Mr. Yogesh Gadekar

In ADL & Quality Control Since 11+ Years

PERSONAL PROFILE

Mr. Yogesh Baban Gadekar

DOB- 10th April 1988

Gender-Male

Marital Status- Married

Languages Known - English, Hindi & Marathi

EDUCATION

Master of Science Chemistry

Institute: Birla college of Arts, Science, Commerce Kalyan

University/Board: Mumbai University, Mumbai
Year of passing: 2012| 56.00 %

SOFT SKILL

PROFESSIONAL summary

Currently leading a role of ***Senior Research executive at Encube Ethicals*** ADL department, Mumbai since 02nd April 2024.

- Out of 11+ years of experience, 3-year experience in field of Quality Control (Stability, Chromatography, Process validation, finished products, Raw Materials, and Non-Routine activities) and remaining in Analytical Development Laboratory Dept.
- Previously worked organization, Macleod's, Ajanta, Cipla Ltd, J. Duncan Ltd.
- Performed Instrument Qualification, Analyst Qualification etc.
- Handling of investigation of OOS /OOT and implementation of CAPA.
- Reviews of Method validation, verification, transfer Protocols and Reports.
- Excellent knowledge of maintaining GMP, cGMP, GDP and Data integrity principle in Quality as per regulatory norms. Demonstrated ability to work under stringent and challenging pharmaceutical work environment.
- Experience of handling multiple dosage forms like, Tablets, capsule, Topical, Ophthalmic formulation etc.
- Exposure to the use of instrumentation software. Handling of 21CFR compliance software i.e. Chromeleon 7.2, Empower, open lab Software, LIMS, SAP, Tiamo, UV probe with class agent etc.
- Quality management system i.e. Change management system, incident and deviation process.
- Operating and troubleshooting of various instruments like HPLC, GC, UV, FTIR, KF, Autotitrator, Disso, DT, Polarimeter, etc.
- Regulatory audit like USFDA, MHRA, MCC, TGA, PICS and Customer audit faced.
- Proven leadership quality to manage, develop and motivate teams to achieve the objective. Dedicated to maintain high quality standard. Able to work on own initiative.

ACHIEVEMENT

- Strong decision making and problem solving skills.
- Able to motivate and lead others in a team environment.
- Able to priorities tasks and workloads in order of importance
- Track record of delivering results with deadlines Strong decision making and problem solving skills.
- Handling, monitoring and review of Raw material, Finished Products, Process Validation, Instrumentation, stability section. Calibration, maintenance and operation of all analytical instruments.

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WORK EXPERIENCE Existent

Encube Ethicals R&D (ADL) Center Mumbai — FROM 02 APRIL 2024

Designation as Senior Research executive ADL

Role & Responsibilities:

- To review Daily calibration, scheduled calibration of All lab instruments & Equipment's like HPLC, UV, Balance, IR, Disso, polarimetry, KF refractometer, ultrasonic bath,
- Preparation of protocols of calibration and validation of equipment and instrument, gap assessment, risk assessment, impact assessment, IQ, OQ, PQ protocol
- Prepare monthly and yearly schedule of calibration and preventive maintenance of instrument and equipment.
- Review monthly audit trial of empower software of HPLC and other instrument and equipment's.
- Daily lab round, spot check,
- Working standard management
- Procurement of chemicals & other materials like column, impurities
- Preparation of SOP as per scheduled
- Communication with user, IT, QA, manufacturing plants, service engineers
- Training Coordinator
- To maintain records like history cards, service reports
- Participation in Internal audits
- Initiation of QMS documents like change control, Incident, Deviation

Macleods pharma R&D center Mumbai — From 27th July 2020 to 28th March 2024

Designation as Senior Research Associate (Validation Analytical Division)

Role & Responsibilities:

- Execution and Monitoring of all activity of department related method Validation (Tablet / Capsule) section including HPLC section / other instrumentation.
- Initiation and investigation of the laboratory change control, Laboratory incidence, Out of calibration etc.
- To ensure that the training with respect to GMP, GLP, Safety & Hygiene, Job, Application is carried out and adopted according to the need.
- Review of hard copy and electronic data of software based instruments such as Chromeleon for HPLC and GC, Lab solution for UV & FTIR, Tiamo for Autotitrator etc.
- Preparation & Review various Quality documents such as SOPs, validation protocols and reports.
- Responsible for preparation, review, tracking of yearly calibration schedule, monthly calibration planner & preventative maintenance schedule.
- Responsible for implementation and compliance as per GLP & cGMP
- Timely calibration / Verification of Instruments like HPLC, Uv-Vis spectrophotometer, FTIR, Dissolution tester,
- Timely logbook entries & daily monitoring activities.
- Timely preventative maintenance of Instruments.
- Responsible for coordinating activities for internal & external quality audits of site.
- Perform & approval of IQ, OQ, PQ of all instruments and equipment's

Ajanta Pharma Ltd, (R & D Center) Mumbai

From Jun 2016 to July 2020

Designation as Research Associate (ADL)

Role & Responsibilities:

- Responsible for routine analysis of Development sample as per pharmacopeia and in-house method and partial method validation for Assay, Dissolution and Related substance test.
- Analysis of Stability Study of different molecule by using different instrument like HPLC, Dissolution & UV of Tablets capsules, Topical & ophthalmic solution.
- To study stability samples as per ICH Guideline.
- Monitoring of Data integrity issues during analysis and Review of stability reports.
- Maintaining of GLP and GMP violations and Data integrity related issues.
- To review and approve the sample login test results in LIMS as per respective SOP
- To follow the safety precaution and good laboratory practices as per respective SOP.

Cipla Pharma Ltd, Mumbai (Patalganga MIDC, Panvel)

From Dec 2014 to May 2016

Engaged in manufacture of finished pharmaceutical Dosage forms (Tablet Capsule & Topical) having approvals of WHO, MHRA, USFDA & other regulatory audits

Designation as Quality Control Officer (Management Staff)

Role & Responsibilities:

- Analysis of Stability samples for Assay, related substance, Dissolution, content uniformity of different formulation like Tablets, Capsules, Topical preparation and Nasal spray.
- Analysis of process validation samples for Hold time study, Blend uniformity, assay dissolution by UV-Vis spectrophotometer and HPLC.
- Analysis of API sample like impurity profile, water content, LOD, residual solvents, by using HPLC &GC instruments.
- Performed cleaning validation analysis sample & reporting.

- Co-operation for Investigation and completion of OOS, OOT and incidents of validation and finished product and Process Validation samples.
- Online reporting in various software like LIMS & TQC, QCMS software for data entry & reporting.

J. Duncan Health Care Pvt. Ltd, Thane

From Nov 2013 to DEC 2014

Engaged in manufacture of finished pharmaceutical Dosage forms (Tablet Capsule & Topical) having approvals of WHO, PICS & other Customer audits.

Designation- Chemist **Department- Quality Control**

Job responsibilities- As below

Nova surface care Vikhroli, Mumbai

From 01 April 2013 to 31 Oct 2013

Research and development of Paints, polymer, additives and Emulsions product

Designation- Chemist **Department- Quality Control**

Job responsibilities-

- Follow GLP & guidelines in Laboratory.
- Analysis of all types of PM materials like (primary, secondary, tertiary) carton, insert, Aluminum foil and fill their records.
- Analysis of in- process, finish products (Tablets, capsule, sachet, syrup) by HPLC (Shimadzu& Agilent), Uv-Vis dissolution apparatus, DT apparatus, friability as per specification and prepare their testing record.
- Responsible Instrument Calibration of Laboratory.

INSTRUMENTS EXPOSURE

- HPLC: Agilent, Shimadzu CST Prominences I and Dionex (Chromeleon 7.2, OpenLab, LC solution Software)
- Dissolution: Lab India, Electrolab
- UV-Visible Spectrophotometer: Shimadzu- Uv Probe
- Karl Fischer Auto-Titrator: Metrohm-Tiamo
- Fourier Transform Infrared Spectrometer: Shimadzu

SOFTWARE

- LIMS
- QCMS
- TQC

AUDIT FACED

- USFDA,
- WHO
- MHRA,
- TGA,
- PICS

DECLARATION

I consider myself familiar with management aspect. I am also confident of my ability to work in a team. I hereby declare that the information furnished above is true to the best of my knowledge.

Place:

Date:

Mr. Yogesh Gadekar