**PERFORMA FOR INSPECTION OF AYURVEDIC PHARMACIES AS PER SCHEDULE T/GMP**

|  |  |  |
| --- | --- | --- |
| **1** | **NAME OF FIRM/COMPANY** |  |
| **2** | **MANUFACTURING ADDRESS & CONTACT DETAILS** |  |
| **3** | **MANUFACTURING LIC NO.** |  |
| **4** | **LICENCE VALID DATE DETAILS** |  |
| **5** | **GMP STATUS** |  |
| **6** | **FIRM ID** |  |
| **7** | **FIRM REGISTERED EMAIL** |  |
| **8** | **FIRM REGISTERED MOBILE** |  |
| **9** | **CONSTITUTION MEMBER DETAIL** |  |
| **10** | **ANY CHANGE IN CONSTITUTION TILL TODAY? IF YES THEN MENTIONED** |  |
| **11** | **TECHNICAL PERSON IN MFG** | **Attached separately with report as Annexure B.** |
| **12** | **TECHNICAL PERSON IN QC** | **Attached separately with report as Annexure B.** |
| **13** | **OUT SIDE LABORATORY TESTING DETAILS. (IF REQUIRED)** |  |
| **14** | **PRODUCT CATEGORY** |  |
| **15** | **TOTAL COVERED AREA OF PHARMACY (Sq.Ft.)** | **Attached separately with report as Annexure A.** |
| **16** | **DATE OF LAST ROUTIN INSPECTION** |  |
| **17** | **DATE OF INSPECTION** |  |
| **18** | **INSPECTION TEAM DETAIL (NAME , DESIGNATION AND SIGNATURE)** |  |

**CHECKLIST OF INSPECTION**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SR.NO.** | **SCHEDULE T /GMP CLAUSE** | **AREAS/ ACTIVITIES TO BE AUDITED** | **OBSERVATIONS** | |
| **Documents Review** | **Remark** |
| **1** |  | **FACTORY PREMISES** |  |  |
|  |  | Does manufacturing unit have adequate space for   * Receiving and storing raw material. * Manufacturing process areas. * Quality Control section. * Finished goods store. * Office * Rejected goods/ drugs store. |  |  |
| **2** | **1.1 (A)** | **LOCATION AND SURROUNDINGS** |  |  |
|  |  | Is the establishment located away from environmentally polluted areas? |  |  |
|  |  | Is the establishment located away from areas adjacent to opae sewerage, drain/ public lacatory or any factory which produce excessive, disagreeable odour. |  |  |
|  |  | Are sewage, trash and other effluent disposal provided? |  |  |
| **3** | **1.1 (B)** | **BULDINGS** |  |  |
|  |  | Do the internal design and layout of establishment permit good hygiene practices including protection from cross- contamination? |  |  |
|  |  | Are surfaces of walls, partitions and floor made of impervious materials and capable of being kept clean? |  |  |
|  |  | Do walls and partitions have smooth surface? |  |  |
|  |  | Are floors constructed to allow adequate cleaning and drainage? |  |  |
|  |  | Are doors, windows, ceiling and overhead fixtures constructed and finished to minimize buildup of dirt, condensation and shedding of particles and easy to clean? |  |  |
|  |  | * Are working surfaces that come into direct contact with drugs of sound condition, durable and easy to clean, maintain and disinfect? * Any open drain blocked sewer or public lavatory nearby? * Are any products other than drugs manufactured in the same building? |  |  |
|  |  | Is there adequate space for equipment, material and movement of personal and materials? |  |  |
|  |  | Is there any programmer/ system to check of birds, rodents and insects? |  |  |
|  |  | Are lightening and ventilation adequate? |  |  |
|  |  | Are facilities for changing street clothes, footwear, washing and toilets adequately and satisfactorily maintained? |  |  |
|  |  | Is the space for drying of raw materials satisfactory? |  |  |
| **4** | **1.1 (C)** | **WATER SUPPLY** |  |  |
|  |  | Is there adequate supply of Pure and potable water? |  |  |
|  |  | Is there provisions of supply of water for washing? |  |  |
| **5** | **1.1 (D)** | **DISPOSAL OF WASTE** |  |  |
|  |  | Are drainage and water disposal systems designed, constructed and maintained in such a way as to avoid contamination of ASU products? |  |  |
| **6** | **1.1 (E)** | **CLEANING OF CONTAINERS** |  |  |
|  |  | Is there proper arrangement for washing, cleaning and drying of containers? |  |  |
| **7** | **1.1 (F)** | **STORES** |  |  |
