenter. | | |  | |
| 8.22.11. Exhaust bypass line | | |  | 8.22.26. Spare nozzle 4 / NA  (Applicable for F104-A,B,C only) | | |  | |
| 8.22.12. Sampling valve | | |  | 8.22.27. Spare nozzle 5 / NA  (Applicable for F104-A,B,C only) | | |  | |
| 8.22.13. Harvest valve steam cross outlet line | | |  | 8.22.28. Spare nozzle 6 / NA  (Applicable for F104-D only) | | |  | |
| 8.22.14. Man hole lid | | |  | 8.22.29. Additional sparger line/ NA  (Applicable for F104-D only) | | |  | |
| 8.22.15. Sampling dip rod line | | | | | | |  | |
| 8.23. Close the vessel isolation valves on G Header line, RM and RM feed line. | | | | | | | | |
| 8.24. Start cooling. | | | | | | | | |

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| **Parameters** | | | **Process value** | **Attaining time** | | \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ | \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ |
| 8.25. Air flow through additional  Sparger (YY±Y Nm3/hr) | | | \_\_\_\_\_\_\_\_\_\_\_\_ Nm3/hr / NA | NA | |
| 8.26. Back pressure SP (ZZ-ZZ bar) | | | \_\_\_\_\_\_\_\_\_\_\_\_ bar | NA | |
| 8.27. Air flow SP (YY±YY Nm3/ hr) | | | \_\_\_\_\_\_\_\_\_\_\_\_ Nm3/hr | NA | |
| 8.28. Air pressure set point  (ZZ – ZZ bar) | | | \_\_\_\_\_\_\_\_\_\_\_\_bar | NA | |
| 8.29. Cooling 1 SP (C1 – C1 °C) | | | \_\_\_\_\_\_\_\_\_\_\_\_ °C | \_\_\_\_\_\_\_\_\_\_\_\_ hrs | |
| 8.30. Cooling 2 SP (C2±C2 °C) | | | \_\_\_\_\_\_\_\_\_\_\_\_°C | \_\_\_\_\_\_\_\_\_\_\_\_ hrs | |
| \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ | \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ | 8.31. Start nutrient dosing and accept the prompt.  8.32. Set back pressure to 1.1 ± 0.2 bar..  8.33. Line up sterilised Antifoam SAG 471 solution.  8.34. Close the Air bypass line.  8.35. Sparge Air through the media for 10 ± 2 minutes  (If foaming occurs, dose Antifoam SAG 471 solution)  8.36. Check the pH of the media.  8.37. pH of the media has to be adjusted to pH1 ± pH1  using sterilised 10% Base solution (w/w) or  10% acid solution (w/w).  8.38. pH of the media after adjustment.  8.39. Qty of 10% Base solution (w/w) /  10% Nitric acid solution used (w/w).  8.39.1. Solution preparation No.  8.40. Take pre-inoculation sample (PIS). 9. INITIAL PARAMETERS SETTING  |  | | --- | | **9.1. Set Back pressure to ZZ bar** | | **9.2. Set Air flow to YY Nm3/ hr** | | **9.3. Set Temperature to T1 °C** | | **9.4. Set Agitator speed to A1 RPM** | | | | \_\_\_\_\_\_\_\_\_\_\_\_ bar  Yes NA  \_\_\_\_\_\_\_\_\_\_\_ minutes  pH \_\_\_\_\_\_\_\_\_\_\_\_  pH \_\_\_\_\_\_\_\_\_ / NA  \_\_\_\_\_\_\_\_\_\_\_\_ Kg  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_bar  \_\_\_\_\_\_\_\_\_\_\_ Nm3/ hr  \_\_\_\_\_\_\_\_\_\_\_\_°C  \_\_\_\_\_\_\_\_\_\_\_\_RPM |

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| \_\_\_\_\_  \_\_\_\_\_ | \_\_\_\_\_    \_\_\_\_\_ | 9.5. Calibrate the 1st DO2 to 100%.  9.6. Calibrate the 2nd DO2 to 100%.  **10. ALARMS SETTING**  10.1. Temperature Low: T1 ° C / High: T1 ° C  10.2. Air flow Low: YY Nm3/hr / High: YY Nm3/hr  10.3. Back pressure Low: ZZ bar  10.4. Agitation : Trip off  10.5. Enable the Foam Switch/Sensor  **11. INOCULATION**  11.1. Set and confirm the recipe parameters.  11.2. Seed fermenter code.  11.3. pH of the inoculum.  11.4. PCV of the inoculum.  11.5. Age of the inoculum.   |  | | --- | | **11.6. Inoculate the fermenter.** |     11.7. Start production.  11.8. Take post inoculation sample (POIS).  11.9. Check the pH of the post inoculation sample. | \_\_\_\_\_\_\_\_\_\_\_\_%  \_\_\_\_\_\_\_\_\_\_\_\_%  Low:\_\_\_\_ /High \_\_\_\_  Low:\_\_\_\_ /High \_\_\_\_    Low: \_\_\_\_\_\_\_\_\_\_\_\_  F102 – A / B / C / D  pH\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_ %  \_\_\_\_\_\_\_\_\_\_\_\_ hrs  pH\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ | \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_  \_\_\_\_\_ |
| 12. MONITORING THE FERMENTER | | | | | |