LFS/Q0203
Production Supervisor/In Charge (Active Pharmaceutical Ingredient) Final Assessment

1. LFS/N0205: Monitor the production process and ensure compliance to all protocols and maintain product quality

Quality Checks

PC1 Determine the minimum amount of API that must be present in the process and finished product to achieve the desired level of confidence in the physical characteristics tests

1. What is the foremost criterion for consistency of specific quantity of material produced in a process or series of processes?
   a. **Homogeneous within the specified limits**
   b. Free of lumps
   c. Quality matches with previous batches
   d. Match with customer requirement

PC2 Coordinate with various teams like store supervisor/ warehouse supervisor, QC and QA teams to ensure maintenance of quality and adherence to production timelines

2. How does the store supervisor help to ensure adherence to production timelines?
   a. **Provide requested materials in-time and in-line with SOP**
   b. Complete the packing activities as per the timeline
   c. Helps to paste labels to the drums to help in maintaining timeline
   d. Complete and hand over the BPR to QA as per the SOP

PC3 Ensure sampling is done as per the process flow sheet with specified control points

3. When should the manufacturing unit submit the 'in-process-sample' to QC for analysis?
   a. **As defined in the BPR**
   b. As per production manual
   c. As per instructions of the production manager
   d. As per the instructions of from QA

PC4 Identify the sample by labelling/numbering as per the SOP and as per BMR/BPR

4. What is the criterion for identification of materials in the manufacturing area?
   a. **Label with product name, batch number, manufacture/ expiry dates and number of containers**
   b. Label on the container number, manufacture/ expiry dates and name of product
   c. Label on the container with batch number, container number and number of containers
   d. Label with name of the product and total number of containers

PC5 Inspect the sample for visual defects, including comparison with approved specimen, and approve the sample dimensionally

5. What criterion should be satisfied on the printed product container label to 'get passed' before dispatch?
   a. **Match with approved specimen for colour and dimensions**
   b. Bold letters and attractive colour instructions
   c. Big in dimensions when compared against the approved specimen
   d. Satisfy the pre-approved agreement of the product

PC6 Monitor the production process (dispensing, granulation, compression, coating, inspection, etc.)

6. What is best done to monitor the dispensing of intermediate for the production of API?
   a. **Adhere to first in first out (FIFO) policy**
   b. Providing the intermediate deviating FIFO
   c. Providing the intermediate with highest quality
   d. Adhere to first in last out policy

PC7 Identify defect/problem in inappropriate sample / raw material / API / in process / packaging material

7. What might be the reason if the wet cake of an API takes more time for drying than the established standard time?
   a. **Centrifuge activity not properly done as per the BPR**
   b. Inappropriate API might have formed due to measuring error
   c. Defective use of solvents or intermediates may have been used
   d. Centrifuge activity in process longer than required

PC8 Ensure that the calibration/verification status of equipment is up to date and is as per the desired levels
PC9 Coordinate with maintenance teams for preventive maintenance and any equipment breakdown via maintenance requisition slip without any delay

8. What should be displayed on all equipment/ instrument once it has undergone calibration?
   a. **Label with details (date of calibration, next due date and sign of person who carried out calibration)**
   b. Label with details (date of calibration and sign of person who carried out the calibration)
   c. Label with next due date and sign of person who carried out the calibration
   d. Label with next due date of calibration and the calibrator's name

PC10 Execute the work as per risk control procedures to ensure production output as per specifications
PC11 Provide line clearance before production of the next batch starts
On what basis should the quality risk management system evaluate the risk to quality?

   a. **On scientific knowledge and experience with the process**
   b. Three consecutive batches results
   c. Initial validation batches
   d. Process validation

Safety Checks
PC12 Start, operate, monitor and adjust process equipment to achieve required quality outcomes and as per GMP
PC13 Conduct pre-start checks on the machinery used for production process

9. What process should all equipment undergo which are used for critical steps of fabrication, packaging/labeling, and testing including computerized systems?
   a. **Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ)**
   b. Inspection from Quality Assurance and Drug Inspector
   c. Inspection from the manufacturer
   d. OQ and PQ

2. LFS/N0206: Assist in preparing effective production schedules and ensure smooth flow of work

Production schedule

PC1 Inspect the manpower requirement based on expected production

10. What is the major criterion to be taken into account while defining monthly production plan?
    a. **Manpower**
    b. Production manual
    c. Training
    d. BPR

PC2 Identify the material requirements for production

11. On what basis is the appropriate quality and quantity of erythromycin base procured for the production of Azithromycin production?
    a. **On BPR specifications**
    b. On BMR detailing
    c. Standard specifications of the customer
    d. On the dosage required for the drug

PC3 Ensure that the equipment is in proper working condition

12. What is the first and foremost thing to be carried out to ensure that the anchor stirrer of a reactor is in proper working condition?
    a. **Clean machine before and after use in-line with the SOP**
    b. Cover the machine to prevent dust from settling on parts
    c. Approve annual maintenance with an external vendor
    d. Clean with anti-scaling agent after every use

PC4 Maintain schedules and records for production

13. How should the centrifuge log book be filled and maintained in the BPR?
    a. **As per the company's policy and rules**
    b. As per instructions of senior manager
    c. Based on the total quantity of output
    d. Based on the different products used

