Annexure-V Vendor Audit Report Template

Company Logo

XX Pharmaceuticals Limited
117 Adams Street, Brooklyn, NY 11201, USA

Audit Report for XXXXXXXXX
Reference No.:XXXXX
Date: XXXX

Auditee details:

Site Location:

Contact person:

XX Pharma Representatives:

Auditor(s)

Report Distribution (Electronically):

Report Contents

5. Audit activities

6. Audit observations: GMP Compliance

Classification of Findings:

Critical:

Major:

Minor:

Other:

6.1 Quality Management:

Principles

Responsibilities of the Quality Unit(s)

Responsibility for Production Activities

Internal Audits (self inspection)

Product Quality Review

6.2 Personnel:

Personnel Qualifications

Personnel Hygiene

Consultants

6.3 Buildings & Facilities:

Design and Construction

Utilities

Water

Containment

Lighting

Sewage and Refuse

Sanitation and Maintenance

6.4 Process Equipment:

Design and Construction

Equipment Maintenance and Cleaning

Calibration

Computerized Systems

6.5 Documentation and Records:

Documentation System and Specifications

Equipment Cleaning and Use Record

Records of Raw Materials, Intermediates, API Labelling and Packaging Materials

Master Production Instructions (Master Production and Control Records)

Batch Production Records (Batch Production and Control Records)

Laboratory Control Records

Batch Production Record Review

6.6 Materials Management:

General Controls

Receipt and Quarantine

Sampling and Testing of Incoming Production Materials

Storage

Re-evaluation

6.7 Production and In-Process Controls:

Production Operations

Time Limits

In-process Sampling and Controls

Blending Batches of Intermediates or APIs

Contamination Control

6.8 Packaging and Identification Labelling of APIs and Intermediates:

General

Packaging Materials

Label Issuance and Control

Packaging and Labelling Operations

6.9 Storage and Distribution:

Warehousing Procedures

Distribution Procedures

6.10 Laboratory Controls:

General Controls

Testing of Intermediates and APIs

Certificates of Analysis

Stability Monitoring of APIs

Expiry and Retest Dating

Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients

Reserve/Retention Samples

6.11 Validation

Validation Policy

Validation Documentation

Qualification

Approaches to Process Validation

Process Validation Program

Periodic Review of Validated Systems

Cleaning Validation

6.12 Change Control

6.13 Rejection and Re-use of Materials

Rejection

Reprocessing

Reworking

Recovery of Materials and Solvents

Returns

6.14 Complaints and Recalls

6.15 Contract Manufacturers (Including Laboratories)

7. Audit observations: List of Deficiencies

8. Conclusion

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Name

Title