|  |  | Is there independent adequate space for storage of different types of materials such as raw material, packaging material and finished products? |  |  |
|  |  | Are storage facilities deigned, constructed and maintained to ensure that malicious or accidental contamination of ASU medicines with harmful materials is prevented? |  |  |
| **8** | **1.1 (F) (A)** | **RAW MATERIALS STORES** |  |  |
|  |  | Are raw materials of ingredients inspected and tested before processing? |  |  |
|  |  | Are raw material of ingredients subjected to effective stock rotation? |  |  |
|  |  | Are the ventilation and lighting of stores adequate? |  |  |
|  |  | Is there area clean? |  |  |
|  |  | Is the Raw Material store segregated for different types of Raw Material?   * Raw materials of metallic origin * Raw material of mineral origin * Raw material of animal source * Fresh herbs * Dry herbs or plant parts * Excipients etc. * Volatile oils/ perfumes and flavors * Plant extracts and exudates/ resins   Others |  |  |
|  |  | Are there labels for material of different status i.e. undertest, Approved and rejected?  Are these labels of different colors? |  |  |
|  |  | Is there the following information on the labels?   * Name of material * Batch number * Analysis number * Date of release/ rejection? * Date of testing? * Date of expiry? |  |  |
|  |  | Is the sampling performed by quality control personal? |  |  |
|  |  | Are there sampling procedures? |  |  |
|  |  | Are the containers provided for storage of raw material suitable to preserve the quality? |  |  |
|  |  | Is the weighing area segregated? |  |  |
|  |  | Do the personal wear appropriate clothing? |  |  |
|  |  | Is there danger of cross contamination during weighing? |  |  |
|  |  | Are the scales and balance calibrated regularly and records maintained? |  |  |
|  |  | Is FIFO principle adopted? |  |  |
|  |  | Are the records of the receipt, testing and approval or rejection and use of raw material maintained? |  |  |
| **9** | **1.1 (F) (B)** | **PACKING MATERIALS** |  |  |
|  |  | Is the area adequate with reference to packing material? |  |  |
|  |  | Are the containers and closures adequately cleared and checked? |  |  |
| **10** | **1.1 (F) (C)** | **FINISHED GOODS STORES** |  |  |
|  |  | Are Finished Goods inspected and tested by experts? |  |  |
|  |  | Is the area adequate with reference to materials stored? |  |  |
|  |  | Are lighting and ventilation adequate? |  |  |
|  |  | Are there inventory records to show:   * Quantities * Batch number * Date of receipt |  |  |
|  |  | Have the distribution records been maintained? |  |  |
|  |  | Do distribution records provided sufficient information for drug recall purpose? |  |  |
|  |  | Is there any marked quarantine area? |  |  |
| **11** | **1.1 (G)** | **WORKING SPACE** |  |  |
|  |  | Name of Product category |  |  |
|  |  | Is space adequate as per approved plan ? |  |  |
|  |  | Is machinery along with working manual orderly placed with adequate space? |  |  |
|  |  | Are there adequate precautions to check cross contamination? |  |  |
| **12** | **1.1 (H)** | **HEALTH, CLOTHING, SANITATION AND HYGINE OF WORKERS** |  |  |
|  |  | Are workers free from contagious disease? |  |  |
|  |  | Are workers properly uniformed? |  |  |
|  |  | Is there provision for changing their cloth and to keep personal belongings? |  |  |
|  |  | Are adequate facilities like wash- basin with running water hand drier & clean towels, etc., available for personal hygiene before entering into production area? |  |  |
|  |  | Are hygiene instructions to observe personal hygiene? |  |  |
|  |  | Are hygiene instructions displayed in change rooms and strategic locations? |  |  |
|  |  | Is the sanitation system monitored for effectiveness? |  |  |
|  |  | Is the sanitation system regularly reviewed and adapted to reflect changed circumstances? |  |  |
| **13** |  | **MEDICAL SERVICES** |  |  |
