| S.No. | Particulars | Verified \ Not Verified | Reference Document | Remark |
|---|---|---|---|---|
| **1.0** | **SOPs** | | | |
| 1.1 | Are a complete index and a complete set of applicable SOPs available in the department? | | | |
| 1.1.1 | Are the index and the SOPs current? | | | |
| 1.1.2 | Is the set of SOP's correctly organized according to the index? | | | |
| 1.1.3 | Select any five SOP's and check its contents for cGMP compliance and effectiveness, in order to identify the gaps if any. | | | |
| **2.0** | **PERSONNEL** | | | |
| 2.1 | Select any employee working in the department.<br>Are their training records up-to-date? | | | |
| 2.2 | Have the employees undergone training in the following areas during the last year?<br>- GMP<br>- SOPs<br>- Quality Assurance Procedures | | | |
| 2.3 | Question several employees about the operations they are performing.<br>Are they knowledgeable about their job functions? | | | |
| 2.4 | Are all employees attired according to the appropriate garmenting SOP? | | | |
| 2.5 | Is an up-to-date organizational chart of the Quality Assurance Department available? | | | |
| **3.0** | **BATCH RECORD REVIEW** | | | |
| 3.1 | Is there an SOP for batch record review prior to release? | | | |
| 3.2 | Is there a comprehensive checklist for batch record review prior to release? | | | |
| 3.3 | Examine one recently released batch records.<br>Product : Batch No.: | | | |
| 3.3.1 | Are the records complete with respect to the following?<br>- Is the batch number legible on each page of the batch record?<br>- Any changes to the master formula are QA authorized prior to Manufacturing.<br>- All relevant signatures are present.<br>- All relevant data are present.<br>- All relevant data are accurate.<br>- Yield calculation at each stage of production. | | | |

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| | - All calculations are verified by a second individual. | | | |
| **4.0** | **CHANGE CONTROL RECORDS** | | | |
| 4.1 | Are all changes that may impact product quality authorized by Quality Assurance prior to implementation? | | | |
| 4.2 | Examine any recent change control form. | | | |
| 4.2.1 | Have the form been completed and closed? | | | |
| 4.2.2 | Were any required tests performed and the results evaluated prior to closing the forms? | | | |
| 4.3 | Have all relevant documentation been updated?<br>Verify that validation protocols have been revised where appropriate. | | | |
| **5.0** | **SELF-INSPECTION** | | | |
| 5.1 | Is there an SOP that requires that self-inspection be performed in all departments? | | | |
| 5.2 | Is self-inspection performed according to the frequency stated in the SOP? | | | |
| 5.3 | Do all personnel required by the SOP to participate in inspections actually do so? | | | |
| 5.4 | Review of last self-inspection report. | | | |
| 5.5 | Is there written evidence of corrective action implemented as a result of the inspections? | | | |
| **6. 0** | **COMPLAINTS** | | | |
| 6.1 | Is there an SOP for dealing with complaints? | | | |
| 6.2 | Examine one recent complaint file.<br>Product: Batch No.: | | | |
| 6.2.1 | Does the file contain all relevant data? | | | |
| 6.2.2 | Have the files been signed by the relevant personnel? | | | |
| 6.2.3 | Could any of the above complaints affect other batches of the product and, if so, has an investigation been initiated and appropriate action taken? | | | |
| 6.3 | Examine the list of complaints for the year preceding the last self inspection.<br>Are there products that have several complaints and, if so, have appropriate corrective action been implemented? | | | |
| **7.0** | **REJECTED BATCHES** | | | |
| 7.1 | Examine the list of rejected batches preceding the last self inspection. | | | |

