

LFS/Q0207
Production Machine Operator (API) - Final Assessment

1. LFS/N0213 – Prepare machines and accessories for the manufacturing process

Equipment Readiness

PC1 Take handover from the colleague in previous shift and ensure that the machine, surrounding areas and classified areas are clean, dry, sterilised (wherever required) and fit for use as per the SOP to avoid contamination and highlight the risk if any

PC2 Set up machines at the beginning of the batch processing to ensure proper working order and refer to the machine history received from the supervisor/colleague at the time of handover

1. What is the most important aspect to be checked while taking charge of a reactor during shift changeover?
 - a. **Reactor status matching with display**
 - b. Colour variations of the reactor readings
 - c. BMR status of the reactor
 - d. Packing of the reactor

PC3 Perform testing procedures to ensure that machines work optimally to carry out production activities

PC4 Ensure that the approach path from the input storage area to storage area for output is free of obstructions to transportation

2. What should be checked to ensure that the stirrer of a reactor is working appropriately to carry out the desired production activity?
 - a. **Exact pre-set RPM reading**
 - b. Stirrer blades are in place
 - c. Size of blades are similar
 - d. Pressure in the reactor

PC5 Select the correct material to be loaded

PC6 Ensure that the material is from a respective batch and is checked by the concerned supervisor and approved by the QA team

3. What should be checked before charging the material from the centrifuge to the fluid bed dryer for drying?
 - a. **The material is a wet cake and with appropriate batch number**
 - b. The material is free from moisture and solvents
 - c. The material has moisture content of above 99%
 - d. The material has required solvent percentage

PC7 Assemble the machinery properly

PC8 Set critical parameters for the machinery (cycle time, temperature, pressure, ampere load, spray rate, etc) as per the company's SOP

4. What should be accurate during crystallisation if the material is heat sensitive?
 - a. **Temperature**
 - b. Blade RPM
 - c. Solvent quantity
 - d. Vapour pressure

PC9 Keep all the accessories like cleaning brush, levers, release agent, etc ready

PC10 Monitor machines during every procedure to ensure optimum performance

5. What is best done to ensure optimum performance of the miller during granulation of an API?
 - a. **Check quantity and particle size**
 - b. Manage variations in colour
 - c. Avoid odour of the API
 - d. Maintain dryness

PC11 Perform random tests to ensure accuracy and maintain online documentation for the same along with justifications for any wrong entries, if any

PC12 Coordinate with maintenance teams for preventive maintenance

6. Which test ensures the accuracy of the fluid bed dryer?
- Moisture content or Loss on drying of the API**
 - Residual solvent content of the API
 - Odour of the API
 - Crystallinity of the API

Raw material / material appropriateness

PC13 Ensure stocks of required materials are ready and available at all times

PC14 Ensure that the compound/material to be fed is approved by the laboratory as per SOP and record the receipt details like product name, batch name and operator name

7. Which of the following ensures the availability/ readiness of stock of required materials at all times?
- Updated inventory**
 - Purchase order
 - Production requirement
 - Delivery schedule

PC15 Match the batch code/item code, Authorized Return (AR) No of each compound/material with the batch code on the job schedule given by the planning department, ensuring FIFO (First in First Out) and further record the name, shelf life and quantities during documentation

PC16 Measure/weigh the raw material/compound as per the desired specifications (shape, size and weight) and return the unused material to warehouse with the appropriate label

8. Which order should be followed to use raw material for manufacturing intermediates and API?
- First in and first out (FIFO)**
 - Last in and first out
 - First in and last out
 - Any desired order

PC17 Ensure, by visual inspection, that the compound is of desired quality (free of contamination/bloom), and reach out to the supervisor for rejection control if disparities exist

9. What needs to be done if black or foreign particles are observed during the process of crystallisation of an API?
- Notify the supervisor immediately**
 - Inform the security department immediately
 - Inform the safety department
 - Notify the QA department

