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**Location:**Downtown Toronto, ON, M6J 1E3, Canada

**Posted:**September 02, 2023

**Contact Info:**

1979mtay@gmail.com

720-300-9054

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**Resume:**

? CURRICULUM VITAE

Personal Details:

Name

Mukesh Kishor Tayade

Current Employer

Mepro pharmaceutical Pvt. Ltd. GIDC, Surendranagar, Gujarat.

Current Designation

Deputy Manager QC

Total Years Of Experience

19 Years

Location

Surendranagar

Qualification

MSc. Chemical Science

Area of Experience

API & Formulation (Tablets, Capsules, Creams, Ointment)

Date of Birth

16 Oct. 1979

Marital status

Married

Languages Known

English, Hindi & Marathi

Permanent Address

Mr. Laxmikant Tayade, Pote Township-1, Amravati, Maharashtra.

Email ID

1979mtay@gmail.com

Contact

7203009054, 8849008143 (Home)

Notice Period

3 Months

Objective:

Looking for a responsible position in a growing Pharmaceutical/Healthcare or similar organization which would explore my experience and potential, which will provide a wide platform for professional growth.

Professional Synopsis

? Over 19 years of professional experience in Quality Control department of pharmaceutical industry in compliance, Maintenance, Instrumentation, Qualification, Calibration, Stability, Documentation & Team Management.

(API & Formulation i.e. in Tablets, Capsules, Creams, Ointment, Gel)

? Competencies in all aspects covering the analysis of raw material, Inprocess/ finished product, Stability, Process validation.

? Good exposure on investigations like laboratory incidents, deviation, OOS, OOT.

? Hand on 21-CFR part 11, Data integrity and QMS system.

? Expertise in GLP compliance, Good documentation practices in laboratory.

? Exposure of CAPA, Change control, compliance for regulatory and customer audits.

? Expertise in troubleshooting, interpersonal, and team building skills.

? Manage Operation, Calibration and maintenance of all QC instruments as per schedule.

? Possess Strong analytical skills in Chromatography.

? Training to analysts on SOP?s, regulatory aspects and guidelines.

? Audits faced: USFDA, MHRA, EU GMP, UNICEF, WHO, WHO Geneva and Customer audits.

? Manpower recruitment.

? Presently working at Mepro Pharmaceuticals Pvt. Ltd. Surendranagar, Gujarat (Formulation Unit)

Duration: Dec.2015 to till date

Reporting To: Head QC

? Current Responsibilities:

? Planning the analysis of In-process/ Finished product/ Stability /Process validation samples and ensure release of material / batches within the time.

? Approval and rejection of material/ batches of Raw material/ Finish product/ Packing material.

? Ensure effective implementation of system and procedures as per GLP, GMP and other regulatory requirements.

? Review and approval of analytical data, reports, protocols generated in QC.

? Review of stability protocol and reports and ensure analysis of stability samples as per SOP.

? Monitor and ensure online documentation during analysis.

? Review and approval of Specification and Test procedures of Raw material/ Finished product.

? Preparation, review and approval of SOP?s in QC department.

? Ensure Good documentation practices followed in QC department.

? Ensure that all the instrument/ equipment?s are in good working condition and timely completion of AMC?s.

? Ensure proper operation, Calibration and maintenance of all QC instruments as per schedule.

? Manage stocks of chemicals, glassware, chromatography columns & instrument spares as required.

? Ensure Qualification of analyst, working standards and instrument/ equipment?s are done on time as per SOP.

? Procurement of chemicals, reference standards, impurity standards and other consumables.

? Investigate OOS /OOT results in Finish products, Stability, Raw material, packing material and review, approval of investigation report.

? Investigate incidents, deviations in laboratory and review and approval of investigation report.

? Initiate change control, CAPA for upgradation of systems, procedures whenever required.

? Ensure 21-CFR part 11, Data integrity and QMS system are followed in laboratory and its continuous improvement.

? Preparation of projects in the Server system.

? Review pendency of work and manage to complete it.

? Review and approval of all calibration records of instruments/ equipment?s in laboratory.