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|---|---|---|---|---|
| | Select any one batch from the list.<br>Product: Batch No.:<br>Reason for rejection: | | | |
| 7.1.1 | Is there a written investigation, including conclusion as to the cause of the failure and, if appropriate, follow-up action taken for the batch? | | | |
| 7.1.2 | Are there any products that have more than one rejected batch and, if so, has corrective action been recommended and implemented? | | | |
| **8.0** | **RECALLS** | | | |
| 8.1 | Is there a written procedure for the recall of drug products that ensures that responsible officials of the firm are notified in writing of the recall? | | | |
| 8.2 | Have there been any recalls preceding the last self inspection? | | | |
| 8.2.1 | Specify: | | | |
| 8.2.2 | List the disposition of the recalled goods. | | | |
| 8.2.3 | Is the disposition adequately justified with a documented investigation and conclusions authorized by Quality Assurance? | | | |
| 8.2.4 | Could the reason for the recall implicate other batches of the product and, if so, has an investigation been initiated and appropriate action taken? | | | |
| **9.0** | **VALIDATION** | | | |
| 9.1 | Is there a written procedure for carrying out validation of drug products? | | | |
| 9.2 | Is Master Validation Plan available? | | | |
| 9.3 | Is it followed? | | | |
| 9.4 | Check the validation file of any one of the products being manufactured. | | | |
| **10.0** | **DEVIATION** | | | |
| 10.1 | Is there SOP for dealing with Deviation | | | |
| 10.2 | Is there Deviation log available? | | | |
| 10.3 | Check the deviation report file? | | | |
| 10.4 | Check corrective / preventive action / suggestion if any taken | | | |
| **11.0** | **OUT OF SPECIFICATION** | | | |
| 11.1 | Is there SOP for dealing with Out of specification? | | | |
| 11.2 | Is there Out of specification log available? | | | |
| 11.3 | Check any one Out of specification report file? | | | |
| **12.0** | **TRAINING** | | | |
| 12.1 | Are there standard operating procedures for training? | | | |
| 12.2 | Check the training calendar | | | |

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| 12.3 | Whether training are performed as per defined schedule. | | | |
| **13.0** | Is there APR completed? | | | |
| **14.0** | **QUALIFICATION OF EQUIPMENT** | | | |
| 14.1 | Check the qualification/requalification record of any equipment carried out preceding to the last self inspection. | | | |
| 14.2 | Is the qualification/requalification performed as per the requirement? | | | |
| 14.3 | All the documents are closed prior to taking the equipment for use. | | | |
| 14.4 | Are the qualification reports approved by all appropriate personnel? | | | |
| 14.5 | Are the reports completely and accurately filled out? | | | |
| **15.0** | **WATER SYSTEM** | | | |
| 15.1 | Examine the validation file for the purified water system. | | | |
| 15.2 | Was the validation performed according to schedule? | | | |
| 15.3 | Does the report indicate that the system is operating in a repeatable and reliable manner? | | | |
| **16.0** | **HVAC SYSTEM** | | | |
| 16.1 | Examine the availability of requalification schedule for AHU. | | | |
| 16.2 | Are requalification performed as per defined schedule | | | |
| 16.3 | Examine the record of any one AHU performed preceding the last audit | | | |
| **16.3.1** | **Filter Integrity Test Records** | | | |
| 16.3.1.1 | Examine records of the most recent tests performed. Is it found in order? | | | |
| **16.3.2** | **Airflow Velocity Test Records** | | | |
| 16.3.2.1 | Examine records of the most recent tests performed. Is it found in order? | | | |
| **16.3.3** | **Air Changes Test Records** | | | |
| 16.3.3.1 | Examine records of the most recent tests performed. Is it found in order? | | | |
| **17.0** | **VENDOR QUALIFICATION** | | | |
| 17.1 | SOP for vendor qualification is available? | | | |
| 17.2 | Calendar for performing vendor qualification is available<br>Are audits performed as per the schedule? | | | |
| 17.3 | Verify any vendor audit report performed preceding last audit. | | | |
| 17.4 | All CAPA has been completed as per response? | | | |
| **18.0** | **LAST AUDIT COMPLIANCE :** | | | |
| 18.1 | Check & Verify the compliance of the observations noted in last audit. | | | |