PC5 Select the suitable alternatives in case the appropriate equipment and materials are not available and inform the appropriate person

14. How can the centrifugation activity be best carried out in case the centrifuge has broken down?
    a. Employ the sedimentation method.
    b. As per the centrifuge operator’s suggestion
    c. Procure a new centrifuge as per the requirement.
    d. Employ the manual whisking method

PC6 Plan the schedule of workmen for production process

PC7 Inform workmen of the planned production process schedule

15. What is the criterion while preparing the schedule of manpower for a production process?
    a. **Daily production output**
    b. Additional workforce for general shift
    c. Additional workforce for night shifts
    d. End of week output

PC8 Display the appropriate signage for the work being conducted
PC9 Prepare vacation schedules for all employees and ensure that production is not affected adversely

16. What signage is generally displayed in the manufacturing area where sulphuric acid is handled?
    a. Adequate hand protection must be worn.
    b. Use of ear plugs is compulsory.
    c. Hairnet should be worn.
    d. **Personal protective clothing must be worn**.

Operations

PC10 Ensure that there is adequate ventilation for the work being carried out
PC11 Ensure that the workmen are on time as per the schedule

17. What is the main focus of designing adequate ventilation and exhaust systems in a manufacturing unit?
    a. **Minimize the risks of contamination and cross contamination**
    b. Improves the risks of contamination and cross contamination
    c. For adequate fresh air
    d. Stop the entry of foreign particles

PC12 Ensure that the workmen are carrying out their work without disturbing others

18. What helps to maintain the focus and discipline in the production area?
    a. Inculcating rest free work environment
    b. Ensure increase in production trends
    c. **Adherence to individual roles and responsibilities**
    d. Enforcing strict and disciplinarian rules

PC13 Report any disturbances in material flow or equipment to the appropriate person

19. Who should be notified for a delay in release of an intermediate by the quality control department?
    a. **Production manager**
    b. Quality control department
    c. Quality assurance department
    d. Research and development department

PC14 Identify and report any additional work required that is outside one's responsibility or skill to the appropriate person
PC15 Ensure that there is no oil/grease/adhesive/ink etc. on the floor

20. What can be avoided by ensuring grease free and clean floors in the manufacturing area?
    a. **Injuries due to slips and trips**
    b. Entry of personnel into the area
    c. Excessive use of lubricants
    d. Frequent use of extinguishers

3. LFS/N0102: Carry out reporting and documentation

Reporting

PC1 Report data/problems/incidents as applicable in a timely manner

21. When should the temperature data of a reactor be submitted to the supervisor?
    a. If it is out of the set temperature
    b. If the stirrers are slower than normal
    c. On transfer of content to the centrifuge
    d. After shutting it down on completion of cycle

PC2 Report to the appropriate authority as laid down by the company

22. Who should be informed about the audit findings if the manager is unavailable when the audit was carried out by quality assurance department?
    a. **Senior manager or production in-charge**
    b. Quality control manager
    c. Vice president
    d. Senior technician

PC3 Follow reporting procedures as prescribed by the company

23. For which of the following instances should the production or maintenance manager be informed?
    a. **Delay in calibrating the vacuum tray dryer**
    b. Increasing the temperature of the fluid bed dryer
    c. Quality of dryness of the API cake
    d. Inconsistency of the API mixture

PC4 Identify documentation to be completed relating to one's role

24. Which document should be provided during an audit to demonstrate the competence of production personnel for API?
    a. Batch inspection record
    b. Production records
    c. **Training records**
    d. Laboratory test reports

PC5 Record details accurately in an appropriate format

25. Where should the details of APIs drying time, drying temperature and dryer ID be entered?
    a. **Batch Production Record**
    b. Dryer log book
    c. Material inventory register
    d. Incident register

PC6 Complete all documentation within stipulated time according to company procedure

26. When should the octagonal blender usage log book be updated and how?
    a. When the blending becomes homogenous, report
    b. In case lumps are noticed in the mixture, manual documentation
    c. **As and when the activity is completed, online**
    d. To be filled in the absence of the supervisor

PC7 Ensure that the final document meets regulatory and compliance requirements

27. What is the criteria to dispatch an anti-epileptic API to an US customer for formulation?
    a. **Final documents meets regulatory and compliance requirements**
    b. After the completion of packing and labelling of product
    c. After pasting the product label of the containers
    d. Logistic arrangements

PC8 Make sure documents are available to all appropriate authorities to inspect

28. Where should the reactor's logbook, usage records and all its controlled SOPs be kept?
    a. **At the designated place easily available to appropriate personnel**
    b. At a place where it is accessible to the reactor operator
    c. In the unit's reading room
    d. Close to the reactor

PC9 Respond to requests for information in an appropriate manner whilst following organizational procedures

29. What is best done when QC requires extra quantity of carbamazepine API for carrying out additional tests such as surface tension test?
    a. **Inform QC to get approval from QA**
    b. Sanction the required quantity for sampling
    c. Insist on an official request with the quantity required
    d. Prior authorization from the production manager is required

PC10 Inform the appropriate authority of requests for information received

30. Who should be informed in case the engineering department requests for additional data regarding the manufacturing process of an API Olanzapine?
    a. Immediate supervisor or Shift in-charge
    b. **Quality assurance**
    c. Safety department
    d. Manufacturing department