Health & Safety

PC18 Ensure housekeeping/safety in the manufacturing area as per the SOP

10. With reference to health and safety, what is a necessary aspect to be followed in a manufacturing area?
- Personal hygiene in-line with established standard operating procedures (SOP)**
 - Product safety in-line with established SOP
 - Cost cutting process in-line with established SOP
 - Disposal of waste in-line with established SOP

2. LFS/N0214 – Perform manufacturing operations

Raw material/material appropriateness

PC1 Handle the chemicals, materials and compounds appropriately to avoid contamination

11. How should chemicals, materials and compounds be handled to avoid contamination?
- Segregate in-line with chemical compatibility chart**
 - Store them in separate containers in the same room
 - Place them in an area with sufficient sunlight
 - Keep them in an air-conditioned room

Operation

PC2 Complete takeover of work and equipment and conduct pre-start checks

12. What must be completed before conducting pre-start checks of equipment during the commencement of the shift?

- a. **Takeover charge of ongoing work and equipment status**
- b. Complete all assigned work before the next shift begins
- c. Wear specified specialty PPE when working with chemicals
- d. Make a head count to ensure sufficient manpower for the next shift

PC3 Start the equipment safely and perform 'dry runs' to warm hydraulics and components to operating temperature before production, as required

13. What should be checked if the contents of the reactor has to be maintained at 60^o temperature for 10 hours?

- a. **Pressure gauge display showing appropriate inflow of steam**
- b. The reactor manhole is properly closed
- c. Capacity of the reactor to withhold the desired temperature
- d. Pressure gauge displays 50^o for first 5 hours

PC4 Load the identified material in the correct pattern as per the SOP to minimize material overflow/wastage/excess flash

14. What ensure the loading of the exact quantity of methanol to a reactor without any overflow or spillage?

- a. **Pump methanol to the reactor through a calibrated flow meter**
- b. Manually transfer the material liter by liter
- c. Allocate a technician to supervise until the completion of work
- d. Use an automated machine to do the job

PC5 Ensure smooth running of machines and the pressure and temperature is maintained in the machines as per the specifications and adhere to the production timelines

15. What is the first thing to be carried out for the smooth running of machines?

- a. **Clean machines before and after every usage in-line with SOP**
- b. Cover the machine with export quality cloth
- c. Annual maintenance with an external vendor
- d. Ensure housekeeping activities at regular intervals

PC6 Adhere to the SOPs and guidelines for maintaining quality

16. What has to be strictly followed in every manufacturing process to achieve the desired product quality?

- a. **SOP and GMP guidelines**
- b. Local drug control instructions
- c. US pharmacopeia
- d. Instructions of factory inspector

PC7 Maintain both online and offline records in the log books and other documentation required as per GMP and GDP like – breakdown time, daily manufacturing record, yield report, etc

17. Where should temperature details of a reactor be recorded which was used for 10 hours?

- a. **In the BPR and at established regular intervals**
- b. In a register and on completion of the process
- c. In the BPR and at beginning of the process
- d. In the BPR and on completion of the process

PC8 Take appropriate safety steps while carrying out manufacturing operations

PC9 Carry out status labelling and segregation of material/ intermediate/ finished goods as per SOPs

18. What are the safety steps to be undertaken while charging acids to the reactor?

- a. Wear appropriate PPE
- b. Use specified tools and equipment for the activity
- c. Add slowly and carefully without any spillage
- d. **All the above**

PC10 Provide support for line clearance before the next batch is produced and handover the work/ equipment to colleague in next shift in adherence of the shift schedule

PC11 Perform broad level in process checks and report results to supervisor

19. What is the most important aspect to be updated during shift handover about the centrifuge?
- The on-going process in the centrifuge and its appropriate documentation carried out**
 - The actual process in the centrifuge and its model name and serial number
 - The temperature maintained in the centrifuge
 - The type of API material and the temperature of the centrifuge

PC12 Ensure and confirm correctness of online process parameters

20. Which of the following helps to ensure and confirm the pH of liquid mass is maintained throughout the process?

- By checking the pH of the liquid mass at regular intervals in-line with BPR**
- By watching the colour shift of liquid mass throughout the process
- By adding pH buffers throughout the process at regular intervals
- All of the above

