

ملحق رقم (١٢)المناطق والأنظمة التي يتم التفتيش عليها

1) Warehouses :

- Receiving area .
- Sampling area .
- Quarantine area .
- Stock control .
- Storage conditions .
- Rejected materials .
- Printed materials .
- Dispatch / Distribution .
- Standard Operation Procedures (SOPs) and records .
- IT inspection .

2) Production :

- Clothing /sanitation and hygiene
- Personnel flow
- Raw material flow ... Process flow
- Finished product flow .
- Dispensary
- Manufacturing operations
- In process control (IPC)
- Production line (liquid, solid, etc .)
- Processing and processing area :

1. Batch records

2. **Time limitation**
3. **SOP's & log book**
 - **Equipment :**
 - A. **Equipment construction**
 - B. **Equipment cleaning and maintenance**
 - **Facilities design**
 - **Packaging operations**
 - **Change part storage and control**
 - **Hygiene and cleanliness**
 - **Standard Operating Procedure (SOPs) and records**
 - **Environmental control and monitoring**
- 3) **Quality Assurance**
 - **Layout of the plant**
 - **Organization and responsibilities .**
 - **Documentation system (document control and issuance)**
 - **Change controls**
 - **Training**
 - **Internal quality audit**
 - **Product recalls**
 - **Product complaints**
 - **Batch record review and release**
 - **Annual product review**
 - **Signature records**
 - **Risk manufacturing system**
 - **Contract manufacturing /analysis**

- Pest control
 - Job description and qualification
 - Returned products
 - Health checking system
 - Vendor Qualification
- 4) QC labs :
- Organization and responsibilities
 - Specifications (Raw material, Packaging material ,finished product) .
 - Test methods
 - Analytical reports
 - Sampling plans
 - Out of specification reports / investigation
 - Microbiology lab and testing
 - Stability rooms and reports
 - Reference / working standards
 - Retained samples
 - QC identification system
 - Standard Operation Procedures (SOP's)and records
 - Analytical instrument , qualification and calibration
 - Release and reject decision
 - Procedure available for :
 - o Contamination prevention
 - o Detergent selection and sanitizer
 - o Raw material retesting system
 - Starting material and finished product approval

- Sampling instruments
- 5) Utilities and engineering :
 - Layout of water treatment system
 - Layout of HVAC system
 - Water treatment system
 - Pure steam
 - HVAC and Dust Extraction
 - Compressed air system
 - Preventive maintenance program
 - Calibration
 - Standard Operating Procedures (SOP's) and records
 - Waste water treatment
- 6) Validation :
 - Validation master plan
 - Equipment qualifications
 - Water treatment qualifications
 - Cleaning validation
 - Process validation of analytical method
 - HVAC qualification
 - Cross – contamination – control
 - Sensitizing and potent product
 - Campaign production
- 7) Calibration :
 - Equipment calibration
 - Balance calibration
- 8) Others