Company Name:

Audit Agenda

Number: ###

Audited Company:

Location of the site:

Country: India/USA/UK

Audit date:

Auditor (lead):

E-mail:

Co-Auditor(s): /

E-mail: /

Participant(s): /

Audit Programme:

First audit of the site Re-audit:

Subject and purpose of the audit:

The subject of audit are the following material(s):

The purpose of the audit is to address the compliance of the manufacturer with the provisions of the Reference documents listed below.

Reference documents:

Eudralex, The rules governing medicinal products in the European Union, Volume 4: Guidelines for good manufacturing practice for medicinal products for human and veterinary use (EU-GMP), Part II – Basic requirements for Active Substances used as Starting Materials.

Introduction meeting

- Presentation of the company:

- **Basic information about the company, if not included in presentation:**

Site layout, Number of employees (total, QA, QC), Organogram and responsibilities of employees (with focus on QA/QC function), Computer/manual material management system, Review of local and foreign inspections: GMP approvals, ISO 9001/14001 certificates, other certificates. Contract manufacturing/laboratory testing.

- Nature of other products manufactured by the audited site: API's, Potent drugs, Hormones, Penicillin or cephalosporin antibiotics, non-medicinal products. (Please prepare list of APIs by individual production blocks with focus on the manufacturing equipment used for audited API's).

- Review of the manufacturing processes (please prepare reaction schemes or flow charts of the processes).

Audited areas: Quality management

Site Master File and Quality manual:

Documentation system, SOP system, list of SOPs:

Annual Product Quality Review for audited API's:

Evaluation and investigation of OOT results, OOS results and deviations:

Change control system:

Vendor approvals:

Other particularities connected to herbal drugs according to GMP Annex 7 (if applicable):

Health, Safety, Environment (HSE) management system:

Personnel

List of key personnel:

Requirements for qualifications and experience on different levels:

Job descriptions, responsibilities:

Training (schedule records):

SOPs about hygiene, clothing, smoking, eating, drinking, personnel suffering from infectious diseases / open lesions:

Premises and equipment

Warehouses (raw material, packaging material and finished products warehouse): Documentation and records, Receipt of incoming materials, Identification and labelling, Sampling, Quarantine, Release, Separation of materials: quarantine/approved/rejected, FIFO/FEFO system, Temperature and humidity monitoring/control, Vermin control, Recalled & returned goods, Access control, Reduced testing program.

Manufacturing equipment: Dedicated or non-dedicated equipment, Identification (equipment, pipelines/processing lines), Logbooks, status boards, Calibrations of instruments, Cleaning procedures and records, Schedule/procedures/records for preventive maintenance, Qualification of equipment.

Documentation

Batch Manufacturing Records for randomly selected batches for audited API's.

Validation documentation for audited API's

Validation of Analytical Procedures

Cleaning validation

Specification requirements for starting materials for herbal substances/preparations (if applicable)

Production

Production operation (preferably we would like to see production of audited API's in operation)

Issuing of batch records

Are the critical steps witnessed by the second person?

IPC sampling and control, records, acceptance criteria, raw data

Process parameter control

Measures to prevent mix-up and contamination/cross contamination

Recovery of solvents and reagents, treatment of mother liquors (second crops?)

Blending/homogenisation of batches

Blending of tails

Packaging and labelling/records of the finished products

Maintenance program – schedule, records

In-line records

Layout of clean area and HVAC system

Material flow and personnel flow in the clean area

Temperature and relative humidity in clean area (requirement and records)

Process water, purified water quality, a pyrogenic water

Layout of purified water system

Measurement to prevent microbial grows and accumulation

Reprocessing and Reworking

Quality control

Description of sample flow

Sampling, procedure, tools

Handling of sample received, sample register

Testing of raw materials, intermediates and finished products

Analytical raw data

Log books

Preparation and standardization of standards/standards solutions

Storing of standards, chemicals and reagent

Qualification or validation of the laboratory equipment

Retention samples

Microbiological tests

Endotoxin testing

Stability testing of APIs

Definition and basis for expiry/retest date

Genotoxic impurities (nitrosamines, etc.)

Outsourced activities

Contract laboratories

Pest control

Complaints and product recalls

Customer complaints, returns and recalls, evaluation, responses

Self-inspection

Tour of the company

As a part of the audit, tour of the company will also be performed. Tour flow should be organized to include the following points:

- Raw material warehouse (solid & liquid)
- Packaging material warehouse
- Bulk solvents storage
- Production (all stages from starting materials on)
- Clean area (final API processing, packaging)
- Finished product warehouse
- Purified water system
- Quality control premises

Closing meeting (Final conclusions)

Please prepare as many documents as possible in advance; additional documentation might also be requested. The schedule might be changed during the audit. Additional topics might be reviewed, depending on findings during the audit.

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