|  |  | Is adequate facility for first aid? |  |  |
|  |  | Is medical file of each worker maintained separately? |  |  |
|  |  | Is recruitment of an employee preceded by medical examinations? |  |  |
|  |  | Is employee periodical check up by a physician once a year? |  |  |
| **14** | **1.1 (J)** | **MACHINERY AND EQUIPMENT** |  |  |
|  |  | Is manually operated or semi operated or, automatic machines are used for Crushing, grinding, powdering, boiling, machining, burning, roasting, filtering, drying, filling, labelling and packing? (As per Category) |  |  |
|  |  | Are equipment and containers coming into contact with ASU drugs designed such that they can be adequately cleaned, disinfected and maintained? |  |  |
|  |  | Are equipment made of nontoxic materials? |  |  |
|  |  | Is the equipment adequate for intended use? |  |  |
|  |  | Is it contracted in such a way lubricants, coolant, etc. cannot contaminate the drug product? |  |  |
|  |  | Does the equipment permit cleaning and maintenance? |  |  |
|  |  | Does the equipment show is status i.e. clean, dirty, batch contents? |  |  |
|  |  | Do all apparatus/ equipment bear appropriate labels to identify the product for which the equipment is used, its batch no., date of manufacturing etc. |  |  |
|  |  | Are SOP’s available for cleaning maintenance and sanitation of major equipment? |  |  |
|  |  | Are log books maintained for cleaning maintenance and sanitation of major equipment? |  |  |
|  |  | Are SOP’s readily available to operators? |  |  |
|  |  | If automatic electronic or mechanical equipment is used are there:  Written programs for calibration/ inspection  Checks to ensure that may changes are made only by authorized persons.  Are suitable closures or lids available to protect the changes in properties of material exposed to outside atmosphere? |  |  |
| **16** | **1.1 (K)** | **BATCH MANUFACTURING RECORDS** |  |  |
|  |  | Are appropriate records of processing, production and distribution kept? |  |  |
|  |  | Are SOP’s available for the following   * Receipt of raw material and other components? * Quarantine and storage? * Quality control system and approval/ rejection * Release of production * In process testing and control * Finished product? * Storage of finished product? * Distribution * Returned goods * Cleaning and maintenance? * Quality control of water * For reworking of non- conforming batches in existence? If yes, check) |  |  |
|  |  | Are there additional documents like log books, notebooks or other similar records available to show execution of various functions? |  |  |
|  |  | Are there records of receipts of material and do these have following information? (goods receipt Note-GRN)   * Receiving GRN documents number? * Date of receipt? * Supplier? * Manufacture? * Manufacture’s batch number? * Type and size of containers? * Number of containers and conditions? |  |  |
|  |  | Are specifications available for all materials? |  |  |
|  |  | Are they dated authorized? |  |  |
|  |  | Are periodic reviews of specification carried out to ensure compliance with new/ revised National/ international pharmacopoeia? |  |  |
|  |  | Are these records of stock and issue of raw materials and do these following information:   * Opening balance? * Date of receipt? * Quantity received? * Name and batch number assigned by the manufacturer? * Invoice number, date name and address of supplier? * Analysis receipt no. and date? * Date of expiry, if any? * Name and batch number of product for manufacture for which issued Balance?   Signature of issuing person? |  |  |
|  |  | Are there master formulation records for each drug product being produced? |  |  |
|  |  | Is there separate master production documents for each dosage form/ batch size? |  |  |
|  |  | Are these master production records signed and dated by competent person? |  |  |
|  |  | Is a batch production record prepared for every batch produced? |  |  |