2. LFS/N0103 - To ensure cleanliness in the work area

Pre housekeeping activities

PC1 Inspect the area while taking into account various surfaces

PC2 Identify the material requirements for cleaning the areas inspected, by considering risk, time, efficiency and type of stain

21. What kind of cleaning is carried out for acid stains on the shop floor tiles?

- Wet mopping using water and stain removing agent**
- Replacing tiles with new ones
- Covering the stained area with tile coloured paint
- Covering the stained area with polyethylene covers

PC3 Ensure that the cleaning equipment is in proper working condition

PC4 Select the suitable alternatives for cleaning the areas in case the appropriate equipment and materials are not available and inform the appropriate person

22. Which of the following ensures that the cleaning equipment is in proper working condition?

- Carry out periodic preventive maintenance**
- Procure new equipment periodically
- Engage in annual maintenance
- Dust and cover it regularly

PC5 Plan the sequence for cleaning the area to avoid re-soiling clean areas and surfaces

PC6 Inform the affected people about the cleaning activity

PC7 Display the appropriate signage for the work being conducted

23. How can the master cleaning schedule and appropriate plan of cleaning be adhered to?

- By informing the affected people about the cleaning activity**
- By carrying out cleaning activity when the area is free
- By carrying out cleaning activity on weekends
- By outsourcing the activity regularly

PC8 Ensure that there is adequate ventilation for the work being carried out

PC9 Wear the personal protective equipment required for the cleaning method and materials being used

24. What should be worn to avoid personal health hazard when cleaning with solvents?

- Solvent and chemical respirator**
- Safety goggles and gloves
- Solvent resistant gloves
- Face shield

Operations

PC10 Use the correct cleaning method for the work area, type of soiling and surface

PC11 Deal with accidental damage, if any, caused while carrying out the work

25. What helps in choosing the appropriate cleaning method for the work area, type of soiling and surface?

- a. **Established SOP**
- b. Cleaning guidelines
- c. Local municipal guidelines
- d. FDA guidelines

PC12 Report to the appropriate person any difficulties in carrying out work

PC13 Identify and report to the appropriate person any additional cleaning required that is outside one's responsibility or skill

26. What can be achieved by highlighting difficulties faced while carrying out the cleaning activity?

- a. **Resolve the issues in-line with GMP guidelines**
- b. resolve the issues and get a promotion
- c. Builds good cross-functional relationship
- d. Harmony among the colleagues

Post housekeeping activities

PC14 Ensure that there is no oily substance on the floor to avoid slippage

PC15 Ensure that no scrap material is lying around

27. What can be avoided with the absence of oily substances on the floor?

- a. **Injuries due to slips and trips**
- b. Mis-understanding amongst the personnel
- c. Entry of insects to manufacturing area
- d. Malfunction of machines in the manufacturing area

PC16 Maintain and store housekeeping equipment and supplies

PC17 Follow workplace procedures to deal with any accidental damage caused during the cleaning process

28. What helps to maintain and store housekeeping supplies without any shortfall?

- a. **An adequate inventory**
- b. Raising purchase order in time
- c. Procuring as and when required
- d. Good relations with the vendor

PC18 Ensure that, on completion of the work, the area is left clean and dry and meets requirements

PC19 Return the equipment, materials and personal protective equipment that were used to the right places making sure they are clean, safe and securely stored

29. What is the criterion to ensure that the cleaning activity is completed?

- a. **The cleaned area should be clean, dry and meet specified requirements**
- b. The area should have a cleaning sign and be free from microbes
- c. The area should be free from soil, dust, oil or any other scrap
- d. The cleaned area should be free from all foreign particles

PC20 Dispose the waste garnered from the activity in an appropriate manner

PC21 Dispose of used and un-used solutions according to manufacturer's instructions, and clean the equipment thoroughly

30. How should waste garnered from the cleaning activity be disposed?

- a. **Sent to the incinerator in-line with established SOP**
- b. Mixed with bio-degradable waste
- c. Dispose off with local municipal waste
- d. Flushed down the sewer/ gutter