? Coordination with other departments like Regulatory, QA, production and stores for necessary requirements.

? Internal and external audits and its compliance.

? Ensure audit trial are checked & online review of data done in the server based system for correctness.

? Review and approval of COA of Finish product / Raw material/ Packing material.

? Ensure water analysis and EM are performed as per set standards.

? Maintain smooth and safe working environment in the laboratory.

? Monitor the team performance and guide them to achieve the set goals.

? Training to new and existing persons on system, SOP?s and any other regulatory aspects or guideline whenever required.

? Providing data to customers and regulatory agencies as per requirement.

? Any other work assigned by management.

? Previous Work Experience:

1) Flamingo Pharmaceuticals Limited, Nanded, Maharashtra (Formulation Unit)

Duration: April.2013 to Dec 2015

Designation: Senior Executive

Reporting To: Manager QC

? Job Responsibilities:

? Worked as a raw material section incharge.

? Responsible for work planning of raw materials, excipients and release as per requirement on time.

? Responsible for Good documentation practice and follow up for sample analysis and release to meet production requirements.

? Responsible for preparation & review of documents in raw material section for its complete and correctness before release.

? Preparation of COA and entry of material release in SAP.

? Responsible for preparation of Specification / Standard test procedures and Test data sheets of raw material & excipient.

? Responsible for method transfer activity, chromatography and investigations.

? Responsible for trouble shooting of instruments during any analysis of raw material section.

? Responsible for online documentation by analysts.

? Responsible for investigating incidents, OOS and preparing the related documents and CAPA.

? Ensure smooth working in the section by following written procedures.

? Training to all the analyst in raw material section and other laboratory analysts whenever required.

? Ensure good condition of laboratory all the time and work in a compliant way.

? Communication with R & D regarding method related issues and its rectification.

? Giving answers of queries of auditors during audits if required.

? Supporting to other sections related to any analysis or document review.

? Audit Faced: USFDA, MHRA and customer audits.

? Handling the SAP QM module for any requisitions or preparation of masters and release of materials.

2) Ranbaxy Labs Limited, Dewas, Madhya Pradesh (API)

Duration: Nov.2006 to April 2013

Designation: Senior Officer

Reporting To: Sr. Executive

? Job Responsibilities:

? Analysis of Finished products and Stability.

? Responsible for calibration and maintenance of QC instruments.

? Online documentation.

? Stability chamber management i.e. sample keeping and withdrawal as per planner.

? Temperature monitoring of stability chambers and its documentation.

3) Lupin Limited, Mandideep, Madhya Pradesh (API)

Duration: Oct.2005 to Oct 2006

Designation: Officer

Reporting To: Sr. Executive

? Job Responsibilities:

? Analysis of In process & Finished products.

? Responsible for calibration and maintenance of QC instruments.

? Online documentation.

? To keep the lab in good condition.

4) Glenmark Pharmaceuticals Ltd, Ankleshwar, Gujarat (API)

Duration: July.2003 to Sept. 2005

Designation: Jr. Officer

Reporting To: Sr. Executive

? Job Responsibilities:

? Analysis of In process & Finished products by chemical and GC.

? Responsible for calibration and maintenance of QC instruments.

? Online documentation.

? To keep the lab in good condition.

Hands on Sophisticated Instruments

? HPLC-LC 2010 & 2030 Shimadzu, Waters Alliance-2695, Agilent-1100

? GC/GCHS Perkin Elmer, Agilent, Shimadzu

? FTIR Perkin Elmer, Shimadzu

? UV/VIS Spectrophotometer of Perkin Elmer, Shimadzu

? Karl Fischer Autotitrater, Mettler & Metrohm

? Potentiometer, Mettler

? Polarimeter Perkin Elmer, Rudolph

? Electrolab Tap Density Tester.

? Melting Point Apparatus, Mettler

? Particle Sizer of Malvern

? Dissolution Test apparatus

? Disintegration Test apparatus

Other Skills

? Windows XP, MS-Office Tools

? Internet Applications

? Document Management system, Stability Software.

? Operation of SAP.