|  |  | Are batch records retained for at least one year after expiry date? |  |  |
|  |  | Has it been checked for accuracy, signed and dated by a responsible person? |  |  |
|  |  | Are the records maintained by QC for all the tests carried out?   * Do these records include: * The number of the product * Number of the batch being manufactured? * Issue slip with lab ref.NO * Job cards? * List of major equipment’s used? * In process testing reports? * Calculations of yield? * Notes on deviations with signed authorization? * Signature of individuals of who performed the tests? * Material returns to store slip? * Lab report of final product? * Review of results for any raw material issued under “Positive Recall”? * Signature of the designated person responsible for the review of records for accuracy and compliance with established standards? |  |  |
|  |  | Are batch production records capable of giving complete history of the batch right from the raw material stage to the distribution of finished products? |  |  |
| **17** | **1.1 (L)** | **DISTRIBUTION RECORD** |  |  |
|  |  | * Are records of sale and distribution of each batch of ASU drugs maintained? * Are records maintained at least up to 5 years of the exhausting of stock? |  |  |
| **18** | **1.1 (M)** | **RECORD OF MARKET COMPLAINTS** |  |  |
|  |  | Are the firm maintain a record of complaint received from market? |  |  |
|  |  | Does the firm have investigated the complaint and has taken any corrective action? |  |  |
|  |  | Are written procedure available for receipt and control of return products? |  |  |
|  |  | Are returned or salvaged drug products destroyed unless QC determines their reprocessing? |  |  |
|  |  | Are records of the returned products maintained including their disposition? |  |  |
|  |  | Is a safety manual available? |  |  |
| **19** | **1.1 (N)** | **QUALITY CONTROL** |  |  |
|  |  | Is the QC area more than 150 sq. ft.? |  |  |
|  |  | Do these control procedures include specifications, test procedure or other control procedure for:  Raw materials  In process materials  Packaging and labelling materials?  Finished products? |  |  |
|  |  | Are the procedure in written form and readily available to QC personnel for acceptance of reprocessed material? |  |  |
|  |  | Are samples collected by QC personal? |  |  |
|  |  | Is there special room for microbiological testing? |  |  |
|  |  | Is there facility for stability study?  If yes,   1. Stability testing related documents & register maintained? 2. Stability chamber calibration record maintained? |  |  |
|  |  | Is the environment of room controlled? |  |  |
|  |  | Are all raw materials, containers, closures, label and printed packaging material approved and released by QC for use in manufacture of drug products? |  |  |
|  |  | Are in- process controls carried out by QC personnel? |  |  |
|  |  | Are semi- finished products tested for appropriate tests when necessary? |  |  |
|  |  | Is every finished product tested for established specification before release for sale? |  |  |
|  |  | Does the QC maintain records of all the tests carried out? |  |  |
|  |  | Does the Qc review all production and control records to ensure compliance with established written procedure before a batch of the product is released for sale? |  |  |

|  |  |
| --- | --- |
| Observation, suggestion and Recommendation of the inspecting officers | |
| Basis of Recommendation |  |
| Suggestion for further improvements |  |
| Reasons for not recommending objectively. |  |
| Name and signature of inspection team member |  |

**ANNEXURE A**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| S.No. | Name of Area/Room | Actual Area  (sq.ft) | Hight  (Ft) | Remarks |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**ANNEXURE B**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| S.No. | Name of TP | Qualification & Experience | Section Name  MFG/QC | Remarks |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |